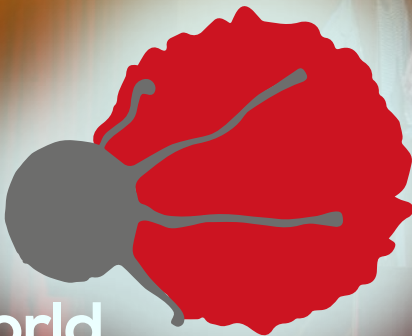


8th Annual

# CAR-TCR

## Engineering A Disease-Free World



August 29 - September 1, 2023 | Boston, MA

### Accelerating the Future of Safe, Efficacious & Accessible Cell Therapies by Harnessing Lessons Learned from Late-Stage Treatments to Develop a Viable Cure for Oncology & Beyond



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Senior Vice President,  
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**2seventy bio**



**Chris Bartiromo**  
Executive Director,  
Worldwide Value &  
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NOW

# Welcome to the 8th CAR-TCR Summit

A Letter from our Program Director

To Our Global CAR-TCR Community,

Last year was momentous for the cell therapy field! As Emily Whithead celebrated 10 years being cancer free, it was the year that CAR-T therapies became curative. This decade of success has triggered the development of next generation approaches including multiplexed editing, armoring, in vivo engineering, and more, each promising to revolutionize the cell therapy field!

The **8th CAR-TCR Summit** will be returning to Boston in August 2023, as the industry's trusted, definitive, end-to-end forum for the global network of cell therapy drug developers. Boasting all key updates across CARs, TCRs and a variety of cell types, this meeting is your unmissable opportunity to collaborate and network with industry pioneers as the focus moves further towards conquering solid tumors and indications beyond oncology.

So, whether you specialize in **discovery**, **translation**, **early-stage clinical strategy**, **clinical operations**, **manufacturing**, **CMC**, **analytics**, **supply chain**, **logistics**, **commercialization**, or **market access**, you can be confident that this forum will address your issues front of mind!

I look forward to welcoming your team to Boston this August to herald in a new frontier of medical marvels that can really cure the incurable.



*Elizabeth Harris*

Senior Program Director  
Hanson Wade

In Proud  
Partnership with:



## 5 Reasons to Attend this Year



**Master** effective delivery, specificity, and durability with *in vivo* CAR-T engineering, revolutionizing the way we manufacture cell therapies with **Capstan Therapeutics**, **Sana Biotechnology**, **Umoja Biopharma** and more.



**Uncover** the blockbuster potential for cell therapies to have curative potential in indications beyond oncology including autoimmune diseases with **Cabaletta Bio**, **Cartesian Therapeutics**, **iCell Gene Therapeutics**, **Kyverna Therapeutics** and more.



**Optimize** cell therapy manufacturing through implementing innovative equipment, reducing production timelines, and retaining skilled staff with **2seventy bio**, **Bristol Myers Squibb**, **Immatics**, **Stanford University** and more.



**Elevate** your CMC and analytical strategy, overcoming challenges preventing effective demonstration of efficacy, safety, and potency with **Alliance for Regenerative Medicine**, **Mustang Bio**, **Takeda** and more.



**Uncover** how leaders in the field have successfully developed effective pricing strategies and launch plans for their approved cell therapies with **Atara Biotherapeutics**, **Kite Pharma**, **Legend Biotechnology**, **Novartis** and more.

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# More than Just a Meeting

In addition to the unrivalled scientific content, in the form of presentations, panels and roundtable discussions, we also organize a variety of extra experiences that you can join on-site at the 8th CAR-TCR Summit. Get involved to make the most of your time with us!

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Drinks Receptions



Poster Session



Tech Slam



Emily Whitehead Foundation Run



Breakfast Briefings



One-on-One Partnering

NEW FOR 2023



You can also look forward to getting involved with ambassador receptions, private lunches, off-site visits, yoga classes, DEI sessions and more!



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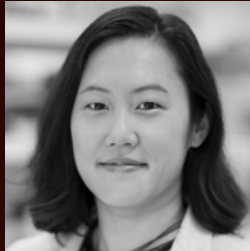
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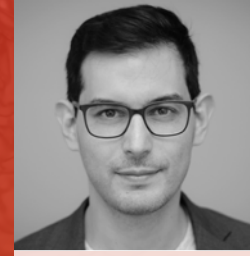
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Software**



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Director, Discovery  
**MiNK Therapeutics**



**Joy Zhou**  
Vice President, CMC  
Head  
**MiNK Therapeutics**



**Albert Ribickas**  
Assistant Director,  
Cell Therapy Facility  
Operations  
**Moffitt Cancer  
Center**



**Jim Edinger**  
Senior Vice President,  
Preclinical Science  
**Mustang Bio**



**Edward Armstrong**  
Vice President,  
Quality  
**Mustang Bio**



**Bruce Dezube**  
Senior Vice President,  
Head of Clinical  
Development  
**Mustang Bio**



**Jie Zhang**  
Vice President, Head  
of Worldwide Value &  
Access, Cell & Gene  
Unit  
**Novartis**



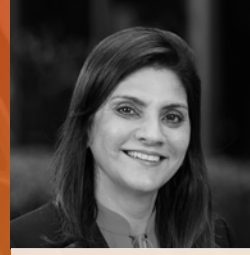
**Lynn Bayless**  
Vice President, Head  
of Regulatory Affairs  
**Mustang Bio**



**Laura Pierce**  
Biomedical Engineer  
**National Institute  
of Standards &  
Technology**



**Hannah Song**  
Product Development  
**NIH Clinical Center,  
Center for Cellular  
Engineering (CCE)**



**Shabnam Tangri**  
Chief Scientific Officer  
**Navigate BioPharma**

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Clinical Operations  
**Nkarta Therapeutics**



**Raphaël Ognar**  
Co-Founder & Chief  
Executive Officer  
**NKILT Therapeutics**



**Henri Bayle**  
Co-Founder & Chief  
Technology Officer  
**NKILT Therapeutics**



**Koji Tamada**  
President & Chief  
Executive Officer  
**Noile-Immune  
Biotech**



**Chris Bond**  
Chief Scientific Officer  
**Notch Therapeutics**



**Serena De Vita**  
Senior Clinical Program  
Leader, Translational  
Clinical Oncology  
**Novartis Institutes for  
BioMedical Research**



**Jennifer Brogdon**  
Head of Cell &  
Gene Therapies,  
Immuno-Oncology &  
Hematology  
**Novartis Institutes for  
BioMedical Research**



**Dan Kirby**  
Chief Commercial  
Officer  
**Orca Bio**



**Noelle Hutchins**  
Investment Associate  
**Omega Funds**



**Paul Bowels**  
Associate Principal  
Scientist  
**OmniaBio**



**Rajesh Krishnan**  
Chief Technology  
Officer  
**Oncternal  
Therapeutics**



**Troy Lionberger**  
Senior Vice President,  
Business Development  
**PhenomeX**



**Kristin Yarema**  
President, Cell  
Therapy  
**Poseida  
Therapeutics**



**Ann Murphy**  
Senior Director,  
Clinical Operations  
**Poseida  
Therapeutics**



**Nooshafarin Sanaie**  
Vice President,  
Process & Analytical  
Development  
**Poseida  
Therapeutics**



**Andy Kinley**  
Vice President,  
Innovation & Clinical  
Science  
**Precision for  
Medicine**



**Teresa Pokladowski**  
Regional Vice  
President, Clinical  
Business Solutions  
**Precision for  
Medicine**



**Anshul Mangal**  
President  
Project Farma &  
**Precision ADVANCE**



**Daniel Shelly**  
Vice President,  
Business Development  
& Alliances  
**Prescient  
Therapeutics**



**John Khoury**  
Executive Vice  
President  
**Project Farma**



**Mei Cong**  
Director, R&D  
Integrated Biology  
**Promega**



**Eytan Abraham**  
Vice President &  
Business Head of  
Emerging Modalities  
**Resilience**



**Catherine Tomaro-  
Duchesneau**  
Senior Director,  
Manufacturing  
Science & Technology  
**RoslinCT**



**Benedikt Steinle**  
Research Scientist  
R&D Cell Culture  
Systems  
**Sartorius CellGenix**

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Officer  
**SIRPant**  
Immunotherapeutics



**Olivier Negre**  
Chief Scientific Officer  
**Smart Immune**



**Amy Jensen-Smith**  
Vice President,  
Discovery Research  
**SOTIO Biotech**



**Steven Feldman**  
Site Head & Scientific  
Director, Laboratory  
for Cell and Gene  
Medicine  
**Stanford GMP  
Facility**



**Robbie Majzner**  
Assistant Professor of  
Pediatrics  
**Stanford University  
School of Medicine**



**Zinaida Good**  
Instructor  
**Stanford University  
School of Medicine**



**Mat Legut**  
Co-Founder & Chief  
Executive Officer  
**OverT Bio**



**Mike Jones**  
Senior Manager,  
Custom Services  
**STEMCELL  
Technologies**



**Shibani Mitra-  
Kaushik**  
Head, Product Control  
Strategy & Analytics,  
Cell Therapies  
**Takeda**



**Praveen Malhotra**  
Vice President,  
Head of Information  
Technology  
**Sana Biotechnology**



**Maura Hobson**  
Senior Director,  
External  
Manufacturing  
**Sana Biotechnology**



**Kutlu Elpek**  
Senior Director,  
T-Cell Therapeutics,  
Research Lead, *In Vivo*  
CAR-T  
**Sana Biotechnology**



**Danielle Quarles**  
Senior Director,  
Clinical Operations  
**Sana Biotechnology**



**Rukmini Ladi**  
Senior Director,  
External  
Collaborations  
Manager CCT  
**Sartorius**



**Alaina Schlinker**  
Senior Manager, Field  
Application Support  
Team  
**Scale Ready**



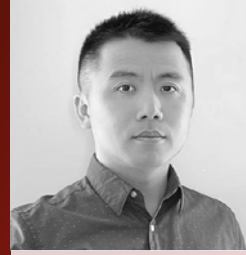
**Abhi Gupta**  
Senior Vice President,  
Head of Cell & Gene  
Therapy  
**Syneos Health**



**Erin Trachet**  
Senior Director,  
Scientific  
Engagement  
**TD2**



**Ramon Tiu**  
Vice President,  
Oncology Cell Therapy  
Development  
**Takeda**



**Yu Qian**  
Associate Director,  
Cell Therapy  
Technologies &  
Product Engine  
**Takeda**



**Leopold Sellner**  
Senior Medical  
Director, Cell Therapy  
Development  
**Takeda Oncology**



**Albeena Nisar**  
Scientific Officer,  
Head of Clinical  
Manufacturing, CAR-T  
Cell Therapy Center  
**Tata Memorial Centre**



**Kevin Zikaras**  
**Industry Expert**



**Gang Zeng**  
President & Chief  
Executive Officer  
**T-Cure Bioscience**



**Erin Trachet**  
Senior Director,  
Scientific  
Engagement  
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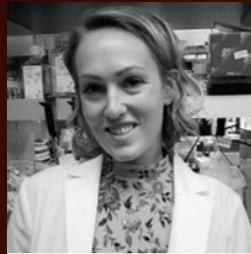
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**Jyotsna Venugopal**  
Director, Product  
Marketing  
**Telesis Bio**



**Stephen Chen**  
Chief Technical Officer  
**Tevogen Bio**



**Mindy Miller**  
Lead Research  
Scientist, Cell Therapy  
Technologies  
**Terumo Blood & Cell  
Technologies**



**Annie Cunningham**  
Field Application  
Scientist  
**Terumo Blood & Cell  
Technologies**



**Xavier de Mollerat  
du Jeu**  
Senior Director, R&D  
**Thermo Fisher  
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**Eugene Kang**  
Senior Product  
Manager  
**Thermo Fisher  
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**Susan Li**  
Senior Client Services  
& Solutions Director  
**Thermo Fisher  
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**Stan Wang**  
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**Thymune  
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**Peggy Sotiropoulou**  
Chief Scientific Officer  
**T-knife Therapeutics**



**Jie Wei**  
Director, Analytical  
Sciences  
**Tr1X Bio**



**Shawn Kubli**  
Director, Cell Therapy  
**Treadwell  
Therapeutics**



**Steven Katz**  
Chief Medical Officer  
**TriSalus Life  
Sciences**



**Gavin MacBeath**  
Chief Executive  
Officer  
**TScan Therapeutics**



**Mark Trusheim**  
Strategic Director,  
NEWDIGS  
**Tufts Medical Center**



**David Fontana**  
Chief Operating  
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**Umoja Biopharma**



**Byoung Ryu**  
Executive Vice  
President  
**Umoja Biopharma**



**Bruce Levine**  
Barbara & Edward Netter  
Professor in Cancer Gene  
Therapy & Center for  
Cellular Immunotherapies  
Director of Technology  
Innovation  
**University of Pennsylvania**



**Evan Weber**  
Assistant Professor of  
Pediatrics  
**University of  
Pennsylvania Perelman  
School of Medicine,  
Children's Hospital of  
Philadelphia**



**Preet Chaudhary**  
Professor & Chief of  
Hematology; Founder  
**University of Southern  
California; Angeles  
Therapeutics**



**Sahil Chopra**  
Vice President,  
Investments  
**Vertex Ventures**



**Jonathan Wofford**  
Senior Director,  
Solution Architecture  
for Biotherapies  
**WellSky**



**Andrea Zobel**  
Senior Director,  
Personalized Supply  
Chain  
**World Courier**



**Linda Brink**  
Head of QA  
**XNK Therapeutics**



**Brian Mullan**  
Chief Technical Officer  
**Yposkesi**

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# CAR-TCR Advisory Board

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Chief Scientific  
Officer  
**Adaptimmune**



**Blake Aftab**  
Chief Scientific  
Officer  
**Adicet Bio**



**Pascal Touchon**  
President & Chief  
Executive Officer  
**Atara  
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**Adrian Bot**  
Chief Scientific  
Officer & Executive  
Vice President, R&D  
**Capstan  
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**Stephan Grupp**  
Director, Cancer  
Immunotherapy &  
Cell Therapy  
**Children's Hospital  
of Philadelphia**

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# Agenda at a Glance

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Pre-Conference Day Tuesday, August 29					Conference Day 1 Wednesday, August 30					Conference Day 2 Thursday, August 31					Conference Day 3 Friday, September 1				
Registration Open					Opening Remarks					Opening Remarks					Opening Remarks				
WS WS WS 101 FD					Fireside Chat & Plenary Presentations					Opening Panel & Plenary Presentations					Plenary Presentations				
					Morning Break & Networking					Morning Break & Tech Slam					Morning Break & Tech Slam				
					A B C D E F G H					A B C D E F G H					A B C D E F G H				
Lunch Break					Lunch Break					Lunch Break					Lunch Break				
WS WS WS 101 FD					A B C D E F G H					A B C D E F G H					Plenary Presentations				
					Afternoon Break & Tech Slam					Afternoon Break & Poster Session					Closing Remarks				
C-Level Think Tank					A B C D E F G H					A B C D E F G H					Close of Conference				
Diversity at CAR-TCR																			
Welcome Reception					Drinks Reception					End of Conference Day 2									

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A - Discovery	B - Translation	C - Early-Stage Clinical Strategy	D - Clinical Operations	E - Manufacturing	F - CMC & Analytics	G - Supply Chain & Logistics	H - Commercialization & Market Access
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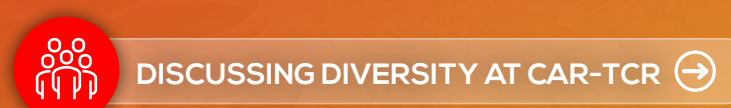


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# PRE-CONFERENCE DAY OVERVIEW

Tuesday, August 29

Use the buttons to below to navigate straight to your preferred pre-conference day!



