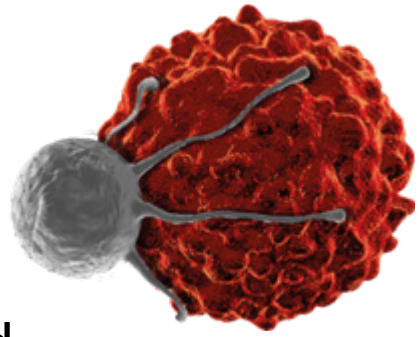
CAR-TCR Summit

Engineering a Cancer-Free World



In Proud Partnership with: emily whitehead foundation

Lead Partner: MACS Miltenyi Biotec

Expertise Partners: GE, PHC Healthcare with Precision, TERUMOBCT Unlocking the Potential of Blood

September 10-13th, 2019, Boston, MA

BOOK EARLY & SAVE UP TO $400

Dedicated to the Durable, Safe & Cost-Effective, Clinical & Commercial Development of CAR & TCR Based Cell Therapies for Patients Globally

1000+ Attendees | 350+ Organizations | 140+ Expert Speakers

James Noble
Chief Executive Officer
Adaptimmune

Barbra Sasu
Chief Scientific Officer
Allogene Therapeutics

Elsy Boglioli
Chief Operating Officer
Cellectis

Katherine Szarama
Evidence Development Division
Centers for Medicare & Medicaid Services

Peter Emtage
Senior Vice President & Global Head of Cell Therapy Research
Kite, a Gilead Company

Knut Niss
Chief Technology Officer
Mustang Bio

Jason Krentz
Chief Technology Officer
Tmunity Therapeutics

Laurence Cooper
Chief Executive Officer
Ziopharm Oncology

Tel: +1 212 537 5898 Email: info@hansonwade.com www.car-tcr-summit.com @CAR_TCell Cell Immunotherapy

hansonwade

Welcome to the 5th Annual CAR-TCR Summit

The definitive, world-renowned summit dedicated to providing comprehensive insight into the full end-to-end pharmaceutical value chain for CAR-TCR therapies in liquid and solid tumor indications.

The *CAR-TCR Summit* remains at the forefront of the industry bringing you never-seen-before data from the movers and shakers in CAR and TCR therapy development.

Dedicated to discussing the next generation candidates beyond CD19, from solid tumor indications to autoimmune disorders, this meeting provides an in depth breakdown of the current strategies to **optimize the durability, persistence and targeting** of approved and novel therapies to **reduce relapse rates and overcome toxicity.**

At the premier, end-to-end summit focused on early research through to commercialization, join the experts to discuss how to **streamline process development and logistics supply chains** for **affordable and accessible CAR-TCR therapeutics.**

Take advantage of the **unrivaled networking opportunities** as we bring together **over 1000 industry leaders** developing CAR-TCR based therapies from across pharma, biotech, regulatory bodies, academia, solution and service providers.

Discussions You Can't Afford to Miss:

Track 1

Review novel CAR and TCR construct design from **Aleta Biotherapeutics** and **Endocyte** which enhance potency with multi-targeting technology

Track 2

Characterize the mechanisms of product and treatment failure with **Kite, a Gilead Company**

Track 3

Reflect on how to set up an infrastructure to run CAR-T trials effectively with **Dana Farber Boston Children's Center for Cancer and Blood Disorders**

Track 4

Discuss manufacturing concepts for gene-edited allogeneic CAR-T cell products with **Cellectis**

Track 5

Optimize supply chain coordination to secure chain of custody with **Allogene's** digital platform support