## WORKSHOP DAY | 9.00 – 4.00

- Extending the reach of cell therapies with *in vivo* therapies and moving beyond oncology
- Streamlining therapeutic development, discussing combination strategies and key regulatory considerations
- Moving towards smarter manufacturing, discussing automation and decentralized manufacturing

## BOOTCAMP DAY | 9.00 – 4.00

- Reviewing the CAR-TCR fundamentals and previous success
- Discussing gene engineering, cell types and solid tumors
- Exploring *in vivo* CAR-T and indications beyond oncology

## FOCUS DAY | 9.00 – 4.00

- Reviewing mechanisms of resistance
- Leveraging innate immune cells for success in overcoming the tumor microenvironment
- Developing next-gen CAR-T and TIL therapies to overcome mechanisms of resistance

## C-LEVEL THINK TANK | 1.00 – 4.00

- This exciting addition to the program is an exclusive free-to-attend session. Top C-level executives will gather in a closed room panel to discuss the most pressing challenges facing the CAR-TCR field and share thought leadership on how to drive the cell therapy field into a new era of more accessible ‘curative’ therapies. If you are interested in getting involved, please get in touch.
- Led by **Adrian Bot**, CSO, Capstan Therapeutics and **Peggy Sotiropoulou**, CSO, T-knife Therapeutics

## DISCUSSING DIVERSITY AT CAR-TCR | 4.00 – 6.00

- Improving diversity, equity, and inclusion in the workplace and clinical trials

## WELCOME RECEPTION | 5.30 – 6.30

- Reunite with old friends and meet new colleagues before the main event begins

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## 8.00 Registration Open & Coffee Networking

Workshop A	Workshop B	Workshop C
<p><b>9.00 Extending the Reach of CAR-T Cell Therapies Beyond Oncology to Autoimmune Diseases</b></p> <p>Long-term studies have displayed the curative potential of CAR-T therapies to treat cancer. However, the number of potential targets amenable for CAR-T is expanding rapidly, meaning the success of this approach in oncology could be further translated to treating other diseases.</p> <p><b>Attend to:</b></p> <ul style="list-style-type: none"> <li>Understand the potential of CAR-T for autoimmune diseases</li> <li>Explore the key differences between developing CAR-T for oncology versus non-oncology indications</li> <li>Identify key regulatory hurdles to overcome</li> </ul> <p><b>Samik Basu</b>, Chief Scientific Officer, <b>Cabaletta Bio</b>  <b>Chris Jewell</b>, Chief Scientific Officer, <b>Cartesian Therapeutics</b>  <b>Greg Deener</b>, Chief Executive Officer, <b>iCell Gene Therapeutics</b></p>	<p><b>9.00 Leveraging Combination Strategies to Optimize the Efficacy of Cell Therapies</b></p> <p>Cell therapies have revolutionized the therapeutic landscape for heme malignancies; however, resistance and relapse remain limitations. Rational combined modality treatments are regarded as a promising strategy to further unlock the anti-tumor potential.</p> <p><b>Attend to:</b></p> <ul style="list-style-type: none"> <li>Overcome the challenges and limitations of monotherapy with combinations</li> <li>Review different combination strategies with promise: viral therapeutics, small molecules and innovative delivery strategies</li> <li>Enable success in solid tumors with combination therapies</li> </ul> <p><b>Francesca Barone</b>, Chief Scientific Officer, <b>Candel Therapeutics</b>  <b>Daniel Corey</b>, Founder &amp; Chief Executive Officer, <b>CERO Therapeutics</b>  <b>Steven Katz</b>, Chief Medical Officer, <b>TriSalus Life Science</b></p>	<p><b>9.00 A CAR-T Cell Manufacturing Life-Cycle Approach for Dramatic Reduction in Cost and Time Towards Making Cell Therapies More Affordable Globally</b></p> <p>A dramatic reduction in the cost and time for CAR-T cell manufacturing necessitates a manufacturing life-cycle approach where each of the steps needs innovation, from apheresis to product release.</p> <p><b>Attend to:</b></p> <ul style="list-style-type: none"> <li>Understand the CAR-T cell manufacturing life-cycle approach with next generation innovations</li> <li>Understand the next generation viral vector manufacturing for CAR-T cells</li> <li>Understand the technology for dramatic reduction in timelines for CAR-T cells manufacturing</li> </ul> <p><b>Bikash Verma</b>, Chief Executive Officer, <b>MedTherapy Biotech</b>  <b>Vladimir Slepishkin</b>, Chief Technology Officer, <b>MedTherapy Biotech</b></p>

## 12.00 Lunch Break

Workshop D	Workshop E	Workshop F
<p><b>1.00 Moving Beyond Ex Vivo: The Promise of In Vivo Engineered Cell Therapies</b></p> <p>Although ex vivo approaches have produced some remarkable clinical responses and approvals, they have several disadvantages including production time, cost, manufacturing delay and more. In vivo CAR-T approaches aim to tackle these challenges head on, having promise as the future of cell therapy.</p> <p><b>Attend to:</b></p> <ul style="list-style-type: none"> <li>Discuss next steps to streamline preclinical and clinical development to fast-track in vivo therapies into the clinic</li> <li>Develop safe and effective delivery mechanisms: viral versus non-viral vectors</li> <li>Unlock the in vivo potential: the potential for treating indications beyond oncology</li> </ul> <p><b>Michael Rosenzweig</b>, Executive Vice President, Strategy &amp; Product Development, <b>Capstan Therapeutics</b>  <b>Jim Edinger</b>, Vice President, Preclinical Science, <b>Mustang Bio</b>  <b>Kutlu Elpek</b>, Senior Director, T-Cell Therapeutics, Research Lead, <b>In Vivo CAR-T, Sana Biotechnology</b></p>	<p><b>1.00 Outlining Key Regulatory Considerations for IND &amp; BLA Approval of Novel Cell Therapies</b></p> <p>Although there is regulatory guidance for the development of cell and gene therapies, emerging novel ideas mean that the cell therapy landscape is constantly evolving. This is also mirrored by an evolving regulatory landscape.</p> <p><b>Attend to:</b></p> <ul style="list-style-type: none"> <li>Define the best approach to submitting filings with regulatory bodies (IND through to BLA)</li> <li>Understand how to best introduce novel ideas and work out flexible plans with regulators</li> <li>Share experience and advice regarding key pain points</li> </ul> <p><b>Brian Kevany</b>, Chief Technical Officer &amp; Head of Research, <b>Abeona Therapeutics</b>  <b>Omer Butt</b>, Vice President, Regulatory Affairs, <b>CytoImmune Therapeutics</b>  <b>Alison Holzer-Speed</b>, Senior Director, Regulatory Affairs, <b>Kite, A Gilead Company</b></p>	<p><b>1.00 Implementing Technological Innovations to Enable Automated Cell Therapy Manufacturing</b></p> <p>Automated cell therapy manufacturing will reduce manual intervention, improve product quality, and reduce costs. However, leaps and bounds in terms of innovation are still required to make this a reality for all.</p> <p><b>Attend to:</b></p> <ul style="list-style-type: none"> <li>Discuss the value proposition for moving towards automated, closed system cell therapy manufacturing</li> <li>Understand the potential these processes have to improve quality, throughput, and cost</li> <li>Develop new bioreactor and sensor technologies to enable automated manufacturing processes</li> </ul> <p><b>Ohad Karnieli</b>, Founder &amp; Chief Executive Officer, <b>Adva Biotechnology</b>  <b>Krishnendu Roy</b>, Director, NSF ERC for Cell Manufacturing Technologies &amp; Marcus Center for Therapeutic Cell Characterization &amp; Manufacturing, <b>Georgia Institute of Technology</b>  <b>Bruce Levine</b>, Barbara &amp; Edward Netter Professor in Cancer Gene Therapy &amp; Center for Cellular Immunotherapies Director of Technology Innovation, <b>University of Pennsylvania</b></p>

## 4.00 End of Workshop Day

## 4.10 Discussing Diversity at CAR-TCR

## 5.30 Welcome Reception

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# Bootcamp Day | Tuesday, August 29

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## Reviewing CAR & TCR Fundamentals

### 8.00 Registration Open & Coffee Networking

### 8.55 Chair's Opening Remarks



**Chantal Kuhn**  
Director, Head of  
T-Cell Platform  
**Clade Therapeutics**

### The Past: Reviewing the Fundamentals & Previous Success

### 9.00 Understanding the Fundamentals of Cell Biology & Oncology

- Reviewing the fundamentals of cell biology, key to cell therapies
- Leveraging cell biology principals and genetic engineering to develop improved cell therapies
- Discovering the promise of different cell types



**Chantal Kuhn**  
Director, Head of  
T-Cell Platform  
**Clade Therapeutics**

### 9.30 Overview of Autologous & Allogeneic Cell Therapies

- Understanding the promises and challenges of autologous and allogeneic cell therapies
- Exploring how the success of autologous cell therapies can guide the development of allogeneic cell therapies
- Providing an outlook on how cell therapies could be offered to a broader patient population



**Leopold Sellner**  
Senior Medical  
Director, Cell Therapy  
Development  
**Takeda Oncology**

### 10.00 Allogeneic CAR-T: State of Union & Perspectives

- Reviewing the current progress made by the allogeneic CAR-T field
- Showcasing the latest clinical data disclosed so far
- Highlighting the upcoming milestones for the field as the first allogeneic CAR-Ts move towards commercialization



**Arthur Stril**  
Chief Business Officer  
**Collectis**

### 10.30 Morning Break & Networking

### The Present: Discussing Gene Engineering, Cell Types & Solid Tumors

### 11.00 Leveraging Gene Engineering Strategies to Improve Cell Therapy Design & Efficiency

- Understanding different gene editing technologies: CRISPR, TALEN, base editing, and other vector design technologies like Sleeping Beauty/PiggyBac Transposon system
- Engineering of 'suicide genes' into the CAR construct, to control the toxicity of CAR-T cells; the shutoff CARs / switch-off CARs to control CAR-T cell function
- Using genetic engineering for exploring the synergistic effects of CAR-T cell therapy with other therapeutic compounds



**Albeena Nisa**  
Scientific Officer  
& Head of Clinical  
Manufacturing,  
CAR-T Cell Therapy  
Center  
**Tata Memorial  
Centre**

### 11.30 Expanding on the Success of Adoptive Cell Therapy: The Promise of iPSC Therapies in Oncology & Beyond

- Working with iPSCs to provide an unlimited source of therapeutic T-cells that are scalable, uniform and can be engineered to overcome multiple mechanisms of resistance and relapse in solid and hematological tumors
- Advancing technologies that deliver the right developmental signals at the right time
- Creating iPSC-T cells that more closely resemble their donor-derived counterparts



**Chris Bond**  
Chief Scientific  
Officer  
**Notch Therapeutics**

### 12.00 Lunch Break

### 1.00 Targeting Solid Tumors: Challenges, Disappointments & Opportunities

- Reviewing the success in hematological malignancies, and why the same strategies aren't effective in solid tumors
- Evaluating the most significant barriers to treating solid tumors
- Describing novel therapeutic methods aiming to the acquirement of a promising therapeutic outcome in non-hematologic malignancies



**Erika Von Euw**  
Vice President,  
Discovery &  
Translational  
Research  
**Deverra  
Therapeutics**

### 1.30 Roundtable Discussion: Discussing Key Disadvantages of Traditional Cell Therapies in Solid Tumor Use

- Why aren't first generation CAR-T (and other cell therapies) effective in solid tumors?
- How can we overcome this barrier to effective treatment?



**Erika Von Euw**  
Vice President,  
Discovery &  
Translational  
Research  
**Deverra  
Therapeutics**



**John Maher**  
Chief Scientific  
Officer  
**Leucid Bio**

### 2.30 Afternoon Break & Networking

### The Future: Exploring *In Vivo* CAR-T & Indications Beyond Oncology

### 3.00 Exploring the Benefits & Challenges of *In Vivo* CAR-T Therapy

- Describing the move from traditional autologous and allogeneic CAR-T to *in vivo* gene delivery
- Reviewing the current preclinical success
- Exploring the main challenges that lie ahead in their translation to the clinic



**Bakul Gupta,**  
Co-Founder & Chief  
Executive Officer  
**ImmTune Therapies**

### 3.30 Development of a Fully Human Anti-CD19 CAR-T Cell Therapy for Autoimmune Diseases

- Promising outlook for treating autoimmune disease patients with CAR-T cells
- Establishing benefits with autologous CAR-T cells
- Expanding to treat this broad patient population with allogeneic CAR-T cells



**Tom Van Blarcom,**  
Senior Vice President,  
Head of Research  
**Kyverna  
Therapeutics**

### 4.00 End of Bootcamp Day

### 4.10 Discussing Diversity at CAR-TCR

### 5.30 Welcome Reception

WELCOME

MORE THAN JUST  
A MEETING

SPEAKERS

AGENDA AT A  
GLANCE

WORKSHOP DAY

FOCUS DAY

DISCUSSING  
DIVERSITY AT  
CAR-TCR

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# Focus Day | Tuesday, August 29

## Overcoming Mechanisms of Resistance & the Solid Tumor Microenvironment

August 29 – September 1, 2023  
Boston, MA



REGISTER IN  
ADVANCE TO  
SAVE \$150

### 8.00 Registration Open & Coffee Networking

### 8.55 Chair's Opening Remarks



**Shon Green**  
Vice President, Nonclinical  
Development  
**Adicet Bio**

### Reviewing Mechanisms of Resistance

### 9.00 Reviewing the Intrinsic Mechanisms of Resistance to Cell Therapy

- CAR-T cells: lack of expression, lack of persistence, exhaustion
- Tumor microenvironment: impaired trafficking, metabolism, immune suppression
- Tumor cells: loss of target antigen, expression of inhibitory ligands, resistance to immune killing



**Sid Kerkar**  
Vice President, R&D  
**EXUMA Biotechnology**

### 9.30 Roundtable Discussion: Discussing Mechanisms of Resistance & How to Overcome Them

- What mechanisms of resistance are the most problematic?
- How can we overcome mechanisms of resistance and develop effective cell-based therapies?



**John Rossi**  
Vice President, Head of  
Translational Medicine  
**CARGO Therapeutics**



**Renaud Vaillant**  
Founder & Chief Executive  
Officer  
**Alaya.bio**

### 10.30 Morning Break & Networking

### Leveraging Innate Immune Cells to Overcome the Tumor Microenvironment

### 11.00 Overcoming Resistance & the Tumor Microenvironment with CAR-Macrophage Therapies

NEW  
DATA

- Pioneering next-generation cell therapies to cure difficult-to-treat cancers
- Developing novel mechanisms to enhance immune cell performance in the solid tumor microenvironment
- Presenting new data on Inceptor Bio's CAR-macrophage product



**Sumiti Jain**  
Vice President, Head of R&D  
**Inceptor Bio**

### 11.30 Leveraging NKT Cells to Tackle the Tumor Microenvironment

- Developing CAR-NKT therapies to tackle tumor microenvironment challenges
- Leveraging multiple killing mechanisms to overcome cancer heterogeneity challenges
- Sharing pre-clinical data



**Jason Damiano**  
Chief Scientific Officer  
**Appia Bio**

### 12.00 Lunch Break

### Developing Next-Generation CAR-T Therapies to Overcome Mechanisms of Resistance

### 1.00 Strategies to Deliver Best-in-Class Engineered CAR-T Cell Products to Overcome Resistance & Address Barriers to Patient Access

- Multiple autologous CAR-T cell products are now commercially approved in the setting of NHL and MM; however, many patients still relapse
- Leveraging scientific data and clinical experience to direct development of next-gen engineered cellular therapy products
- Discussing known resistance mechanisms and strategies to overcome resistance



**John Rossi**  
Vice President, Head of  
Translational Medicine  
**CARGO Therapeutics**

### 1.30 Targeting Solid Tumors with SMART CAR-T by Overcoming Suppressive Tumor Microenvironment

- Overcoming the suppressive tumor microenvironment, a major obstacle for CAR-T cell therapy in solid tumors
- Converting negative signaling of suppressive TME molecules into a positive signal to promote T-cell proliferations and survival
- Revealing preclinical data showing SMART CAR-T cells have improved resistance to suppressive tumor microenvironment and superior efficacy in immune cold tumor models
- Sharing updates on ongoing clinical testing



**LJ Shen**  
Senior Vice President, Head of  
R&D  
**Gracell Biotechnologies**

### 2.00 Overcoming the Challenges of CAR-T in Solid Tumors

- Reviewing CAR-T proof-of-concept data in solid tumors
- Developing next-gen technology to improve persistence and homing of CAR-T
- Driving improvements in the delivery of CAR-T



**Hong Ma**  
Senior Vice President, Clinical  
Development  
**CARsgen Therapeutics**

### 2.30 Afternoon Break & Networking

### Developing Next-Generation TIL Therapies to Overcome Mechanisms Resistance

### 3.00 Next-Gen TIL: Counteracting the Solid Tumor Microenvironment

- Targeting immune checkpoint targets using gene editing
- Developing tethered cytokine approaches to increase TIL persistence post-infusion
- Enhancing tumor-specific immunity through enrichment and selection



**Michelle Simpson Abelson**  
Executive Director, Research  
**Iovance Biotherapeutics**

### 3.30 Developing Gene-Edited TIL Cell Therapy Products to Revolutionize the Treatment of Solid Tumors

NEW  
DATA

- Systematically identifying targets that have the potential to improve T-cell function in the tumor microenvironment
- Developing a pipeline of gene-edited TIL cell products
- Demonstrating improved tumor-killing abilities in preclinical tumor models



**Karrie Wong**  
Senior Director, Head of Cell  
Therapy  
**KSQ Therapeutics**

### 4.00 End of Focus Day

### 4.10 Discussing Diversity at CAR-TCR

### 5.30 Welcome Reception

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# Discussing Diversity at CAR-TCR | Tuesday, August 29

August 29 – September 1, 2023  
Boston, MA



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## Diversity, Equity & Inclusion in Cell Therapy Biopharma

### 4.00 End of Workshop Day, Bootcamp Day, Focus Day & C-Level Think Tank

#### 4.10 Chair's Opening Remarks



**Gregory Fiore**  
Board Member  
**Eterna Therapeutics**

#### 4.15 Strengthening Clinical Trial Diversity to Understand Efficacy Across Population Groups

- Distinguishing why safety and efficacy of group treatment analyses are important for trial interpretation
- Understanding and overcoming barriers to patient accrual of historically underrepresented groups in the US
- Preparing for true global inclusion: cancer burden and clinical research needs of sub-Saharan Africa



**Adalynn Harris**  
President & Chief Executive  
Officer  
**Equity Bridge**

#### 4.45 Panel Discussion: Fostering Diversity in Cell Therapy Clinical Trials

- How do we motivate clinical trial sites to recruit diverse patient populations?
- What can we do to increase enrollment and improve retention?
- How do we overcome patient mistrust and lack of understanding of clinical trials?



**Adalynn Harris**  
President & Chief Executive  
Officer  
**Equity Bridge**



**Albeena Nisar**  
Scientific Officer & Head  
of Clinical Manufacturing,  
CAR-T Cell Therapy Center  
**Tata Memorial Centre**

#### 5.30 Welcome Reception

Reunite with old friends and meet new colleagues before the main event begins.



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# DAY 1 OVERVIEW

Wednesday, August 30

Use the buttons to below to navigate straight to your favourite track!



DISCOVERY



TRANSLATION



EARLY-STAGE CLINICAL STRATEGY



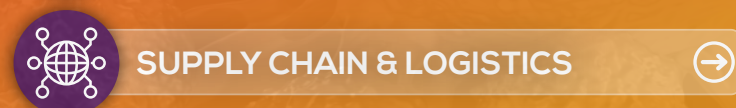
CLINICAL OPERATIONS



MANUFACTURING



CMC & ANALYTICS



SUPPLY CHAIN & LOGISTICS



COMMERCIALIZATION & MARKET ACCESS

## MORNING PLENARY SESSIONS

→ Autologous versus allogeneic versus *in vivo*: which will prevail?

### DISCOVERY TRACK

- Discovering and testing TCRs for the next generation of cell therapies
- Developing and translating a robust early TCR pipeline
- Evaluating and improving CAR design to increase anti-tumor efficacy

### EARLY-STAGE CLINICAL STRATEGY TRACK

- Preparing for IND submission to the FDA
- Sharing early-stage clinical results and strategy

### MANUFACTURING TRACK

- Optimizing manufacturing process and quality control
- Reducing vein-to-vein time to improve speed to patient
- Building and optimizing your own manufacturing facility

### SUPPLY CHAIN & LOGISTICS TRACK

- Transitioning from clinical to commercial supply volumes
- Implementing effective risk mitigation strategies for a robust supply chain
- Interfacing effectively with internal and external stakeholders

### TRANSLATION TRACK

- Translating therapies for hard-to-treat indications
- Identifying clinical biomarkers to predict and assess response
- Enhancing cell therapy persistence and reducing exhaustion

### CLINICAL OPERATIONS TRACK

- Establishing new clinical programs, teams, and operations
- Managing complex cell therapy clinical trials
- Overcoming challenges in patient recruitment, retention & follow up

### CMC & ANALYTICS TRACK

- Optimizing characterization to better predict cellular attributes
- Developing characterization strategies for ancillary materials & cell product
- Discussing regulatory guidance to ensure CMC regulatory compliance

### COMMERCIALIZATION & MARKET ACCESS TRACK

- Gaining insight into the payers' perspective
- Exploring strategies for pricing and reimbursement success
- Developing a strategy to reach markets beyond the United States

## DRINK'S RECEPTION

→ Join your peers for some informal networking, drinks, and nibbles.

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## MORNING PLENARY SESSIONS

### 7.30 Registration Open & Coffee Networking

### 8.20 Chair's Opening Remarks



**Adrian Bot**  
Chief Scientific Officer &  
Executive Vice President,  
R&D  
**Capstan Therapeutics**

## Autologous Versus Allogeneic Versus *In Vivo*: Which Will Prevail?

### 8.30 Academic & Industry Leaders Fireside Chat: Discussing the Past, Present & Future of Cell Therapy

- Where are we now and what is the future of cell therapy?
- What are the main challenges we have largely overcome versus the ones we have still yet to conquer?
- Which therapy will prevail ...auto, allo or *in vivo*?



**Stephan Grupp**  
Medical Director, Cell & Gene Therapy Lab  
**Children's Hospital of Philadelphia**



**Frank Neumann**  
Senior Vice President & Global Head of  
Clinical Development  
**Kite, A Gilead Company**



**Jennifer Brogdon**  
Head of Cell & Gene Therapy, Immuno-Oncology &  
Hematology  
**Novartis Institutes for BioMedical Research**

### 9.10 Teaching T-Cells to Be All That They Can Be to Target Cancer

- Enhancing the potency of CAR-T cells through the integration of armor, switches, and combinations
- Shortening *ex vivo* culture and automation to reduce costs and enhance potency
- Moving beyond CRISPR and vector free cargo delivery for implementing gene editing



**Bruce Levine**  
Barbara & Edward Netter  
Professor in Cancer Gene  
Therapy & Center for Cellular  
Immunotherapies Director of  
Technology Innovation  
**University of Pennsylvania**

### 9.30 The CDMO Value Proposition of Experience for Your Autologous Cell Therapy

- In an emerging market with few approved autologous products, established CDMOs bring the unique experience of having been through the commercialization phase before
- The added comfort of leveraging already-approved manufacturing sites and quality systems
- The flexibility to scale up and out, or ramp up or down operational personnel based on post-approval demand



**Joe Garrity**  
Head, Autologous Cell Therapy Commercial Development  
**Lonza**



**Anne Kantardjieff**  
Vice President, Manufacturing  
**Bluebird Bio**

### 10.00 Morning Break & Networking

DISCOVERY TRACK	TRANSLATION TRACK	EARLY-STAGE CLINICAL STRATEGY TRACK	CLINICAL OPERATIONS TRACK	MANUFACTURING TRACK	CMC & ANALYTICS TRACK	SUPPLY CHAIN & LOGISTICS TRACK	COMMERCIALIZATION & MARKET ACCESS TRACK
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## MORNING SESSIONS

**Chair: Luke Pase**, Chief Technology Officer, **Anocca**

### Discovering & Testing TCRs for the Next Generation of Cell Therapies

#### 11.00 Fast & Reliable Discovery of Safe TCRs with Tunable Antigen Specificity

- Describing variational synthesis (ability to create high quality libraries incorporating patient repertoire/HLA/neo-antigen information)
- Leveraging benefits of variational synthesis (incorporating benefits of stochastic synthesis with cutting edge ML pipeline)
- Sharing results of our eTCR discovery pipeline for patients where traditional TCR discovery approaches have failed in oncology setting

**Cameron Gardner**, Director, Research Development, **JURA Bio**

#### 11.30 Rapid Engineering of Soluble TCRs for Enhanced Affinity via a High-Throughput Yeast-Based Platform

- Validating the expression and binding of yeast-produced soluble TCRs to their cognate peptide-HLAs
- Optimizing the affinity of two literature TCRs through selections of large yeast libraries
- Expressing and characterizing optimized TCR variants in a high-throughput platform
- Evaluating the specificity and T cell killing activity of optimized TCR leads as CD3 bispecifics

**Garrett Rappazzo**, Scientist, Platform Technologies, **Adimab**

#### 12.00 Panel Discussion: De-Risking TCRs to Ensure their Safety

- How do we pick the right target?
- How do we identify the right parental TCR?
- How should we best screen for cross-reactivity and allo-reactivity?

**Leah Sibener**, Co-Founder, Vice President of Therapeutic Discovery, **3T Biosciences**

**Reagan Jarvis**, Co-Founder & Chief Executive Officer, **Anocca**

**Gang Zeng**, President & Chief Executive Officer, **T-Cure Biosciences**

**Panel Moderator:**

**Gavin MacBeath**, Chief Executive Officer, **TScan Therapeutics**

**12.30 Lunch Break**

## POST-LUNCH SESSIONS

**Chair: Luke Pase**, Chief Technology Officer, **Anocca**

### Developing & Translating a Robust Early TCR Pipeline

#### 1.30 TCRs for Cancer Therapy & Where to Find Them!

- Leveraging iNKT cell properties for targeting tumors in an allogeneic format
- Enabling high-throughput rapid selection and optimization of functional TCRs via our proprietary TrxTM platform
- Developing a robust and scalable “off-the-shelf” TCR-iNKT manufacturing process

**Eleni Chantzoura**, Director, Discovery, **MiNK Therapeutics**

#### 2.00 Harnessing the Power of the Mobius® Breez Microbioreactor to Address Cell Therapy Process Optimization Challenges

- Leveraging a 2 mL automated perfusion system for process development (PD) across cell therapy unit operations
- Implementing a small-scale perfusion technology to improve cell therapy process understanding
- Demonstrating the Mobius® Breez Microbioreactor as a tool to define, monitor, and control critical process parameters (CPP) in T cell bioprocessing

**Kara Levine**, Senior R&D Manager, Cell Therapy Applications, **MilliporeSigma**

#### 2.30 Mediating Successful Discovery & Effective Translation of Quality TCR

- Integrating functional HTS with *in silico* analyses to accelerate TCR and cognate p-HLA discovery
- Mining safe, tumor-reactive, specificities from TIL harboring optimal TCR affinities
- Leveraging reductionist *in vitro* analytics for asset translation, and optimal T-cell priming in manufacturing

**Shawn Kubli**, Director, Cell Therapy, **Treadwell Therapeutics**

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

**Chair: Luke Pase**, Chief Technology Officer, **Anocca**

### Evaluating & Improving CAR Design to Increase Anti-Tumor Efficacy

#### 4.00 Engineering T-Cells with Novel Receptor Architectures & Potency Enhancements for Driving Efficacy of Cell Therapeutics

- Utilizing sophisticated engineering approaches to drive safe and effective anti-cancer cell therapies
- Developing novel receptor architectures that enable dual antigen and cross-modality targeting for exquisitely sensitive tumor cell recognition and killing
- Developing a suite of potency enhancements, including switch receptors, inducible cytokines, and complementary costimulatory signaling, for driving highly potent anti-tumor responses

**Steve Shamah**, Senior Vice President, Oncology Research, **2seventy bio**

#### 4.30 From CAR Concept to Cure: Challenges in CAR Discovery and Solutions for Clinical Success

- Highlighting the process of CAR discovery and identifying common pitfalls from our 20+ years of experience in the field
- Developing solutions to navigate common pitfalls and streamline our client's CAR discovery, sharing case studies of successful programs and unique applications
- Sharing benefits of partnering with Charles River, navigating through the entire process of developing a CAR-based therapeutic

**Gemma Moiset**, Senior Group Leader, Advanced Modalities Discovery, **Charles River**

#### 5.00 Evolution of Solid Tumor-Targeting CAR-T cells from Linear to Lateral Architectures

- Summarizing a phase 1 clinical trial of panErbB CAR-T cells in patients with head and neck cancer
- Optimizing novel lateral CAR platforms
- Demonstrating superior anti-tumour activity of lateral CARs in several tumor model systems

**John Maher**, Chief Scientific Officer, **Leucid Bio**

#### 5.30 Drink's Reception

Join your peers for some informal networking, drinks & nibbles.

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COMMERCIALIZATION &  
MARKET ACCESS TRACK

## MORNING SESSIONS

Chair: Shannon Dahl, Industry Expert

### Translating Therapies for Hard-to-Treat Indications

#### 11.00 A Landscape Overview of CAR & TCR Therapies

- Reviewing current trends in the CAR and TCR therapy landscape
- Looking to the future: how will therapies become successful in hard-to-treat solid tumors?
- Utilizing this database to accelerate the clinical development of your own cell therapy pipeline

Rachel East, Lead Research Analyst, Beacon

#### 11.30 Rapid Manufacturing on Automated Bioreactor to Accelerate Clinical Translation of Cell & Gene Therapies

- Challenges and opportunities in cell therapy process
- Next generation manufacturing strategies
- Easily translate your process to the Cocoon® Platform

Tamara Laskowski, Senior Director, Clinical Development, Lonza

#### 12.00 Panel Discussion: Developing Novel Therapies for Hard-to-Treat Indications

- What progress have we made in the past few years?
- What are the main challenges when translating therapies for hard-to-treat solid tumors?
- How can we address these challenges?

Arthur Stril, Chief Business Officer, Collectis

Chantal Kuhn, Director, Head of T-Cell Programs, Clade Therapeutics

Preet Chaudhary, Professor & Chief of Hematology; Founder, University of Southern California; Angeles Therapeutics

#### 12.30 Lunch Break

## POST-LUNCH SESSIONS

Chair: Shannon Dahl, Industry Expert

### 1.30 CAR ProTcell, Toward New Generation Allogeneic CAR-T Cell

- Leveraging the potential of T-cell progenitors for allogeneic cell therapy
- Achieving in vivo differentiation and thymic education of cellular immunotherapy products
- Developing a new generation of allogeneic CAR and TCR-T cells

Olivier Negre, Chief Scientific Officer, Smart Immune

### Implementing a Strategy to Measure & Optimize Clinical Performance

#### 2.00 In Process Measurements of Critical Quality Attributes of CAR-T Cells for Advanced Process Development and Manufacturing

- The importance of identifying and measuring critical quality attributes of CAR-T cells for designing safe and efficacious CAR-T
- The importance of in-process measurements for advanced process development and manufacturing workflows
- The importance immune cell metabolic measurements, effector function (potency) and cell phenotype for designing safe and efficacious CAR-T products

Yama Abassi, Associate Vice President, Strategic Marketing & Business Development, Agilent

#### 2.30 Implementing a Customized Biomarker Strategy to Measure & Optimize Clinical Performance of Allogeneic Cell Products

- Implementing a relevant suite of customized assays to track development of immunogenicity against allogeneic cell products
- Developing standardized quantitative assays alongside innovative exploratory methods to evaluate cellular PK
- Implementing use of pharmacodynamic markers to measure product activity and establish mechanisms of actions

Gloria Jih, Principal Scientist, Century Therapeutics

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

Chair: Shannon Dahl, Industry Expert

### Enhancing Cell Therapy Persistence & Reducing Exhaustion

#### 4.00 Enforcing Memory-Associated Programs to Enhance CAR-T Cell Persistence & Potency

- Overexpressing memory-associated transcription factors to promote a memory-like phenotype, thus increasing persistence
- Enhancing CAR-T cell anti-tumor activity in multiple *in vitro* and *in vivo* models
- Providing a universal approach for achieving optimal therapeutic T-cell states for cancer immunotherapies

Evan Weber, Assistant Professor of Pediatrics, University of Pennsylvania Perelman School of Medicine, Children's Hospital of Philadelphia

#### 4.30 The Power of Immune Receptor Sequencing to Inform the Next Frontier of Cancer Cell Therapy Development & Disease Burden Assessment

- Adaptive's state-of-the-art T-cell and B-cell sequencing capabilities can be leveraged in multiple phases of CAR T-cell development - from product characterization and in vivo persistence tracking to long-term clinical response monitoring
- TCR sequencing at unparalleled scale enables quantitative product characterization and sensitive in vivo tracking of infused T cells - across multiple tissues types and time points
- The FDA-cleared and CLIA-validated clonoSEQ MRD assay helps improve patient outcomes in the setting of novel cellular therapies with industry leading sensitivity, specificity, and standardization
- By combining CAR-T in vivo tracking with NGS-MRD, Adaptive can provide unmatched response characterization, sensitive disease burden assessment, and help adequately address regulatory concerns

Matt Knight, Senior Manager, Biopharma, Adaptive Biotechnologies

Jay Patel, Senior Medical Science Liaison, Adaptive Biotechnologies

#### 5.00 Improving TCR-T Therapeutics Persistence & Efficacy with Switch Receptors

- Developing MDG1015, a 3rd generation NY-ESO-1 targeted TCR-T therapy
- Merging the TCR with diverse enhancement tools like our PD1-41BB switch receptor
- Resulting in increased T-cell persistence, reduced T-cell exhaustion and elevated tumor killing

Dolores Schendel, Chief Scientific Officer, Medigene

#### 5.30 Drink's Reception

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## MORNING SESSIONS

**Chair: Leopold Sellner**, Senior Medical Director, Cell Therapy Development, **Takeda Oncology**

### Preparing for IND Submission to the FDA

#### 11.00 Bringing Solid Tumor & Hematologic Pipeline Through IND into Early Clinical Development

- Sharing aspects of our IND preparations and package for our allogeneic cell therapy pipeline
- Discussing the strategy for early clinical development
- Assessing choices and tradeoffs when submitting INDs

**Kristin Yarema**, President, Cell Therapy, **Poseida Therapeutics**

#### 11.30 Specificity Testing of Antibodies, Bispecifics & CAR-T Therapeutics for IND Using the Membrane Proteome Assay

- Assessing off-target antibody reactivity is a regulatory requirement for clinical development; however, conventional screening methods are often ineffective in screening newer therapeutic modalities including cell therapies
- Presenting the Membrane Proteome Array (MPA), a 6,000-protein cell-array for specificity screening and include case studies describing its successful use for regulatory filings
- The MPA has been proposed for qualification as new Drug Development Tool, and we will provide an update on its status with the FDA

**Rachel Fong**, Director, Sales & Alliances, **Integral Molecular**

#### 12.00 Panel Discussion: Discussing Initial Considerations When Planning for IND Submission

- At what point should the regulatory strategy for IND be in place?
- What are the common pitfalls with respect to initial IND applications?
- How can you plan to avoid these issues?

**Lynn Bayless**, Vice President, Head of Regulatory Affairs, **Mustang Bio**

**Kristin Yarema**, President, Cell Therapy, **Poseida Therapeutics**

**Mike Jones**, Senior Manager, Custom Services, **STEMCELL Technologies**

### 12.30 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Leopold Sellner**, Senior Medical Director, Cell Therapy Development, **Takeda Oncology**

### Sharing Early-Stage Clinical Results & Strategy

#### 1.30 Dual Targeting of BCMAxCD19 & FasTCAR Cell Therapy Leads to Excellent Clinical Efficacy & Safety

- Developing a BCMAxCD19 and FasTCAR dual targeting CAR-T cell therapy with next day manufacturing capabilities
- Overcoming safety concerns such as CRS and ICANS
- Sharing clinical results from 29 4L+ multiple myeloma (MM) patients, as well as 16 newly diagnosed MM patients

**Samuel Zhang**, Chief Business Officer, **Gracell Biotechnologies**

#### 2.00 Using Past Trial Data to Increase the Probability of Regulatory & Technical Success

- Understanding how AI and modeling can help design trial protocols that predict and mitigate key risks or patient safety events
- Understanding and selecting patient subpopulations to positively respond to your therapy
- Using commonly collected lab markers from trial participants and benchmarking against past trial data to predict and mitigate severe adverse events
- Understanding how to generate compelling evidence for market access

**Tanmay Jain**, Senior Director, Trial Design Solutions, **Medidata**

#### 2.30 Clinical Activity & Biological Correlatives of Response to CART-ddBCMA in Patients with Relapsed/Refractory Multiple Myeloma

- Utilizing a novel D Domain-based CAR
- Observing 100% ORR and 71% CR rate in 38 patients in phase 1
- Discussing correlatives of response in apheresis, drug products and patients

**David Tice**, Chief Scientific Officer, **Arcellx**

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

**Chair: Leopold Sellner**, Senior Medical Director, Cell Therapy Development, **Takeda Oncology**

#### 4.00 Clinical Insights from a Novel BCMA-directed CAR-T Manufactured Using the T-Charge Platform

- Reducing manufacturing time to <2 days using T-Charge™, an innovative platform
- Resulting in robust expansion and prolonged CAR-T cell persistence
- Presenting updated clinical and biomarker data from the ongoing Phase 1 study of PHE885, a T-Charge™ manufactured BCMA-directed CAR-T cell therapy, in patients (pts) with r/r multiple myeloma (RRMM)

**Serena De Vita**, Senior Clinical Program Leader, Translational Clinical Oncology, **Novartis Institute for Biomedical Research**

#### 4.30 Panel Discussion: Strategies for Successful Clinical Development of Cell Therapies

- Explore the latest strategies for navigating the complexities of clinical trial execution
- Identify clinical development best practices
- Learn insights into the cutting-edge advancements that are driving the future of cell therapies

**Moderator: Teresa Pokladowski**, Regional Vice President, Clinical Business Solutions, **Precision for Medicine**

**Andy Kinley**, Vice President, Innovation & Clinical Science

**Precision for Medicine**

**Dawn Buchanan**, Vice President, Clinical Operations, **Affymune Therapeutics**

**Christopher Heery**, Chief Medical Officer, **Arcellx**

#### 5.00 Sharing CD20-Directed CAR-T Clinical Data & Strategy

- Giving an overview of the CD20-directed CAR-T landscape
- Presenting data from clinical trials, sharing a cross-trial comparison
- Sharing overarching clinical strategy

**Bruce Dezube**, Senior Vice President, Head of Clinical Development, **Mustang Bio**

#### 5.30 Drink's Reception

Join your peers for some informal networking, drinks & nibbles.