Track 6

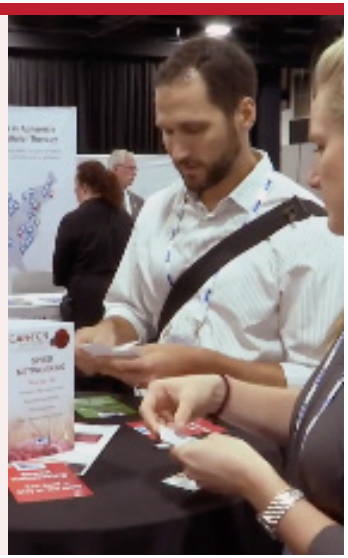
Understand how the **Centers of Medicare** value CAR-TCR to ensure these therapies are accessible for all

CONTENTS

"This conference continues to bring together thought leaders, with real world experiences who are willing to share their learnings to continue to accelerate and advance the field for patients."
GE Healthcare

What's New for 2019?

Clinical Management Track



Explore the the patient treatment pathway for clinical and commercial CAR and TCR therapies.

Delve into the challenges around building an effective **operational infrastructure, managing patient toxicities** and **scheduling a patient specific therapy.**

Discuss key topics in depth with:

- Clinical Directors
- Coordinators
- Operational Experts

Strategic Dives

With **15 in-depth and thought provoking workshops** available, dive straight into the discussion and explore strategies to overcome limiting challenges in the field.

Covering discovery to commercialization, takeaway actionable insights on the following:

- Overcome off-target toxicity
- Strategies for IND submissions
- Scaling out manufacturing
- Labelling to secure tracking
- Pricing models to enhance accessibility

3 Focus Day Agendas

Dedicating a full day's agenda to explore the largest opportunities in the field:

- Hear current strategies to overcome the tumor microenvironment and **target specific solid tumor antigens**
- Overcome current manufacturing bottlenecks by understanding the current and novel **gene editing technologies**, comparing talen, lenti-viral vector and CRISPR
- Advance the **TCR-T cell drug development** field by exploring TCR targeting to overcome evasion and enhancing potential in solid tumors and allogeneic settings

6 Tracks of Dedicated Content

Bring your team to **divide and conquer** ensuring your whole company can benefit from the expertise being showcased.

- **Discovery**; novel research for to enhance potency and regulation
- **Translation**; new clinical trial readouts
- **Clinical Management**; setting up an efficient clinical trial infrastructure
- **Manufacturing**; overcoming challenges managing heterogeneity and large scale expansion
- **Logistics**; optimizing supply chains to secure chain of identity
- **Commercialization**; international regulations and reimbursement to ensure accessibility

"This is a best in class and top summit in the CAR-TCR area which is an invaluable asset to both industry and academia"

University of Pennsylvania

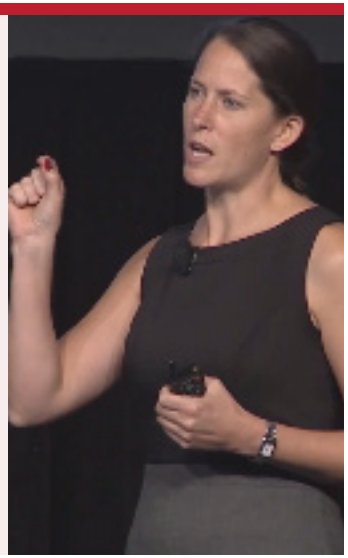
Highlights & Experiences

Women of CAR-TCR

This pre-conference discussion session highlights pioneering women working in CAR and TCR drug development.

Shining a light on their experience and success, this expert female panel will discuss their backgrounds in becoming key opinion leaders, identifying themselves as business experts and breaking through the glass ceiling in this industry.

Join this conversation to support gender equality in CAR-TCR drug development.