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## MORNING SESSIONS

**Chair: Ekatherina Goryachikov**, Vice President, Head of Clinical Operations, **Adicet Bio**

### Establishing New Clinical Programs, Teams & Operations

#### 11.00 From Mouse to Human Clinical Trial in Under 2 Years & Under \$10 Million

- Translating autologous mouse Sirpa low macrophage therapy to autologous human Sirpa low macrophage therapy
- Establishing operations for a new clinical program
- Choosing the right CRO and CDMO

**Robert Towarnicki**, Founder, President & Chief Executive Officer, **SIRPant Immunotherapeutics**

#### 11.30 Group Discussion Session

#### 12.00 Panel Discussion: Building New Clinical Programs & Operations in Small Biopharma

- With limited resources, how can small biotech set up a cell therapy trial effectively?
- What challenges have we encountered, and what are the main lessons learned?
- How do we find the right CRO to work with?

**Dawn Buchanan**, Vice President, Clinical Operations, **AffyImmune Therapeutics**

**Ann Murphy**, Senior Director, Clinical Operations, **Poseida Therapeutics**

**Kevin Zikaras**, Industry Expert

**Abhi Gupta**, Senior Vice President, Head of Cell & Gene Therapy, **Syneos Health**

#### 12.30 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Ekatherina Goryachikov**, Vice President, Head of Clinical Operations, **Adicet Bio**

### Managing Complex Cell Therapy Clinical Trials

#### 1.30 Deliver High Quality Cell & Gene Therapy Clinical Trials by Selecting & Managing the Right CRO & Vendor Partners

- Selecting the right CRO and vendor partners
- Managing a trial in coordination with a CRO/vendor oversight

**Danielle Quarles**, Senior Director, Clinical Operations, **Sana Biotechnology**

#### 2.00 Group Discussion Session

#### 2.30 Setting Up a Multicentered CAR-T Clinical Trial

- Setting up a clinical trial with increasing complexity and tight timelines
- Building the budget
- Determining the number of sites you need to recruit for the number of patients required

**Ann Murphy**, Senior Director, Clinical Operations, **Poseida Therapeutics**

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

**Chair: Ekatherina Goryachikov**, Vice President, Head of Clinical Operations, **Adicet Bio**

### Overcoming Challenges in Patient Recruitment, Retention & Follow Up

#### 4.00 Recruitment Strategy in a Highly Competitive Cell Therapy Landscape

- Developing patient/site-centric study designs
- Out-of-the-box thinking for site identification/selection
- Leveraging relationships with study investigators and site staff

**Paulius Ojeras**, Executive Director, Clinical Operations, **Nkarta Therapeutics**

#### 4.30 Biomarker Sample Collections in the Age of Personalized Medicine – Operational Challenges Associated with CAR-T Trials

- Understanding key immune monitoring questions during CAR-T cell therapies
- Optimizing Schedule of Activities to maintain high patient compliance for longitudinal biomarker studies
- Customizing testing logistics for samples with short stability window on a global scale

**Vincent Leveque**, Principle Scientific Manager, **Genentech**

#### 5.00 End of Track

#### 5.30 Drink's Reception

Join your peers for some informal networking, drinks & nibbles.

WELCOME

MORE THAN JUST  
A MEETING

SPEAKERS

AGENDA AT A  
GLANCE

WORKSHOP DAY

FOCUS DAY

DISCUSSING  
DIVERSITY AT  
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## MORNING SESSIONS

**Chair: Sanjin Zvonić**, Senior Vice President, Business Development & Practice Expert, **Dark Horse Consulting**

### Optimizing Manufacturing Processes & Quality Control

#### 11.00 Delivering Next Generation Cell Therapy Manufacturing Faster Without Compromising Quality

- Establishing new capabilities to improve manufacturing efficacies
- Overcoming challenges in scaling out cell therapy production while maintaining QC
- Sharing future directions and opportunities for further optimizing cell therapy manufacturing processes

**Vaishali Shukla**, Vice President, Quality, Commercial Manufacturing, **Kite, A Gilead Company**

#### 11.30 Catalyzing Market Approval & Driving Sustainable Manufacturing of Allogeneic CGT through Healthy Donor Materials

- Improving patient access: is the industry ready to innovate?
- Cultivating an industry-driven donor ecosystem
- Novel approaches to accelerate speed to market and future-proof CGT manufacturing

**Yuki Maves**, Senior Product Manager, **AllCells**

#### 12.00 Panel Discussion: Reducing Manufacturing Timelines While Ensuring Product Quality

- What can be done to innovate the manufacturing process?
- Should we ship unreleased products?
- How can we optimize time-limiting quality control processes?

**Lisa McClintock**, Vice President, Site Leader, Cell Therapy Manufacturing, **Bristol Myers Squibb**

**Vaishali Shukla**, Vice President, Quality, Commercial Manufacturing, **Kite, A Gilead Company**

**Brian Mullan**, Chief Technical Officer, **Yposkesi**

#### 12.30 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Sanjin Zvonić**, Senior Vice President, Business Development & Practice Expert, **Dark Horse Consulting**

### Reducing Vein-to-Vein Time to Improve Speed to Patient

#### 1.30 Streamlining Manufacturing Processes to Improve Vein-to-Vein Time

- Discussing the evolution of the manufacturing process for TCR-T cell therapies through various stages of clinical development
- Enhancing manufacturing and optimizing QC testing
- Making continuous improvements to expedite release testing and reduction of vein-to-vein time

**Ali Mohamed**, Senior Vice President, CMC, **Immatic**

#### 2.00 Key Considerations in Building Successful Strategic Partnerships for Cell Therapy Manufacturing

- Reviewing a case study for strategic manufacturing between an innovative biotech startup and services provider for cell therapy, sharing experience from both parties
- Exploring the current manufacturing obstacles and challenges faced by new industry entrants, how the proper strategic partnership can help them assess, prepare and eventually overcome these hurdles
- Sharing best practice examples of how to develop the right synergistic relationship to bring therapies to patients

**John Trzupsek**, Chief Operating Officer, **Abata Therapeutics**

**Andrew Sandford**, President, **ElevateBio BaseCamp**

#### 2.30 Fully Automated High Yield Autologous CAR-T Clinical Manufacturing Process

- Leveraging a flexible, closed, fully automated manufacturing platform
- Developing a one week manufacturing process that is reproducible, and scalable
- Optimizing a process that supports production of CAR-T cells with a favourable phenotype

**Rajesh Krishnan**, Chief Technology Officer, **Oncternal Therapeutics**

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

**Chair: Sanjin Zvonić**, Senior Vice President, Business Development & Practice Expert, **Dark Horse Consulting**

### Building & Optimizing Your Own Manufacturing Facility

#### 4.00 From Innovation to Clinical Manufacturing: How to Boost a Phase I Cell Therapy Engine

- Innovating in cell therapy product development
- Bringing innovation in Phase I clinical manufacturing, a unique setting
- Optimizing facility design for clinical manufacturing

**Nelly Viseux**, Senior Vice President, Process & Analytical Development & Clinical Manufacturing, **2seventy bio**

#### 4.30 Panel Discussion: Keys to Success for Commercial Ready Cell Therapy Facilities

- Hear from industry experts on their approach to scaling an innovative commercial cell therapy manufacturing facility
- Gain key insights into building out the appropriate technical operations infrastructure and project workstreams and quality systems
- Learn about various phased implementation, CQV, quality and regulatory strategies

**Moderator: John Khoury**, Executive Vice President, **Project Farma**  
**Narinder Singh**, Chief Technical Officer, **Arcellx**

#### 5.00 Moving from External to Internal Manufacturing for iNKT Cell Therapy Products

- Sharing the benefits and challenges from working with CMOs and building your own internal manufacturing process
- Ensuring process consistency and product yield
- Gaining the process knowledge to define PV and commercial production strategy

**Joy Zhou**, Vice President, CMC Head, **MiNK Therapeutics**

NEW DATA

#### 5.30 Drink's Reception

Join your peers for some informal networking, drinks & nibbles.

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## MORNING SESSIONS

**Chair: Damien Fink**, Director, Analytical Development, Century Therapeutics

### Optimizing Characterization to Better Predict Cellular Attributes

#### 11.00 Establishing Fit-for-Purpose Cell Measurements to Better Predict Cellular Attributes

- Designing fit-for-purpose cell assays that are correlative with cell outcome
- Utilizing concepts from existing standards to design experiments and optimize measurement techniques
- Developing a matrix-based approach toward cell viability measurements

**Laura Pierce**, Biomedical Engineer, National Institute of Standards & Technology



#### 11.30 An Academic Lab Perspective on Next-Generation CART19 Products' Identity, Purity & Potency

- Session details to be announced

**Patrizia Porazzi**, Senior Research, Investigator, Center for Cellular Immunotherapy, University of Pennsylvania

#### 12.00 Panel Discussion: Exploring the Future of Cell Therapy Characterization to Ensure High Quality Products

- What are the current challenges when characterizing your therapy? How can we solve this issue?
- How can we provide more systematic and unbiased insights to enable deeper characterization?
- What new equipment and methodologies can we utilize?

**Edward Armstrong**, Vice President, Quality, Mustang Bio

**Troy Lionberger**, Senior Vice President, Business Development, PhenomeX

**Shibani Mitra-Kaushik**, Head, Product Control Strategy & Analytics, Takeda

**Jie Wei**, Director, Analytical Sciences, Tr1X Bio

12.30 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Damien Fink**, Director, Analytical Development, Century Therapeutics

### Developing Characterization Strategies for Ancillary Materials & Cell Product

#### 1.30 Best-in-Class Characterization of Ancillary Materials

- Leveraging supplier data for introduction of new materials
- Developing phase appropriate characterization strategies for raw materials
- Applying ancillary material best practices based on existing guidance documents

**Lili Belcastro**, Senior Principal Scientist, Bristol Myers Squibb

#### 2.00 Overcoming Challenges to Lock your CAR-T Cell Therapy Process & Speed Your Path to Clinic

- Developing closed, controlled and automated processes for CAR-T therapies remains a challenge
- Catalent's fully closed GMP compliant autologous CAR-T cell platform uses data-driven guidance to build a seamless, robust, modular workflow for both autologous and allogeneic cell therapies, minimizing risk without compromising on quality.
- Learn more about Catalent's UpTempoSM CAR-T Cell Therapy Platform

**TBC, Catalent**

#### 2.30 Exploring Innovation in Analytical Development to Facilitate Cell Therapy Product Development

- Discussing the CMC consideration for cell therapies
- Discussing the analytical strategy for the characterization of starting materials and product for quality, safety, and efficacy
- Discussing what and how innovation analytics to facilitate cell therapy product development

**Yu Qian**, Associate Director, Cell Therapy Technologies & Product Engine, Takeda

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

**Chair: Damien Fink**, Director, Analytical Development, Century Therapeutics

### Discussing Regulatory Guidance to Ensure CMC Regulatory Compliance

#### 4.00 Regulatory CMC Landscape for CAR-T Products

- Overviewing CAR-T regulatory CMC guidance
- Discussing the significance of re-organization at CBER and the new super office (OTP)
- Exploring CMC opportunities and challenges in 2023 and beyond

**Michael Lehmicke**, Vice President, Science & Industry Affairs, Alliance for Regenerative Medicine

#### 4.30 Achieving Efficient & Scalable Lentiviral Vector Platform

- What is the EuLV stable producer cell line development platform
- How to develop lentiviral vector producer cell lines using the EuLV platform
- What is the EuBioX - an automated monoclonal screening platform
- A real-world case study of a reliable and scalable LVV production workflow

**Roy Li**, Chief Operation Officer, Eureka Bio

#### 5.00 Lentiviral Vector CMC Considerations for CAR-T Therapies

- Developing best practice for using lentiviral vectors in gene transfer for gene-modified T-cell therapy manufacturing
- Describing lentiviral vector CMC considerations for clinical use
- Understanding how vector quality impacts CAR-T cell quality

**Seraphin Kuate**, Director, Global Regulatory CMC, CAR-T Cell Therapy, Bristol Myers Squibb

#### 5.30 Drink's Reception

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## MORNING SESSIONS

**Chair: Lee Buckler**, Senior Vice President, Advanced Therapies & Business Development, **Blood Centers of America**

### Transitioning from Clinical to Commercial Supply Volumes

#### 11.00 Setting Up & Managing an Optimized Supply Chain to Support Phase Appropriate Growth

- Demonstrating good operations management and organizational set up for optimized and cost effective end-to-end logistics
- Introducing cell therapy supply chain models and phase appropriate setup
- Addressing challenges in setup and operation of manufacturing sites and logistics processes for clinical trials and key takeaways from global commercial launch experiences

**Shah Ahmad**, Senior Director, External Manufacturing & Supply Chain, **Immunomic Therapeutics**

#### 11.30 Capacity for Autologous Therapies: Neutral Third-Party Platforms to Support Growth

- Limiting variability in starting materials and ensuring a high-quality product through an ISO 9001:2015 certified Quality Management System
- Growing capabilities and geographic footprint: setting up supply chain to support phase appropriate growth thereby saving time and money
- Ensuring an integrated work flow: key considerations when building a partnership
- Detailing a centralized, single source, account management team to ensure services meet your current and evolving needs

**Michelle Hensey**, Process Excellence, Therapeutic & Cellular Solutions (TCS), **American Red Cross Blood Services**

#### 12.00 Panel Discussion: Overcoming Logistical Challenges with a Solution to Commercialization

- How can we prepare to scale logistical workflows?
- How do we achieve standardization?
- What future challenges can we expect as the field moves further towards commercialization?

**Chris Baldwin**, Senior Director, Cell & Gene Therapy Supply Chain, **GSK**

**Shah Ahmad**, Senior Director, External Manufacturing & Supply Chain, **Immunomic Therapeutics**

12.30 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Lee Buckler**, Senior Vice President, Advanced Therapies & Business Development, **Blood Centers of America**

### Implementing Effective Risk Mitigation Strategies for a Robust Supply Chain

#### 1.30 Patient Considerations for the Management of Cycle Times for Autologous Cell Therapies

- Exploring parallels and touch-points between the patient and cell journey
- Working with your partners to hit cycle times

**David Kim**, Head of Supply Chain, **Arcellx**

#### 2.00 Developing a Robust Supply Chain Through Contingency Planning

- Understanding the importance of contingency planning in a dynamic world
- Positioning yourself for success through pre-clearance and supplier balancing
- Thinking ahead; planning for growth and scalability

**Matthew Plaud**, Chief Operations Officer, IntegriCell, **Cryoport Systems**

#### 2.30 Presentation TBC

- Session details to be announced

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

**Chair: Lee Buckler**, Senior Vice President, Advanced Therapies & Business Development, **Blood Centers of America**

### Interfacing Effectively with Internal & External Stakeholders

#### 4.00 Implementing an Effective Logistics Strategy for Clinical Trial Onboarding

- Managing the interface with CDMOs and clinical sites to ensure supply
- Providing a start-up company perspective on how to supply planning
- Developing systems to manage early clinical logistics

**Thomas Tredennick**, Associate Director, Clinical Supply Chain, **Arsenal Bio**

#### 4.30 De-Risking Your Ultra Cold Supply Chain with Best-in-Class Solutions

- Discussing ultra cold supply chain challenges for temperature sensitive critical materials
- Improving visibility of your critical materials in transit to ensure compliance
- Mitigating cost and timeline risks through customized solutions for commercial packaging, just-in-time labeling, and cold chain distribution

**Susan Li**, Senior Client Services & Solutions Director, **Thermo Fisher Scientific**

#### 5.00 Roundtable Session: Coordinating Communications to Streamline End-to-End Supply Chain

- How can we improve internal and external communications?
- What is the best way to establish an effective supply chain infrastructure?

#### 5.30 Drink's Reception

Join your peers for some informal networking, drinks & nibbles.

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## MORNING SESSIONS

**Chair: Jodie Wehling**, Vice President, Market Access & Trade, **Mesoblast**

### Gaining Insight into the Payers Perspective

#### 11.00 Future Directions on Drug Pricing Models for Cell & Gene Therapies

- Discussing what is on the horizon for access, pricing and reimbursement for cell therapies
- Outlining the CMMI Cell & Gene Therapy Access Program (as mentioned in the Secretary's EO Report)
- Reviewing the structure of outcomes-based agreements: bringing states and manufacturers together
- Measuring the impact and success of CMMI's efforts in cell and gene therapies

**Laura McWright**, Deputy Director, Seamless Care Models Group, CMMI, **Centers for Medicare & Medicaid Services**

#### 11.30 Panel Discussion: Discussing the New Cell & Gene Therapy Access Model

- How can we utilize new payment and service delivery models to achieve better care for patients?
- How should the new payment models be implemented?
- What challenges still lie ahead?