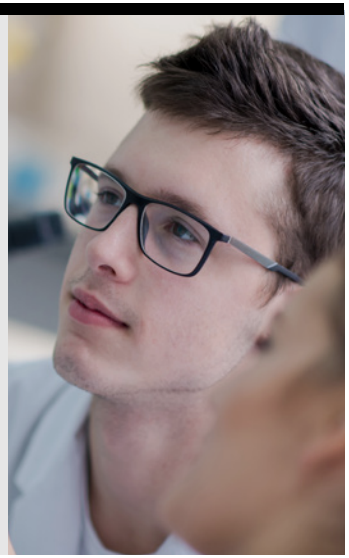


Rising Stars of CAR-TCR

Supporting the next generation of scientific and business leaders, we are inviting 30 budding pioneers of CAR-TCR therapy to join the CAR-TCR Summit.

This is an opportunity for PhD and Post Doc students to present their posters whilst joining in discussions with industry and academic experts to understand the key to success in their careers.

Join this recruitment drive to identify the up-and-coming CAR-TCR innovators.



The Cell-ebration of CAR-TCR!

After an action packed day of meeting new people, discussing strategies and reviewing data... take a breath and grab a cheeky cocktail with your new colleagues at the CAR-TCR Cell-ebrations! With a live band in full swing, dancing is strongly encouraged!

Join this celebration to take the time to reward the successes in the field.

Network, Learn... Run!

Working together with the Emily Whitehead Foundation, a virtual sponsored 5k run will be held on the morning of Summit Day 2. Support the foundation and take part with us in Boston or anywhere in the world!

Join this fundraising effort to help support the Emily Whitehead Foundation and activate a cure.

"The CAR-TCR Summit is the go to meeting for researchers in this field"

TCBioPharm

The CAR-TCR Mission

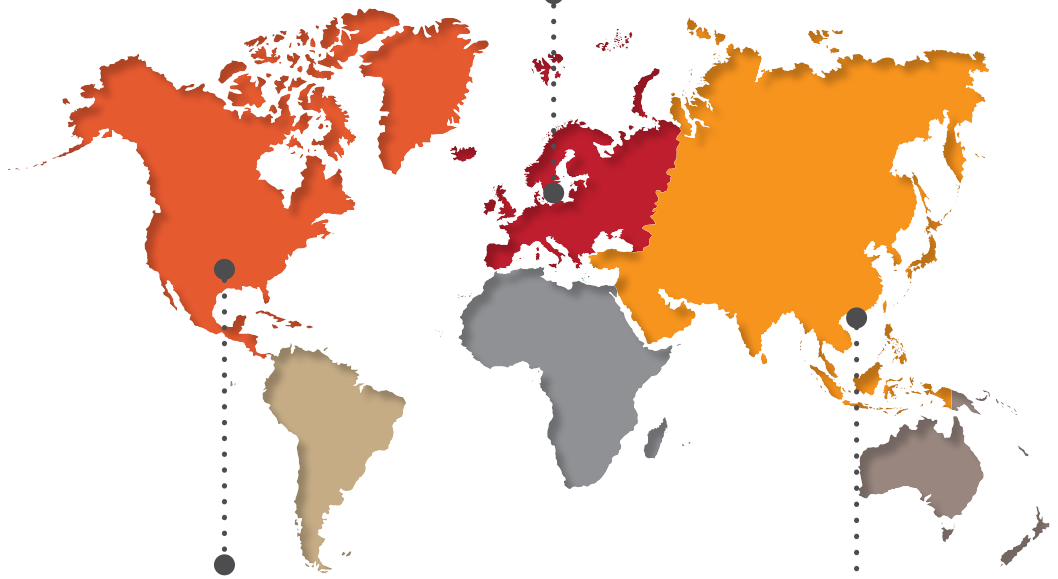
The CAR-TCR Summit celebrates 5 years of bringing together the world's leaders in innovating, developing and delivering CAR and TCR cell based immunotherapies to patients.

From the UPenn/Novartis deal to the approval of Kymriah; from clinical setbacks to billions of dollars in M&As. We've been here with you, through it all. And we're proud to see the industry move from strength to strength.

The CAR-TCR team has one mission, to work in this transformational field to **ENGINEER A CANCER-FREE WORLD**.