##### Moderator:

**Vinod Mitta**, Seamless Care Models Group, **CMMI Centers for Medicare & Medicaid Services**

##### Speakers:

**Katherine Szarama**, Director, Drug Pricing, **Arnold Ventures**

**Brett Logan**, **Independent Expert**

**Brent Rice**, Senior Vice President, Chief Commercial Officer & Head US, **Autolus**

**Aurelia Chaudhary**, Cell & Gene Therapy Access Model Lead, Seamless Care Models Group, **CMMI Centers for Medicare & Medicaid Services**

#### 12.30 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Jodie Wehling**, Vice President, Market Access & Trade, **Mesoblast**

### Exploring Strategies for Pricing & Reimbursement Success

#### 1.30 Exploring Provider Driven Reimbursement & Access Challenges

- Moving from inpatient to outpatient settings may trigger US Federal 340B reduced drug prices for hospitals
- Increasing provider capacity is critical for market access
- Designing innovative payment models must consider provider incentives as well as the payer and developer needs

**Mark Trusheim**, **Strategic Director**, NEWDIGS, **Tufts Medical Center**

#### 2.30 Roundtable Session: Implementing Pricing Models & Strategies to Make Cell Therapy Affordable

- What is the right pricing strategy for cell and gene therapies?
- What are the potential solutions to drive down price?

#### 3.00 Afternoon Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!

## AFTERNOON SESSIONS

**Chair: Jodie Wehling**, Vice President, Market Access & Trade, **Mesoblast**

### Developing a Strategy to Reach Markets Beyond the United States

#### 4.00 Developing Market Access Strategy Beyond the US for CAR-T Cell Therapies

- Discussing access hurdles and challenges in value assessment of CAR-T cell therapies
- Driving practical solutions to achieve timely and broad access
- Helping patients in hard-to-reach areas – cross-border treatment

**Jie Zhang**, Vice President, Head of Cell & Gene Value & Access, **Novartis**

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#### 4.30 Building a Successful Market Access & Commercialization Strategy for Allogeneic Cell Therapy Products

- Developing a US and global market access strategy and execution to maximize patient access and revenue gains
- Discussing readiness strategies for commercialization
- Optimizing a unique “Go To Market” commercialization strategy based on the precise needs of the cell therapy and the size of the potential market

**Jodie Wehling**, Vice President, Market Access & Trade, **Mesoblast**

#### 5.00 End of Track

#### 5.30 Drink's Reception

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# DAY 2 OVERVIEW

Thursday, August 31

Use the buttons to below to navigate straight to your favourite track!



DISCOVERY



TRANSLATION



EARLY-STAGE CLINICAL STRATEGY



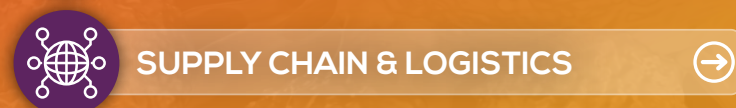
CLINICAL OPERATIONS



MANUFACTURING



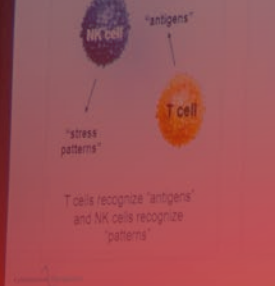
CMC & ANALYTICS



SUPPLY CHAIN & LOGISTICS



COMMERCIALIZATION & MARKET ACCESS



## MORNING PLENARY SESSIONS

→ Demonstrating success in solid tumors

### DISCOVERY TRACK

- Transforming solid tumor treatment with innovative platform technology
- Leveraging novel approaches to targeting solid tumors
- Utilizing high throughput methods to revolutionize drug discovery and development

### TRANSLATION TRACK

- Using novel gene engineering technologies to improve cell therapy function
- Demonstrating success through use of preclinical models
- Spearheading therapeutic development by leveraging the innate immune system

### EARLY-STAGE CLINICAL STRATEGY TRACK

- Developing combination strategies to enhance cell efficacy
- Enhancing clinical efficacy with immunosuppression strategies
- Exploring different administration/dosing regimens to optimize clinical efficacy

### CLINICAL OPERATIONS TRACK

- Preparing for large-scale national and international clinical trials
- Expanding access to cell therapy clinical trials
- Ensuring clinical trial best practice and compliance

### MANUFACTURING TRACK

- Optimizing manufacturing with innovative technology and equipment
- Leveraging partnerships to accelerate development
- Recruiting, training, and retaining skilled workers in manufacturing

### CMC & ANALYTICS TRACK

- Exploring CMC strategy to ensure product safety and efficacy
- Overcoming potency assay development challenges to elucidate biological activity
- Assessing safety of genetically modified cell therapies

### SUPPLY CHAIN & LOGISTICS TRACK

- Implementing digital systems to transform end-to-end development
- Addressing chain of identity and custody concerns to improve traceability
- Outlining best practices from world-class research centers

### COMMERCIALIZATION & MARKET ACCESS TRACK

- Developing an effective infrastructure to support commercialization
- Highlighting key considerations for a successful commercial launch
- Incorporating the patient voice into market access strategies

## AFTERNOON POSTER SESSION

- Submit your abstract here before Friday, July 28 to get involved
- High-quality abstracts will be judged by our esteemed CAR-TCR Advisory Board, who will decide the CAR-TCR Poster Award winner

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## MORNING PLENARY SESSIONS

### 6.30 Emily Whitehead Foundation 5K Run/Walk

- Join the Emily Whitehead Foundation and CAR-TCR for a run (or walk) around Boston
- Participate in person or virtually, with funds being raised benefiting the Emily Whitehead Foundation



### 7.00 Morning Arrival & Coffee Networking

### 8.00 Chair's Opening Remarks



**Adrian Bot**  
Chief Scientific Officer &  
Executive Vice President,  
R&D  
**Capstan Therapeutics**

### 8.05 Panel Discussion: The Journey of Commercializing Cell Therapies

- Identifying active strategies to enable a smooth plan from preclinical development to commercialization
- Discussing new approaches for regulatory approval and commercialization
- Anticipating and overcoming potential hurdles specific to cell therapies



**Moderator: Anshul Mangal**  
President  
**Project Farma & Precision ADVANCE**



**Lisa McClintock**  
Vice President, Site Leader, Cell Therapy Manufacturing  
**Bristol Myers Squibb**



**Warner Biddle**  
Senior Vice President & Global Head of  
Commercial  
**Kite, A Gilead Company**



**Kristin Yarema**  
President, Cell Therapy  
**Poseida Therapeutics**

## Demonstrating Success in Solid Tumors

### 8.50 Customized, Multiplexed TCR-T Cell Therapy for Solid Tumors

- Treating solid tumors with multiplexed TCR-T therapy to overcome tumor heterogeneity and HLA loss
- Enhancing TCR-T to overcome the hostile tumor microenvironment
- Sharing clinical trial design to enable multiplexing in phase 1



**Gavin MacBeath**  
Chief Executive Officer  
**TScan Therapeutics**

### 9.10 Empowering the Future of Cell Therapy: Leveraging Partnerships to Support Advancement

- Defining the importance of collaborative relationships between industry stakeholders to help drug developers overcome major obstacles associated with transitioning cell therapies from early discovery to clinical and commercial phases
- Discussing the barriers to execution, opportunities to provide support, and the responsibility and implications for drug developers, tools providers and early discovery teams
- Examining the anatomy of a collaboration; inside look at what it takes to set up infrastructure that is relevant and functional (training, investment, continued support) and what benefit it offers to the incubator residents



**Juan Patarroyo**  
Director, Science Operations & Strategy  
**LabCentral**



**Luke Wallrich**  
Senior Manager, Business Strategy & Partnerships  
**LabCentral**



**Stan Wang**  
Founder & Chief Executive Officer  
**Thymune Therapeutics**



**Xavier de Mollerat du Jeu**  
Senior Director, R&D  
**Thermo Fisher Scientific**

### 9.40 Targeting Solid Tumors Combining Best-in-Class TCRs, Optimized Manufacturing & Next-Generation Enhancements

- Identifying TCRs of optimal affinity against tumor associated antigens
- IMAG1NE: Lead clinical program targeting MAGE-A1 expressing solid tumors
- Developing next-generation TCR-T therapies for hard-to-treat indications



**Peggy Sotiropoulou**  
Chief Scientific Officer  
**T-knife Therapeutics**

### 10.00 Innovations in T-Cell Manufacturing on Hollow Fiber Bioreactors

- Displaying the latest innovations in cell therapy manufacturing
- Using T-cells to meet the needs of new and emerging CAR-T cell platforms



**Mindy Miller**  
Lead Research Scientist, Cell  
Therapy Technologies  
**Terumo Blood & Cell  
Technologies**

### 10.30 Morning Break & Tech Slam

Hear the latest innovations that promise to revolutionize cell therapy development!



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## MORNING SESSIONS

**Chair: John Maher**, Chief Scientific Officer, **Leucid Bio**

### Transforming Solid Tumor Treatment with Innovative Platform Technology

#### 11.30 Nanrilkefusp Alpha, IL-15 Superagonist in Combination with CAR-T & BOXR-T Cells Enhances Anti-Tumor Efficacy

- Combining IL-15 agonism with CAR-T enhances T-cell response in preclinical models
- Enhancing treatment with tunable dosing scheme
- Adding benefit in addition to T-cell coded enhancements

**Amy Jensen-Smith**, Vice President, Discovery Research, **SOTIO Biotech**

NEW  
DATA

#### 12.00 Cell Avidity Drives the Functional Responses of Cell Therapies, Providing Superior Correlates to *In Vivo* Performance

- Developing a quick in vitro assay with robust correlation *in vivo* ( $R^2$ : 0.9)
- Leveraging avidity assays to positively rank and negatively cull candidates in the same assay
- Reducing the time and expense to murine studies while increasing confidence in lead selection

**Will Singletery**, Director, Immuno-oncology & Commercial, **Lumicks**

#### 12.30 Panel Discussion: Transforming a Novel Idea into a Successful Biotech Company

- How do you start up your own company beginning with an innovative idea?
- When starting a company, should you be technology focused or problem focused?
- How have you gained investment?

**JJ Kang**, Chief Executive Officer, **Appia Bio**

**Gregory Fiore**, Board Member, **Eterna Therapeutics**

1.00 Lunch Break

## POST-LUNCH SESSIONS

**Chair: John Maher**, Chief Scientific Officer, **Leucid Bio**

### Leveraging Novel Approaches to Targeting Solid Tumors

#### 2.00 Cytotoxic Immune Cells Engineered with a Chimeric ILT-Receptor

- Chimeric ILT-Receptor (CIR): a novel approach in cell therapy using natural receptor binding to tackle leukemia and solid tumors
- Addressing tumor immunosuppressive effect with engineered CIR-NK/CIR-T cells
- Building a cost-effective off-the-shelf technology to improve accessibility

**Raphaël Ognar**, Co-Founder & Chief Executive Officer, **NKILT Therapeutics**

#### 2.30 Therapeutics Efficacy & Mechanism of IL-7/CCL19-Producing CAR-T Cells in Solid Cancers

- Engineering PRIME CAR-T cells to produce IL-7 and CCL19 for the treatment of solid cancers containing CAR target-negative population
- Inducing epitope-spreading to endogenous tumor neoantigens following the treatment with PRIME CAR-T cells
- Promoting DCs with a potential of cross presentation by the treatment with PRIME CAR-T cells

**Koji Tamada**, President & Chief Executive Officer, **Noile-Immune Biotech**

#### 3.00 Roundtable Discussion: Discussing Current & Emerging Strategies to Target Solid Tumors

- Why has there not been much success targeting solid tumors to date?
- What novel engineering approaches can we utilize?
- How do we circumnavigate the solid tumor microenvironment?

**Henri Bayle**, Co-Founder & Chief Technology Officer, **NKILT Therapeutics**

**Raphaël Ognar**, Co-Founder & Chief Executive Officer, **NKILT Therapeutics**

3.30 Afternoon Break & Poster Session

## AFTERNOON SESSIONS

**Chair: John Maher**, Chief Scientific Officer, **Leucid Bio**

### Utilizing High Throughput Methods to Revolutionize Drug Discovery & Development

#### 4.30 Automation at Arsenal: Enabling Massively Parallel Genetic Engineering for Drug Product Development

- Developing and scaling Arsenal's automation to enable large scale research experiment for drug development and produce high quality data at an unprecedented scale
- Leveraging Arsenal's automation capability to explore new compositions in the CAR-T and TCR space

**Sophie Xu**, Associate Director, Automation & High Throughput Assay Development, **Arsenal Bio**

#### 5.00 Automated Solutions for Streamlining CAR-TCR Discovery Workflows

- Automating synthetic biology and multiomic workflows to streamline CAR engineering
- Enabling rapid expression and screening of TCRs through automated mRNA synthesis
- Overcoming synthesis bottlenecks for novel mRNA modalities with push-button solutions
- Applying the next-generation molecular biology workstation to optimize workflows throughout CAR-TCR discovery

**Jyotsna Venugopal**, Director, Product Marketing, **Telesis Bio**

#### 5.30 High-Throughput Discovery of Novel Regulators of T-Cell Function to Build Better Immunotherapies

- Developing a scalable gain-of-function discovery platform in human T-cells
- Applying discovered modulators across different contexts: CARs and TCRs, T-cell subsets, tumor types
- Leveraging synthetic biology to design improved versions of natural human genes

**Mat Legut**, Co-Founder & Chief Executive Officer, **OverT Bio**

NEW  
DATA

6.00 End of Conference Day 2

WELCOME

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## MORNING SESSIONS

Chair: Shannon Dahl, Industry Expert

### Using Novel Gene Engineering Technologies to Improve Cell Therapy Function

#### 11.30 Novel Non-Viral Gene Writing for Immune Cell Therapy

- Leveraging circular single stranded DNA for superior non-viral targeted genome integration
- Engineering clinically meaningful cells with extra-large transgene integration
- Developing functional CAR-T cells with cssDNA based non-viral gene writing platform

**Howard Wu**, Co-Founder & Chief Scientific Officer, **Full Circles Therapeutics**

#### 12.00 Unlocking Allogeneic & Solid Tumor T Cell Therapies with Multiplexed Genome Editing

- Building durable allogeneic therapies resistant to T and NK cell rejection with an HLA pruning approach
- Ensuring scalable genome editing with lipid nanoparticles to address off-the-shelf manufacturing
- Enhancing efficacy in solid tumors by bypassing immune suppressive mechanisms

**Birgit Schultes**, Senior Vice President, Head of Cell Therapy, **Intellia Therapeutics**

#### 12.30 Panel Discussion: Engineering the Next-Generation of Cell-Based Therapeutics

- What are the best engineering modalities and approaches to create 'better' cells for clinical use?
- How can we increase persistence and cell fitness?
- What is the best way to protect cells from the tumor microenvironment?

**Sven Kili**, Principal, **Sven Kili Consulting**

**Howard Wu**, Co-Founder & Chief Scientific Officer, **Full Circles Therapeutics**

**Birgit Schultes**, Senior Vice President, Head of Cell Therapy, **Intellia Therapeutics**

1.00 Lunch Break

## POST-LUNCH SESSIONS

Chair: Shannon Dahl, Industry Expert

### Demonstrating Success Through Use of Preclinical Models

#### 2.00 Developing & Translating Multi-Specific Cytotoxic CD4+ T-Cell (CD4 CTL) Therapy for Cancers

- Understanding CD4 CTL biology
- Developing multi-specific CD4 CTL therapy in preclinical animal models
- Translating CD4 CTL therapy to humans

**Baochun Zhang**, Assistant Professor of Medicine, Dana-Faber Cancer Institute, **Harvard Medical School**

#### 2.30 Determinants of Resistance to CAR-T Cell Therapy in Large B Cell Lymphoma

- CAR T cell expansion in blood is linked to toxicity but has weak to no association with response in large B cell lymphoma (LBCL)
- Using mass cytometry, flow cytometry, single-cell sequencing, and functional studies, we identified and validated that prevalence of CAR+ T regulatory (CAR Treg) cells in blood at peak CAR T cell expansion is linked to progression
- A model combining CAR Treg prevalence with baseline lactate dehydrogenase (LDH) levels, as a surrogate for tumor burden, was superior for predicting durable clinical response compared to models relying on each feature alone
- CAR Treg cells originate from pre-existing natural Treg (nTreg) cells

**Zinaida Good**, Instructor, **Stanford University School of Medicine**

#### 3.00 Roundtable Discussion: Emerging Challenges of Using Preclinical Models

- How do we choose preclinical animal models that predict outcomes in human trials?
- What are the limitations of non-human primates as translational models in immuno-oncology?
- How can we overcome these challenges?

3.30 Afternoon Break & Poster Session

## AFTERNOON SESSIONS

Chair: Shannon Dahl, Industry Expert

### Spearheading Therapeutic Development by Leveraging the Innate Immune System

#### 4.30 ViveNKTM: Genetically Modified Stem Cell Derived Natural Killer Cells, a New Hope for Cancer Immunotherapy

- Off-the-shelf, cryopreserved, allogeneic stem cell derived NK cells
- Closed feeder free system for generation of CAR-NK cells
- Chimeric antigen receptors, CAR vector design, transduction platform development
- Stable and functional CAR expression against a novel target as well as against CD19 and Her2 as PoC

**Adil Duru**, Senior Research Manager, **Glycostem**

#### 5.00 A Universal Tool for Monitoring Multiple CAR-T Therapies in the Clinic - A Case Study for Future Clinical Development

- Describing development and application of multiplexed ddPCR to simultaneously monitor the levels of three approved CD19-directed CAR-Ts
- Presenting design principals and POC data for a futuristic assay that can detect bispecific CAR-Ts, safety and reference genes in a single sample
- Aiding the development of next generation CD19-directed CARs but also other novel therapeutic modalities (e.g., bispecific or CRISPR edited CARs)

**Shabnam Tangri**, Chief Scientific Officer, **Navigate BioPharma**

#### 5.30 Identification of NK Cell Specific CARs for iNK Targeted Knock In & Combination Treatments with CYT-303 Flex-NK™ Cell Engagers for Hepatocellular Carcinoma

- Developing a pipeline of iNK cell therapies and Flex-NK™ cell engagers to unleash the full potential of NK cells in the tumor microenvironment
- Treating indications including HCC, MM and GB
- Demonstrating that the combination iNK cells and Flex-NK™ cell engagers can reverse dysfunctional NK cells in the immunosuppressive tumor microenvironment

**Tony Arulanandam**, Senior Vice President & Head of Preclinical R&D, **Cytovia Therapeutics**

6.00 End of Conference Day 2

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## MORNING SESSIONS

**Chair: Sonal Gupta**, Senior Vice President, Head of Clinical Development, **Affymune Therapeutics**

### Developing Combination Strategies to Enhance Cell Efficacy

#### 11.30 Addressing T-Cell Therapy into Earlier Treatment Settings

- Addressing the unmet medical need
- Moving towards regulatory approval
- Progression of therapy – combining immune checkpoint inhibitors and T-cell therapy into earlier lines of treatments

**Friedrich Graf Finckenstein**, Chief Medical Officer, **Iovance Biotherapeutics**

#### 12.00 Large-Scale Isolation of T Cells & Other Populations for Research

- Startup costs and ease of use with products for the isolation of T cells and other cell populations
- Processing apheresis products with negative selection without ficoll gradients

**Tim Waters**, Director, Advanced Cell Processing, **Bloodworks Northwest**

#### 12.30 Panel Discussion: Discussing Combination Therapy as an Opportunity for Improved Efficacy

- How can combination therapy enhance its success in treating cancer?
- What combinations seem the most promising?
- What challenges must be considered when pairing therapies?

**Tony Arulanandam**, Senior Vice President, Head of Preclinical R&D, **Cytovia Therapeutics**

**Friedrich Graf Finckenstein**, Chief Medical Officer, **Iovance Biotherapeutics**

**Leopold Sellner**, Senior Medical Director, Cell Therapy Development, **Takeda Oncology**

**1.00 Lunch Break**

## POST-LUNCH SESSIONS

**Chair: Sonal Gupta**, Senior Vice President, Head of Clinical Development, **Affymune Therapeutics**

### Enhancing Clinical Efficacy with Immunosuppression Strategies

#### 2.00 Allogeneic CAR-T Cell Therapy for Acute Leukemias: Where are we Now?

- Reviewing progress in both acute lymphoid and acute myeloid leukemias
- Highlighting the role of alemtuzumab in the lymphodepletion regimen
- Discussing next steps

**Mark Frattini**, Chief Medical Officer, **Collectis**

#### 2.30 Strategies for Navigating Early-Phase Trials to Develop Successful CGT Products

- Highlighting aspects of Candel's clinical platforms
- Exploring the importance of having a clear CMC strategy in the development of cell and gene therapies (CGT)
- Addressing key CMC issues in CGT
- Outlining best practices to achieve regulatory and pre-launch success

**Seshu Tyagarajan**, Chief Technical & Development Officer, **Candel Therapeutics**

#### 3.00 Roundtable Discussion: Impacting CAR-T Efficacy with Pre-Conditioning Regimens

- What is the optimal approach to lymphodepletion for liquid and solid tumors?
- Should we intensify or not intensify preconditioning regimens, and why?
- What is the best lymphodepletion approach to balance between safety and efficacy?

**Pamela Garzone**, Chief Development Officer, **Anixa Biosciences**

**3.30 Afternoon Break & Poster Session**

## AFTERNOON SESSIONS

**Chair: Sonal Gupta**, Senior Vice President, Head of Clinical Development, **Affymune Therapeutics**

### Exploring Different Administration/Dosing Regimens to Optimize Clinical Efficacy

#### 4.30 Optimizing Non-Engineering Clinical Approaches to Improve Outcomes in Cell Therapies

- Discussing ways to leverage lymphodepletion therapies to maximize efficacy in cell therapy
- Leveraging dose optimization strategies to overcome response challenges to cell therapies
- Discussing emerging information on multi-dosing and combination therapy

**Ramon Tiu**, Vice President & Head of Oncology Cell Therapy Development, **Takeda**

#### 5.00 CellReady, A New Paradigm in Cell Manufacturing

- Crossing the chasm - the time has arrived to expedite cell therapies to market
- Optimizing cell therapy manufacturing through standardizing processes
- Accelerating the learning curve and overcoming roadblocks from research to GMP
- CDMOs vs CMOs and reshaping the common goal

**Anastasiya Smith**, Senior Director, R&D, **Marker Therapeutics**

#### 5.30 Developing a CAR-T for Ovarian Cancer & Other Solid Tumors

- Developing CAR-T in solid tumors
- Exploring routes of administration beyond IV
- Discussing the role of lymphodepletion for CAR-T in solid tumors
- Sharing translational and early clinical data

**Pamela Garzone**, Chief Development Officer, **Anixa Biosciences**



**6.00 End of Conference Day 2**

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## MORNING SESSIONS

**Chair: Dawn Buchanan**, Vice President, Clinical Operations  
**AffyImmune Therapeutics**

### Preparing for Large-Scale National & International Clinical Trials

#### 11.30 Building a Team & Plan to Prepare for International Clinical Trials

- Developing best approaches and strategies to build and internal clinical operations team from the ground up
- Scaling the team appropriately, ensuring you have the resources to effectively support clinical trials
- Developing and enhancing clinical operations infrastructure to support global clinical operations

**Ekatherina Goryachikov**, Vice President, Head of Clinical Operations, **Adicet Bio**

#### 12.00 Group Discussion Session

#### 12.30 Panel Discussion: Building & Training Teams to Deliver Effective Cell Therapy Clinical Trials

- How should we build new teams to deliver clinical trials effectively?
- Given that cell therapy trials have so many unique aspects and challenges, how do we onboard new staff?
- How do we train and develop internal and external teams effectively?

**Ekatherina Goryachikov**, Vice President, Head of Clinical Operations, **Adicet Bio**

**Rachelle Senzon**, Director, Clinical Trial Operations, **BioNTech**

**Heather Hughes**, Industry Expert

#### 1.00 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Dawn Buchanan**, Vice President, Clinical Operations  
**AffyImmune Therapeutics**

### Expanding Access to Cell Therapy Clinical Trials

#### 2.00 Improving Patient Access to CAR-T Clinical Trials

- Improving patient access and experience: review of the CAR-T access team structure
- Exploring financial clearance strategies for CAR-T clinical trials and commercial product coverage
- Overviewing clinical trial access barriers and strategies to mitigate them

**Claire White**, Administrative Manager, Cell Therapy & Transplant Section, **Children's Hospital of Philadelphia**

#### 2.30 Supporting Patients & Families on their Journey to Activate the Cure

- Giving an update on Emily Whitehead, now cured after becoming the first pediatric patient to receive CAR-T cell therapy
- Discussing how the Emily Whitehead Foundation helps connect patients and families to clinical trials and treatment programs
- Exploring how the Emily Whitehead Foundation will grow going into the next decade of CAR-T, and how you can help

**Tom Whitehead**, Co-Founder, **Emily Whitehead Foundation**

#### 3.00 Roundtable Discussion: Discussing Strategies to Meet Wider Patient Populations

- How are you encouraging diversity in clinical trials?
- How are you trying to improve geographical and financial accessibility?
- Discussing initiatives you have tried - what worked, what did not?

**Christopher Heery**, Chief Medical Officer, **Arcellx**

#### 3.30 Afternoon Break & Poster Session

## AFTERNOON SESSIONS

**Chair: Dawn Buchanan**, Vice President, Clinical Operations  
**AffyImmune Therapeutics**

### Ensuring Clinical Trial Best Practice & Compliance

#### 4.30 Introduction to the FDA's Bioresearch Monitoring Program

- Explaining the objectives of the FDA's Bioresearch Monitoring Program
- Understanding the inspectional process
- Examining CAR-T cell regulatory inspectional findings/trends

**Anne Johnson**, Program Division Director, Bioresearch Monitoring, Division I, **FDA**

#### 5.00 Developing SOPs, Working Instructions & Training to Guide Cell & Gene Therapy Clinical Trials

- Creating Standard Operating Procedures (SOPs) and working instructions (WI) which cater to the details of cell and gene therapy clinical trials
- Developing strategies to ensure the team is well trained
- Ensuring research is conducted in accordance with the relevant legislation and guidelines

**Rachelle Senzon**, Director, Clinical Trial Operations, **BioNTech**

#### 5.30 End of Track

#### 6.00 End of Conference Day 2

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## MORNING SESSIONS

**Chair: Sanjin Zvonić**, Senior Vice President, Business Development & Practice Expert, **Dark Horse Consulting**

### Optimizing Manufacturing with Innovative Technology & Equipment

#### 11.30 A Novel GD2 CAR-T Manufacturing Process for the Treatment of GD2+ Pediatric Brain Cancer: From PD to Patient Treatment

- Sharing preclinical data and development of a novel CAR-T manufacturing process
- Process feasibility of manufacturing and development optimization of the mode for delivery of drug product
- Sharing process data, product attributes and a clinical trial update

**Steven Feldman**, Site Head & Scientific Director, Laboratory for Cell and Gene Medicine, **Stanford GMP Facility**

#### 12.00 Design Considerations for Large Scale Stem Cell Manufacturing Facilities

- Introduction to current state of stem cell manufacturing and shift to large scale
- Facility design consideration (Open vs. closed processing, risk assessments, regulatory compliance)
- Identifying operational challenges (upstream, downstream, and support areas)

**Daniel Swanson**, Senior Process Technologist, **IPS - Integrated Project Services**

**Christian Estes**, Process Group Lead, **IPS - Integrated Project Services**

#### 12.30 Panel Discussion: Unlocking Digital Capabilities for Accelerating Cell Therapy Manufacturing

- Develop a custom digital transformation roadmap
- Create intuitive and user-friendly workflows to enable all team members to utilize and gain insights effectively
- Foster a culture shift within your team to establish a sustainable transformation journey

**Moderator: John Lee**, Senior Vice President, Cell Therapy, **Center for Breakthrough Medicines**

**Jeet Sarkar**, Vice President, Information Technology, **Center for Breakthrough Medicines**

1.00 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Sanjin Zvonić**, Senior Vice President, Business Development & Practice Expert, **Dark Horse Consulting**

### Leveraging Partnerships to Accelerate Development

#### 2.00 Working with a CDMO to Support Cell Therapy Manufacturing

- Discussing critical factors for successful selection and collaboration with a CDMO
- Working together successfully to meet strict timelines
- Overcoming challenges

**Maura Hobson**, Senior Director, External Manufacturing, **Sana Biotechnology**

#### 2.30 Ensuring a Smooth Technology Transfer to a CDMO

- Keys to setting the stage for a successful handoff
- Technology Transfer strategies to ensure right-first-time
- Selecting the right partner and ensuring robust communication and transparency

**Catherine Tomaro-Duchesneau**, Senior Director, Manufacturing Science & Technology, **Roslin CT**

#### 3.00 Roundtable Discussion: Selecting & Working with a CDMO Effectively

- Does the CDMO have all the technical and practical expertise you require?
- How do you manage the tech transfer process to a vendor successfully?

**Cécile Bauche**, Chief Scientific Officer, **Alaya.bio**

**Maura Hobson**, Senior Director, External Manufacturing, **Sana Biotechnology**

#### 3.30 Afternoon Break & Poster Session

## AFTERNOON SESSIONS

**Chair: Sanjin Zvonić**, Senior Vice President, Business Development & Practice Expert, **Dark Horse Consulting**

### Recruiting, Training & Retaining Skilled Workers in Manufacturing

#### 4.30 Improving Training & Internal Collaboration Initiatives to Address the Demand for Skilled Workers in Cell Therapy Manufacturing

- Improving the collaboration between clinical manufacturing and research and development is critical for success
- Providing clear career paths leading to better retention of key individuals and a better recruitment base

**Linda Brink**, Head of QA, **XNK Therapeutics**

#### 5.00 De-risking Cell Therapy New Product Introduction: Harnessing the Power of Integrated Tech Transfer to GMP

- Discuss the state of the cell and gene therapy market and the complex path to transfer a preclinical process to comply with regulatory standards that can cause significant program setbacks
- Share what is required for a standardized, scalable and robust technology transfer framework for new products that incorporates effective risk management strategies and integrated analytical services to reliably guide cross-functional teams to GMP and beyond
- Introduce a cell therapy new product introduction approach focusing on process and analytics harnessing the power of integrated tech transfer to streamline program path to market 50% compared to traditional timelines

**Matthew Hewitt**, Vice President, Technical Officer, CGT & Biologics, **Charles River**

#### 5.30 Building & Retaining a Team of Skilled Cell Therapy Manufacturing Workers

- Hiring a skilled and diverse workforce of over 500 people
- Developing an effective new hire orientation and training programs whilst ensuring GMP compliance
- Motivating and retaining a talented workforce

**Lisa McClintock**, Vice President, Site Leader, Cell Therapy Manufacturing, **Bristol Myers Squibb**

6.00 End of Conference Day 2

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## MORNING SESSIONS

**Chair: Ivone Bruno**, Vice President, Preclinical Affairs & Process Development, **CytoImmune Therapeutics**

### Exploring CMC Strategy to Ensure Product Safety & Efficacy

#### 11.30 Designing an Effective CMC Strategy for Cell Therapy Products

- Characterizing cell-based products to ensure product safety and consistency
- Continually evaluating critical quality attributes (CQAs) and critical process parameters (CPPs) during product development
- Planning for inevitable manufacturing changes

**Emily Lowe**, Senior Director, Head of Analytical Development, **Appia Bio**

#### 12.00 Addressing Cell Therapy CMC Challenges with GenScript Solutions

- Sharing a cell therapy process overview
- Discussing CMC challenges experienced in cell therapy development
- Overcoming these challenges with GenScript cell and gene therapy solutions

**Xinpo Jiang**, Associate Vice President, Catalog Product Division, **GenScript**

#### 12.30 Panel Discussion: Developing a Robust CMC Strategy

- When should we begin to develop a CMC strategy?
- What are the strengths and limitations of quality by design (QbD) and quality risk management (QRM) for cell therapy manufacturing processes?
- How can we develop an effective CMC regulatory compliance strategy to avoid delays in clinical development?

**Damien Hallet**, Vice President, Head of CMC, **Affini-T Therapeutics**

**Patricia Bettinger**, Senior Director, Process Development, **AGC Biologics**

**Emily Lowe**, Senior Director, Head of Analytical Development, **Appia Bio**

**Joy Zhou**, Vice President, CMC Head, **MiNK Therapeutics**

**1.00 Lunch Break**

## POST-LUNCH SESSIONS

**Chair: Ivone Bruno**, Vice President, Preclinical Affairs & Process Development, **CytoImmune Therapeutics**

### Overcoming Potency Assay Development Challenges to Elucidate Biological Activity

#### 2.00 Luciferase Based Potency Assays for Cell Therapies

- Understanding limitations of potency assays in current use
- Understanding Matador and Matador-Glo cytotoxicity assays, high-throughput luciferase-based cytotoxicity assays
- Understanding Topanga assay, a luciferase-based assay for measuring expression of CAR-T cells

**Preet Chaudhary**, Professor & Chief of Hematology; Founder, **University of Southern California; Angeles Therapeutics**

#### 2.30 Bioluminescent Bioassays for the Discovery & Development of Molecular & Cellular T-Cell Redirecting Cancer Therapy

- T-cell therapies involving genetic modification of T-cell to redirect their activity towards tumor-associated antigens, are a new paradigm in cancer treatment
- Potency testing of in-process material in such therapies, like lentiviral preps, is a challenge in T-cell therapies
- Developing a new set of bioluminescent cell-based bioassay tools for the discovery and development of T-cell based immunotherapies, to allow for rapid and simple potency qualification of CAR-T and TCR-engineered T-cells

**Mei Cong**, Director, R&D Integrated Biology, **Promega**

#### 3.00 Roundtable Discussion: Developing Best-in-Class Potency Assays for Cell Therapy Products

- When should potency assay development begin?
- What should be considered during potency assay design and validation plan?
- How should reference materials and controls be used?

**Ann Durbin**, Senior Director, Assay Development & Quality Control, **Abeona Therapeutics**

**3.30 Afternoon Break & Poster Session**

## AFTERNOON SESSIONS

**Chair: Ivone Bruno**, Vice President, Preclinical Affairs & Process Development, **CytoImmune Therapeutics**

### Assessing & Ensuring Safety of Cell Based Therapies

#### 4.30 Development of Flow Cytometry Based Safety Assays for Allogeneic CAR-T Product Release

- Developing a Flow Cytometry based safety assay for allogeneic CAR-T therapies
- Identifying proper assay conditions to fit the product profile
- Designing product specific controls

**Susan Foster**, Research Associate II, **Beam Therapeutics**

#### 5.00 Digitalization of the Environmental Monitoring for the Contamination Control of Cell & Gene Therapy Facilities

- Maintaining aseptic environment are crucial to prevent product contamination that can compromise the safety and efficacy of cell and gene products
- Monitoring and controlling environmental factors to ensure optimal conditions for cell growth and to prevent contamination
- Automating and digitalizing environmental monitoring will increase data integrity and traceability, streamline the process, and improve operational efficiency

**Félix Montero Julian**, Scientific Director, **bioMérieux**

#### 5.30 Overview of Testing Protocols, Stability Studies & Shelf-Life Determination for Cell Products

- Developing protocols (recovery, viability, identity, potency, post-thaw recovery, homogeneity) to determine the shelf-life of cell and gene therapy products and ensure product safety throughout cryopreservation, storage, transportation and clinic
- Optimizing testing approaches for Inline stability, freezing & thawing profiles

**Yishara Chandler**, Head of Manufacturing, **CytoImmune Therapeutics**

**6.00 End of Conference Day 2**

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## MORNING SESSIONS

**Chair: Lee Buckler**, Senior Vice President, Advanced Therapies & Business Development, **Blood Centers of America**

### Implementing Digital Systems to Transform End-to-End Development

#### 11.30 Connecting People & Processes with Technology & Driving Digital Transformation

- Implementing a digital platform that allows full traceability end-to-end
- Improving control and tracking of raw material source, supply and quality
- Monitoring the manufacturing environment, tracking the performance of production equipment and conducting real-time analysis of cell culture samples to ensure product quality and consistency

**Stephen Chen**, Chief Technical Officer, **Tevogen Bio**

#### 12.00 The Iterative Approach to a Digital Cell & Gene Therapy Process: An Overview & Best Practice

- Identifying challenges in the digitization of CGT manufacturing
- Providing digital enablement of traceability in patient-specific processes
- Implementing electronic batch records for CGT with a best practice approach
- Summarizing digital data management for CGT processes

**Judith Koliwer**, Principal Consultant, Cell & Gene Therapy, **Körber Pharma Software**

#### 12.30 Panel Discussion: Demonstrating the Value of Digital Transformation

- What are the challenges that are being faced in the journey to digital transformation?
- Why and when should you invest in it? How do you decide the timing of those investments?
- What are the main lessons learned?

**Augie Zepka**, Global Head of IT, **Adaptimmune**

**Dale Hanna**, Director, Cell & Gene Therapy Solutions, **AmerisourceBergen**

**Praveen Malhotra**, Vice President, Head of Information Technology, **Sana Biotechnology**

**Stephen Chen**, Chief Technical Officer, **Tevogen Bio**

1.00 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Lee Buckler**, Senior Vice President, Advanced Therapies & Business Development, **Blood Centers of America**

### Addressing Chain of Identity & Custody Concerns to Improve Traceability

#### 2.00 Improving Traceability Throughout the End-to-End Cell Therapy Supply Chain

- Employing cell orchestration platforms to guarantee traceability
- Limiting chain of identity errors through use of digital platforms
- Discussing what personal information manufacturers should handle

**Edward Armstrong**, Vice President, Quality, **Mustang Bio**

#### 2.30 Are Cell & Gene Therapies Dangerous Goods?

- An understanding of the purpose and regulatory framework of dangerous goods classifications, with a focus on UN3373 for specimens and UN3745 for genetically modified organisms
- The applicability of UN3373 and UN3745 classifications to cell and gene therapy shipments: our analysis yields surprising results
- How to reduce costs and mitigate risk: practical tips and guidance

**Andrea Zobel**, Senior Director, Personalized Supply Chain, **World Courier**

#### 3.00 Implementing the ISBT 128 Chain of Identity (CoI) Identifier

- Utilizing the CoI Identifier to link collection(s) associated with a given therapy
- Using the ISBT 128 CoI Identifier on a non-ISBT 128 label
- Becoming an ISBT 128 CoI Issuing Organization

**Karen Moniz**, Technical Director, **ICCBBA**

3.30 Afternoon Break & Poster Session

## AFTERNOON SESSIONS

**Chair: Lee Buckler**, Senior Vice President, Advanced Therapies & Business Development, **Blood Centers of America**

### Outlining Best Practices from Large Scale Facilities

#### 4.30 Strategies for Overcoming the Challenges Associated with the Supply Chain & Logistics for Cellular Products

- Building an infrastructure to adapt to the constant evolution of therapeutic products
- Planning and executing the steps needed to have a reliable process
- Communicating the implementation of a new process; the consequences of a drift within a process and how to prevent it from happening

**Albert Ribickas**, Assistant Director, Cell Therapy Facility Operations, **Moffitt Cancer Center**

#### 5.00 Critical Considerations Leveraging Success in Allogeneic HSCT/BMT to Inform Scalable Launches of Emerging Allogeneic Cell Therapies

- Discuss key successes and challenges in the facilitation of the most widely used life saving allogeneic cell therapy, hematopoietic stem cell transplant (HSCT/BMT)
- Buildout of critical, reliable infrastructure for cell harvest and therapy delivery
- Expanding beyond centers of excellence to improve patient access
- Securing a reliable and ongoing source for allogeneic donor cells from a registry of 7M+ volunteer donors

**Joy Aho**, Director, Product Management, **Be The Match**

#### 5.30 Lessons Learned from Experience & FDA Reviewers RE Supply Chain & Manufacturing Logistics at an Academic Cell Processing Facility

- Identifying current and future challenges in obtaining raw materials (e.g., apheresis or tumor harvests)
- Leveraging FDA comments on key materials and approaches to facilitate IND submissions
- Highlighting differences between Phase 1 Proof of Concept and Phase 2 Requirements

**Sarah Nikiforow**, Medical Director, Cell Manipulation Core Facility & Technical Director, Immune Effector Cell Program, **Dana-Farber Cancer Institute**

6.00 End of Conference Day 2

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FOCUS DAY

DISCUSSING  
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## MORNING SESSIONS

**Chair: Jodie Wehling**, Vice President, Market Access & Trade, **Mesoblast**

### Developing an Effective Infrastructure to Support Commercialization

#### 11.30 Exploring Readiness Strategies for Cell Therapy Commercialization

- Discussing how best to structure your company internally for successful commercial production
- Exploring the current and future challenges faced to properly prepare for sustainable commercialization of these promising therapies

**Warner Biddle**, Senior Vice President & Global Head of Commercial, **Kite, A Gilead Company**

#### 12.00 Approaching a Successful Product Launch: Building a Commercial Organization from the Ground Up

- Discussing the value in organizing various cross-functional teams early to support a successful commercial cell therapy launch
- Identifying the unique challenges and advantages of launching a novel cell therapy as a smaller company
- Ensuring patients who could benefit are ultimately able to access these potentially life-saving cell therapies

**Dan Kirby**, Chief Commercial Officer, **Orca Bio**

#### 12.30 Panel Discussion: The Future of Cell Therapy Commercialization - Taking the Next Step

- How do we get cell therapies to become “mainstream” treatments?
- Can we tackle the issues of infrastructure by setting up a commercialization network in the US?
- How do we find a way together – industry, government, payers?
- How can we commercialize next-gen cell therapy products?

**Chris Bartiromo**, Executive Director, Worldwide Value & Access Strategy, Cell Therapy, Lymphoma & Myeloma, **Bristol Myers Squibb**

**Jie Zhang**, Vice President, Head of Cell & Gene Value & Access, **Novartis**

1.00 Lunch Break

## POST-LUNCH SESSIONS

**Chair: Jodie Wehling**, Vice President, Market Access & Trade, **Mesoblast**

### Highlighting Key Considerations for a Successful Commercial Launch

#### 2.00 What's Not in Your Launch Playbook?

- Identifying the “watch outs” for any cell therapy launch
- De-risking the downsides
- War-gaming the unexpected

**Steve Gavel**, Senior Vice President, Cell Therapy Commercial Development, **Legend Biotech**

#### 2.30 Roundtable Discussion: Developing a Strategy for a Successful Cell Therapy Launch

- What challenges have you experienced in your quest to commercialization?
- How did you overcome these challenges?
- How should we properly prepare the market, the product, and the company for future launches?

**Steve Gavel**, Senior Vice President, Cell Therapy Commercial Development, **Legend Biotech**

3.30 Afternoon Break & Poster Session

## AFTERNOON SESSIONS

**Chair: Jodie Wehling**, Vice President, Market Access & Trade, **Mesoblast**

### Incorporating the Patient Voice into Market Access Strategies

#### 4.30 Supporting Patients & Families on their Journey to Activate the Cure

- Giving an update on Emily Whitehead, now cured after becoming the first pediatric patient to receive CAR-T cell therapy
- Discussing how the Emily Whitehead Foundation helps connect patients and families to clinical trials and treatment programs
- Exploring how the Emily Whitehead Foundation will grow going into the next decade of CAR-T, and how you can help

**Tom Whitehead**, Co-Founder, **Emily Whitehead Foundation**

#### 5.00 Group Discussion Session

#### 5.30 Roundtable Discussion: Mapping the Patient Journey to Enhance Market Access

- How can we improve patient access to cell therapies?
- How can we better support patients and caregivers through the highly complex and often multiyear journey?
- How do we best identify patients who would benefit most from these types of therapies?

6.00 End of Conference Day 2

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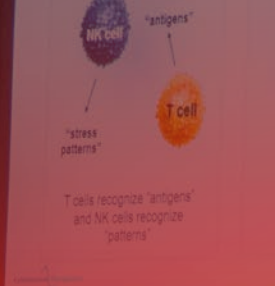


# DAY 3 OVERVIEW

Friday, September 1

Use the buttons to below to navigate straight to your favourite track!

-  DISCOVERY 
-  TRANSLATION 
-  EARLY-STAGE CLINICAL STRATEGY 
-  CLINICAL OPERATIONS 
-  MANUFACTURING 
-  CMC & ANALYTICS 
-  SUPPLY CHAIN & LOGISTICS 
-  COMMERCIALIZATION & MARKET ACCESS 



## MORNING PLENARY SESSIONS

→ Moving beyond  $\gamma\delta$  T-cells: the rise of novel cell types



### DISCOVERY TRACK

→ Leveraging next generation gene delivery and transduction



### EARLY-STAGE CLINICAL STRATEGY TRACK

→ Sharing clinical results and strategy for solid tumor treatments



### MANUFACTURING TRACK

→ Aligning manufacturing capacity to patient demand



### SUPPLY CHAIN & LOGISTICS TRACK

→ Enabling stable and secure cell storage and delivery through effective cryopreservation



### TRANSLATION TRACK

→ Leveraging dual targeting to improve therapeutic efficacy and safety



### CLINICAL OPERATIONS TRACK

→ Optimizing cell therapy clinical trial design



### CMC & ANALYTICS TRACK

→ Ensuring satisfactory product integrity with improved release testing strategies



### COMMERCIALIZATION & MARKET ACCESS TRACK

→ Attracting investors to improve speed to clinic and commercialization

## AFTERNOON PLENARY SESSIONS

→ Understanding the regulatory landscape for complex cell therapies

## Patient Story Highlight: Why is Cell Therapy so Important?

Hear about Oaklynn Keller's journey receiving CAR-T cell therapy



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## MORNING PLENARY SESSIONS

### 7.00 Morning Arrival & Coffee Networking

### 7.50 Chair's Opening Remarks



**Adrian Bot**  
Chief Scientific Officer &  
Executive Vice President,  
R&D  
**Capstan Therapeutics**

## Moving Beyond $\alpha\beta$ T-Cells: The Rise of Novel Cell Types

### 8.00 Making the Right Decision the First Time: Closing the Distance between Research Scale and Commercialization

- Discussing key factors in choosing the right raw materials for cell culture media development
- Understanding the importance of preparing the product and the process for testing and cGMP compliance
- Minimizing risk and reducing the time during raw material qualifications
- Outlining how a close partnership with your supplier can accelerate the development process all the way to therapy



**Marlin Frechette**  
Chief Quality & Compliance  
Officer  
**FUJIFILM Irvine Scientific**

### 8.30 The Evolution of $\alpha\beta$ T-Cells to Other Leading-Edge Modalities Including $\gamma\delta$ T-Cells

- Overcoming challenges experienced in the development of  $\alpha\beta$  T-cell-based with other cell types
- Exploring current opportunities and future horizons for  $\gamma\delta$  T-cell-based therapeutics
- Sharing supporting clinical data and new preclinical data



**Blake Aftab**  
Chief Scientific Officer  
**Adicet Bio**

### 8.50 Congratulations on Your Successful Phase 1, Now What?

- Maturing your program into later-stage with the right manufacturing partner
- Launching your cell therapy in a commercial-ready supply chain network (vertical integration)
- Leveraging the Resilience network to help you progress your program



**Eytan Abraham**  
Vice President & Business  
Head of Emerging Modalities  
**Resilience**

### 9.20 CAR-M: Pioneering a Novel Approach for Solid Tumor Immunotherapy

- Reviewing preclinical development of CAR-M for solid tumor immunotherapy
- CT-0508 (anti-HER2 CAR-M): Sharing clinical data from the first-in-human CAR-M clinical trial
- Developing next-gen approaches to *ex vivo* and *in vivo* genetically engineered macrophage-based therapy



**Michael Klichinsky**  
Co-Founder & Chief Scientific  
Officer  
**Carisma Therapeutics**

### 9.40 The Future of Cell Therapy Manufacturing is Here

- Improving cell therapy manufacturing capacities through the introduction of parallel cell processing technologies
- Introducing flexibility into cell therapy manufacturing to overcome limitations in existing paradigms
- Solving bottlenecks in patient access by reducing cell therapy manufacturing costs and decreasing process failure rates



**Fabian Gerlinghaus**  
Chief Executive Officer  
**Cellares**

### 10.10 Morning Break

DISCOVERY TRACK	TRANSLATION TRACK	EARLY-STAGE CLINICAL STRATEGY TRACK	CLINICAL OPERATIONS TRACK	MANUFACTURING TRACK	CMC & ANALYTICS TRACK	SUPPLY CHAIN & LOGISTICS TRACK	COMMERCIALIZATION & MARKET ACCESS TRACK
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## MORNING SESSIONS

Chair: **Cécile Bauche**, Chief Scientific Officer, **Alaya.bio**

### Leveraging Next Generation Gene Delivery & Transduction

#### 11.00 Surface Engineering of VivoVec Generates Potent In Vivo CAR-T Achieving Durable B Cell Aplasia in Non-Human Primate Model

- Developing VivoVec particles for in vivo CAR-T cell generation
- Engineering VivoVec surface to enable preferential binding, activation and transduction of T cells in vivo
- Achieving durable B cell aplasia more than 70 days along with multiple CAR-T cell expansions in non-human primate

**Byoung Ryu**, Executive Vice President, **Umoja Biopharma**

NEW DATA

#### 11.30 Advancing Targeted In Vivo Cell Engineering

- Developing a novel targeted lipid nanoparticle (tLNP) platform with enhanced payload delivery to target cells
- Capstan's tLNPs are well tolerated with significantly decreased off-target uptake
- Demonstrating efficient and specific reprogramming of human T cells and T cell subsets in vitro and in vivo

**Haig Aghajanian**, Co-Founder & Vice President, Research, **Capstan Therapeutics**

#### 12.30 Exploring Viral Phylogeny for Engineered Optimized Gene Delivery Vectors

- Implementing large-scale sequence search algorithms to identify candidate virus proteins in deep sequencing databases
- Building gene delivery vectors from these naturally occurring viruses and testing them *in vitro* and *in vivo* for specificity and efficiency of gene delivery in various cell types
- Using this technology for *in vivo* targeted gene delivery of TCRs and CARs to treat oncology and autoimmune indications

**David Johnson**, Founder & Chief Executive Producer, **GigaMune**

NEW DATA

#### 12.30 Post-Infusion Control Features for Ex Vivo and In Vivo Engineered CAR Immune Cells

- The OmniCAR technology can be incorporated into ex vivo or in vivo engineered CAR immune cells such as T-cells, NK, Macrophages, Gamma/Delta T, CAAR-Ts, and CAR-Tregs
- Post-infusion control features such as the ability to turn the system on/off and back on again; to re-direct the immune cells from one target to any other; and the ability to multi-arm cells against more than one target are increasingly important for safety and efficacy
- These features can all be incorporated into a single master cell or vector/method which can be used for any target and in any indication reducing manufacturing costs and streamlining the regulatory filing process

**Daniel Shelly**, Vice President, Business Development & Alliances, **Prescient Therapeutics**

1.00 Lunch Break

2.00 Return to Afternoon Plenary Sessions

“ Lots of new innovation and maturation of existing technologies and strategies for cell therapy were presented, very helpful ”

**Eric von Hofe**, President & Chief Operating Officer, **Affymune**

“ Good value, relevant content and useful network with companies really active and relevant for the space ”

**Helen Tayton-Martin**, Chief Business Officer, **Adaptimmune Therapeutics**

DISCOVERY TRACK	<b>TRANSLATION TRACK</b>	EARLY-STAGE CLINICAL STRATEGY TRACK	CLINICAL OPERATIONS TRACK	MANUFACTURING TRACK	CMC & ANALYTICS TRACK	SUPPLY CHAIN & LOGISTICS TRACK	COMMERCIALIZATION & MARKET ACCESS TRACK
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## MORNING SESSIONS

**Chair: Shannon Dahl, Industry Expert**

### Leveraging Dual Targeting to Improve Therapeutic Efficacy & Safety

#### 11.00 Novel Engineering Platforms for CAR-T Cell Signaling

- Studying T-cell signaling networks reveals CAR biology
- Coopting proximal signaling molecules enables unique CAR-T cell engineering
- Developing logic-gated CAR-T cell platforms

**Robbie Majzner**, Assistant Professor of Pediatrics, **Stanford University School of Medicine**

#### 11.30 Title TBC

- Session details to be announced

#### 12.00 Utilizing & Overcoming Antigen Escape in Leukemia CARs

- Reviewing antigen escape (expansion of cells not expressing target protein)
- Developing a non-gene edited CAR for T-ALL, as non CD7 healthy cells can rapidly expand
- Developing a combination CAR to overcome antigen escape in AML

**Greg Deener**, Chief Executive Officer, **iCell Gene Therapeutics**

#### 12.30 Synthetic Immune Receptor, A Next Generation CAR-T Platform

- Introducing SIR, a next generation HLA-independent TCR platform that provides physiological TCR signaling
- Describing the activity of SIR against blood cancers and solid tumors
- Describing bispecific and multispecific targeting using SIR-T

**Preet Chaudhary**, Professor & Chief of Hematology; Founder, **University of Southern California; Angeles Therapeutics**

#### 1.00 Lunch Break

#### 2.00 Return to Afternoon Plenary Sessions

Great speakers with a broad range of experience and lots of time to meet and network

**Sven Kili**, Chief Executive Officer, **Antion Biosciences**

Comprehensive. Exceptionally well organized and good quality content

**Samik Basu**, Chief Scientific Officer & Vice President, Preclinical & Translational Research, **Cabaletta Bio**

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## MORNING SESSIONS

**Chair: David Fontana**, Chief Operating Officer,  
**Umoja Biopharma**

### Sharing Clinical Results & Strategy for Solid Tumor Treatments

#### 11.00 Understanding the Impact of Patient & Product Characteristics on the Clinical Outcome of Autologous TCR-T Therapy

- Sharing clinical results from a clinical TCR-T trial in PRAME-positive patients
- Discussing clinical relevance of patient characteristics
- Exploring impact of cell product manufacturing on engraftment, persistence and tumor infiltration

**Delfi Krishna**, Vice President, Cell Therapy Portfolio  
Development, **Immatics**

#### 11.30 Important Factors Looking into a New Cultivation Medium for T-Cells

- Outlining critical process parameters during CAR-T cell manufacturing
- Which role does the cultivation medium play?
- Presenting a novel T-cell medium, CellGenix GMP TCM, and the latest application data

**Benedikt Steinle**, Research Scientist R&D, Cell Culture Systems,  
**Sartorius CellGenix**

#### 12.00 Bringing T-Cell Therapies Towards Approval – Afami- cel – The First Potential TCR T-Cell Therapy in Solid Tumors

- Designing and developing a registrational study in a rare cancer
- Navigating the complexities of cell therapy BLA including CMC and companion diagnostic needs
- Leveraging BLA roadmap-insights for subsequent products and cancer indications

**Helen Tayton-Martin**, Co-Founder & Chief Business & Strategy  
Officer, **Adaptimmune**

#### 12.30 Title TBC

- Session details to be announced

#### 1.00 Lunch Break

#### 2.00 Return to Afternoon Plenary Sessions

“ The most tightly focused CAR-T cell conference there is ”

**Miloš Miljković**, Chief Medical Officer, **Cartesian Therapeutics**

“ Well organized conference with industry leading speakers. ”

Strong presentations and excellent networking opportunities ”

**Bradley Glover**, Executive Vice President & Chief Technology  
Officer, **Celularity**

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## MORNING SESSIONS

Chair: TBC

### Optimizing Cell Therapy Clinical Trial Design

#### 11.00 Clinical Trials in the Age of Cell Therapy

- Designing clinical trials of autologous CAR-T and TCR therapeutics has unique requirements for which there is little prior experience
- Using adaptive trial designs can shorten dose-finding and speed up establishment of an optimal dosing schedule
- Expanding indications to areas outside of oncology may require development of adequate placebo controls

**Miloš Miljković**, Chief Medical Officer, **Cartesian Therapeutics**

#### 11.30 Study Design & Clinical Dose Escalation Data from ANTLER Phase 1 Trial for CB-010, an Allogeneic Genome-Edited Anti-CD19 CAR-T Cell Therapy

- Utilizing chRDNA genome-editing technology to develop armoring strategies that improve antitumor response in allogeneic CAR-T cell therapies
- Designing early-stage clinical trials for allogeneic CAR-T cell therapies
- Reporting safety and efficacy dose escalation data from the ongoing CB-010 ANTLER Phase 1 trial

**Enrique Zudaire**, Senior Vice President, Translational Sciences & Therapeutics Discovery, **Caribou Biosciences**

12.00 Group Discussion Session

12.30 Group Discussion Session

1.00 Lunch Break

2.00 Return to Afternoon Plenary Sessions

“ Cross-sectional look at the cell therapy industry as a whole. I was impressed from start to finish ”

**Damien Fink**, Director, Analytical Development, **Century Therapeutics**

“ Good conference, good energy, cross-functional topics ”

**Arvind Natarajan**, Vice President, CMC & Process Development, **Iovance**

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## MORNING SESSIONS

**Chair: Sanjin Zvonić**, Senior Vice President, Business Development & Practice Expert, **Dark Horse Consulting**

### Aligning Manufacturing Capacity to Patient Demand

#### 11.00 Optimizing Allogeneic Cell Therapy Manufacturing Processes

- Design and scaling up of a fully non-viral allogeneic platform to clinical scale and beyond
- Producing highly desirable Tscm cells with high yield, purity, and robustness
- Continuously improving productivity and flexibility of process

**Nooshafarin Sanaie**, Vice President, Process & Analytical Development, **Poseida Therapeutics**

#### 11.30 Novel Isolation & Activation Platform with Active-Release Technology for Scalable Cell Therapy Manufacturing

- CTS™ Detachable Dynabeads™ build upon Dynabeads™ and CaptureSelect™ technologies with an active release mechanism for clinical/GMP space
- CTS™ Detachable Dynabeads™ CD3/CD28 Kit shows >98% isolation efficiency, cell viability >90%, and CD25 activation >95%
- Studies show our CD4 and CD8 versions have efficient isolation, high cell recovery, and low non-target impurities

**Eugene Kang**, Senior Product Manager, **Thermo Fisher Scientific**

#### 12.00 Moving Towards Feeder-Free iPS/ES-Derived Cell Manufacturing in Scalable Single-Use-Bioreactor

- Generating unlimited numbers of hematopoietic organoids capable of producing innate killer cells in bioreactor at industrial scale
- Harvesting CD8+ ProtoNK with natural effector phenotype and consistent killer activity
- Optimizing downstream processes, maximizing *in vivo* target killing

**Allen Feng**, Founder & Chief Scientific Officer, **HebeCell**

#### 12.30 CAR-T Cell Expansion Platforms Generate Distinct T Cell Differentiation States

- We compared 4 commonly used CAR-T cell manufacturing platforms (CliniMACS Prodigy, Xuri W25 rocking platform, G-Rex gas-permeable bioreactor, static bag culture) using identical media, stimulation, and donor starting material.
- There were considerable differences in the output CAR-T cell phenotype, with the Prodigy significantly enriched for stem/central memory-like (Tscm-like) T cells, while the bag and G-Rex cultures were more enriched for effector memory T cells. Expansion protocols were based on phase I/II clinical trials at the NIH Clinical Center.
- By analyzing differences among the platforms, we identified key physical differences that promote a more naive/Tscm-like differentiation state in the Prodigy and have further identified a method by which Tscm-like cells can be enriched in multiple bioreactor platforms

**Hannah Song**, Product Development, NIH Clinical Center, **Center for Cellular Engineering (CCE)**

#### 1.00 Lunch Break

#### 2.00 Return to Afternoon Plenary Sessions

Overall great event with good opportunity for learnings of what others are doing in the community and opportunity for networking. Event staff were friendly and helpful and the event was very well organized

**Michelle Andraza**, Senior Associate Director, CMC, Global Quality Assurance, **EXUMA Biotechnology**

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## MORNING SESSIONS

**Chair: Emily Lowe**, Senior Director, Head of Analytical Development, **Appia Bio**

### Ensuring Satisfactory Product Integrity with Improved Release Testing Strategies

#### 11.00 Safety Strategy for iPSC-derived Allogeneic Cell Therapy Drug Product Release

- Leveraging non-clinical data to inform drug product release strategy
- Identifying informative variant class assessments at each manufacturing stage
- Selecting appropriate methods for genetic characterization

**Damien Fink**, Director, Analytical Development, **Century Therapeutics**

#### 11.30 Critical Considerations in the Aseptic Manufacture of CAR-T Cell Products

- CAR-T products require sterile manufacturing using specialized aseptic processing procedures. Final products must pass sterility testing and meet appropriate microbiological quality standards.
- While the pharmaceutical industry has a rich history of producing sterile drugs, aseptic processing for CAR-T cells is still evolving
- This presentation will cover vital aseptic processing procedures applied to CAR-T products, including current techniques and regulatory requirements. The speaker will draw from scientific literature, regulatory guidance, and consulting group experiences to provide insights into CAR-T product manufacturing

**Andrew Trammel**, Director, Regulatory Sciences, **Cardinal Health**

#### 12.00 Adapting Analytical Control Strategies to Rapid Evolution of Cell Therapies

- Defining analytical methods for each component of cell therapy products
- Utilizing phase appropriate validation of methods for release and characterization
- Discussing method transfers, comparability, and lifecycle management

**Shibani Mitra-Kaushik**, Head, Product Control Strategy & Analytics, **Takeda**

#### 12.30 Group Discussion Session

#### 1.00 Lunch Break

#### 2.00 Return to Afternoon Plenary Sessions

“ A very engaging and interactive program that allowed for learning new developments in the field and to connect with others involved in the area. Relevant topics, high quality speakers, opportunity to network. ”

**Gregory Fiore**, Chief Executive Officer, **Exacis Biotherapeutics**

“ It was a very good meeting with excellent talks. ”

**Aishwarya Sathyanarayan**, Senior Scientist, Process Analytical Development, **Poseida Therapeutics**



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## MORNING SESSIONS

**Chair: Lee Buckler**, Senior Vice President, Advanced Therapies & Business Development, **Blood Centers of America**

### Enabling Stable & Secure Cell Storage & Delivery Through Biopreservation & Cryopreservation

#### 11.00 Overcoming Cell Therapy Formulation Challenges

- Discussing cell therapy formulation challenges and potential solutions to overcome negative impact of cryopreservation on drug product CQA
- Optimizing cryopreservation process based on drug product presentation and batch size
- Assessing the impact of cryopreservation on post-thaw drug product quality

**Lavanya Peddada**, Director, Drug Product Development, **Century Therapeutics**

#### 11.30 Innovative Biopreservation Solutions for Cell-Based Therapy

- Discovering how chemically-defined cryopreservation solutions can address gaps of conventional biopreservation approaches
- Understanding when cold storage can be a suitable alternative to cryopreservation
- Exploring how custom solutions with recombinant human albumin support post-thaw cell viability

**Rukmini Ladi**, External Collaborations Manager CCT, **Sartorius**

#### 12.00 Cellular Therapy Cryopreservation: Considerations for Overcoming Cell Batch Variability (Virtual Presentation)

- Developing an analytical method suitable for characterizing and testing cell therapy products
- Understanding the impact of a controlled rate freezing device on cell batch variability
- Considering the impact of transient warming events on the storage stability of cellular products

**Olga Mykhailova**, Scientist II, Cryopreservation, Process Development **BlueRock Therapeutics**

#### 12.30 Group Discussion Session

#### 1.00 Lunch Break

#### 2.00 Return to Afternoon Plenary Sessions

Extremely enjoyable and a valuable experience. The quality of the talks was exceptional and the opportunity to network was extremely valuable.

**Marc Davies**, Vice President, CAR Engineering, **Leucid Bio**

Very glad I went. I learned several ideas and met new colleagues for potential collaborations.

**Marie Koren-Gluzer**, Associate Director, Cell Therapy, **AstraZeneca**

DISCOVERY  
TRACK

TRANSLATION  
TRACK

EARLY-STAGE CLINICAL  
STRATEGY TRACK

CLINICAL OPERATIONS  
TRACK

MANUFACTURING  
TRACK

CMC & ANALYTICS  
TRACK

SUPPLY CHAIN &  
LOGISTICS TRACK

COMMERCIALIZATION &  
MARKET ACCESS TRACK

## MORNING SESSIONS

**Chair: Renaud Vaillant**, Founder & Chief Executive Officer, **Alaya.bio**

### Attracting Investors to Improve Speed to Clinic & Commercialization

#### 11.00 Panel Discussion: Entrepreneurs & Investors Discuss...

- What do investors look for in a company and product?
- Why would someone decide against investing? (i.e., key issues seen)
- Where do investors see cell therapy in 5 years?

**Noelle Hutchins**, Investment Associate, **Omega Funds**

**Justin Zelin**, Director & Senior Biotechnology Analyst, **BTIG**

**Sahil Chopra**, Vice President, Investments, **Vertex Ventures**

#### 11.30 Elevator Pitch Session

- **Presentation 1:** ML Guide Library vs Library Screens: From Discovery to Clinic
- **Presentation 2:** Session details to be announced

**Elizabeth Wood**, Founder & Chief Executive Officer, **JURA Bio**

#### 12.00 Panel Discussion: Giving Feedback on Elevator Pitches

- Pitch your company/product to a panel of investors for feedback
- Asking them questions that you would ask in a real-life scenario

**Noelle Hutchins**, Investment Associate, **Omega Funds**

**Justin Zelin**, Director & Senior Biotechnology Analyst, **BTIG**

**Sahil Chopra**, Vice President, Investments, **Vertex Ventures**

#### 12.30 End of Track

#### 1.00 Lunch Break

#### 2.00 Return to Afternoon Plenary Sessions

“ The 7th CAR-TCR Summit 2022 was the best one so far! The perfect combination of crowd, talks and vendors to do high quality networking! A must go meeting if you work in cell therapy ”

**Erika von Euw**, Vice President, Discovery & Translational Research, **Deverra Therapeutics**

“ Great event. Excellent and enjoyable. ”

**Karen Wen**, Chief Strategy Officer, **Genome Frontier**

WELCOME

MORE THAN JUST  
A MEETING

SPEAKERS

AGENDA AT A  
GLANCE

WORKSHOP DAY

FOCUS DAY

DISCUSSING  
DIVERSITY AT  
CAR-TCR

CONFERENCE  
DAY 1

CONFERENCE  
DAY 2

CONFERENCE  
DAY 3

PARTNERS

PARTNERSHIP  
OPPORTUNITIES

PRICING &  
DISCOUNTS



## AFTERNOON PLENARY SESSIONS

### Understanding the Regulatory Landscape for Complex Cell Therapies

#### 2.00 Reviewing Regulatory Advice to Guide the Development of the Next Wave of CAR & TCR Therapies

- Addressing the evolving regulatory environment and expectations
- Sharing information on updated guidance to assure the safety and effectiveness of cell therapies
- Providing answers to common key questions asked by product developers



**Peter Marks**  
Director, Center for Biologics  
Evaluation & Research  
(CEBR)  
**FDA**

#### 2.30 Paving the Way for Off-the-Shelf Treatments: Securing the First Regulatory Approval of an Allogeneic T-cell Immunotherapy

- Reviewing the regulatory path towards the commercialization of the first allogeneic cell therapy product
- Sharing solutions to key regulatory challenges experienced along the way
- Highlighting the implications for the broader cancer and autoimmune disease treatment landscape



**Cokey Nguyen**  
Executive Vice President &  
Chief Scientific Officer  
**Atara Biotherapeutics**

### Patient Story Highlight: Why is Cell Therapy Development so Important?

#### 3.00 Oaklynn's Story: How She Remains Cancer Free!

- At two years old, Oaklynn was diagnosed with B-cell acute lymphoblastic leukemia
- The rollercoaster that followed would include multiple failure to reach remission with standard protocol, leading her to seek CAR-T cell therapy as an alternative option
- In his own words, Oaklynn's father Luke shares the story of his daughter's diagnosis, treatment journey, and faith in CAR-T cell therapy



**Luke Keller**  
Father to Oaklynn Keller &  
Patient Advocate  
**Emily Whitehead  
Foundation**



**Oaklynn Keller**  
CAR-T Recipient  
**Emily Whitehead  
Foundation**

#### 3.30 Chair's Closing Remarks



**Adrian Bot**  
Chief Scientific Officer &  
Executive Vice President,  
R&D  
**Capstan Therapeutics**

#### 3.40 End of Conference

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# Partnership Opportunities

Your Ultimate Platform to Foster New & Existing Relationships within the Cell Therapy Field

## Why Partner with CAR-TCR?

- Elevated Brand Visibility:** Increase market share through pre-conference and at-event advertising
- Thought Leadership:** Speak on the main agenda to showcase your expertise and position yourself as an essential partner for success
- Showcase Your Product:** Give potential customers a hands-on insight into your capabilities in the exhibition room
- Access Hard-to-Reach Decision Makers:** Organize a private lunch or dinner to gain exclusive access to your top prospects in a ring-fenced environment
- Lead Generation:** Secure valuable face time with key decision makers during networking sessions and pre-organized 1-2-1 meetings

## How Will the CAR-TCR Team Support You?

- Pre-Event Consultation:** Work together to create a clear plan and strategy to ensure you maximize the opportunity
- Customer Profiling:** Understand who to prioritize at the event based on who's actively asking for support
- Networking Support:** Develop an approach to help facilitate introductions with your top prospects



**Andreea Dogaru**  
Commercial  
Manager



**Luke O'Neill**  
Commercial  
Manager

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# Attendees by Industry Stage

August 29 – September 1, 2023  
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**300+**  
**Companies**

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- 4 Passes - 15% Discount
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**Hynes Convention Center**  
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### 3 Easy Ways To Book



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#### TERMS & CONDITIONS

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Cancellations must be received in writing. If the cancellation is received more than 14 days before the conference attendees will receive a full credit to a future conference. Cancellations received 14 days or less (including the fourteenth day) prior to the conference will be liable for the full fee. A substitution from the same organization can be made at any time.

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Conference + 1 Workshop	\$4,949	\$5,099
Conference Only	\$4,499	\$4,649

Start-Up Pricing**	Register Online	On the Day Rate
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Conference + 1 Workshop	\$3,699	\$3,849
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\*Must be from a biotech or pharma company that is currently and publicly developing an in-house cell therapy to be eligible for this price

\*\*Must be from a biotech company with less than 50 full-time employees that is currently and publicly developing an in-house cell therapy to be eligible for this price. This is also available for academics and not-for-profit organizations.

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