The CAR-TCR Summit promises to always bring you novel updates, key case studies and the best and most expert leaders from around the world.

CAR-TCR Summit Europe
February, 2020
London



CAR-TCR Summit
September 10-13, 2019
Boston

CAR-TCR Summit Asia
June 18-20, 2019
Shanghai

Supported by:

immatics
ICT Innovative Cellular Therapeutics
SERVIER
TSCAN THERAPEUTICS

In Proud Partnership with:

emily whitehead foundation

The Emily Whitehead Foundation's mission is to raise awareness and funding for innovative childhood cancer treatments, such as immunotherapy, that will improve survival rates and quality of life.

www.emilywhitehead foundation.org

Agenda at a Glance

CAR-TCR Summit

Strategic Dives, Tuesday September 10th 2019

9.00-11.00	**A** Next Generation Constructs	**B** T Cell Fitness	**C** Facility Design	**D** Managing Leukopheresis	**E** Commercial Marketing Strategy
12.00-14.00	**F** Clean Targets	**G** IND Submission	**H** Scaling Out	**I** Standardized Labelling	**J** Target Product Profile
15.00-17.00	**K** Affinity Tuning	**L** Translating Off-the-Shelf	**M** Scaling Gene Therapy	**N** Patient Support	**O** Payment Models
18.00	**Women of CAR-TCR Round Table Discussion**		**Ambassador Reception, Hosted by Bio-Rad**		

Focus Day, Friday September 13th 2019

Solid Tumor Targeting	Genetic Editing Technologies	TCR Drug Development
Tumour Microenvironment	Comparison of Current & Novel Platforms	Targeting to Overcome Evasion
Clinical Exploration		
Promising Targeting Strategies		Enhancing TCR Potential

Agenda at a Glance Continued

CAR-TCR Summit

Summit Day 1 | Wednesday September 11th, 2019

Coffee & Registration

Industry Leaders Panel

Speed Networking

Discovery	Translation	Clinical Management	Manufacturing	Logistics	Commercialization
Improving Tumor Targeting	Reducing Toxicity	Managing Adverse Events	Automation	Supply Chain Optimization	Realities of Commercializing Products
Overcoming Rejection	Tackling Persistence	Institutional Readiness	Managing Heterogeneity	Managing Supply Chain Ecosystems	International Regulations & Best Practice

Tech Slam @ Innovation Hub

Poster Session & Rising Stars of CAR-TCR

Overcoming Rejection	Enhancing Efficacy with Combinations	Institutional Readiness	Product Characterization	Allogeneic Considerations	Accessibility of CAR-TCR Therapies

Summit Day 2 | Thursday September 12th, 2019

Coffee & Registration

Late Breaking Abstracts

Tech Slam

Discovery	Translation	Clinical Management	Manufacturing	Logistics	Commercialization
CAR for Autoimmune Disorders	Enhancing Efficacy with Combinations	Patient Scheduling	Define Manufacturing Standards	Supply Chain Digitization	CAR-TCR Partnerships & Stakeholders
Controlling Safety	Transformative Trials	Patient Management	Overcoming Allogeneic Challenges	Risk Management & Scheduling	Ethical Reimbursement & Pricing: Payer Perspectives

Emily Whitehead Foundation - An Update from the Patient Perspective

Expert Scientific Advisory Board

James Noble
Chief Executive Officer
Adaptimmune

Barbra Sasu
Chief Scientific Officer
Allogene Therapeutics

Bob Valamehr
Chief Development Officer & Vice President, Cancer Immunotherapy
Fate Therapeutics

Adrian Bot
Vice President of Translation
Kite, a Gilead Company

Dolores Schendel
Chief Executive Officer
Medigene

Christina Coughlin
Chief Medical Officer
Tmunity Therapeutics

Bruce Levine
Founding Director, Clinical Cell, Vaccine Production Facility
University of Pennsylvania

Women of CAR-TCR | Roundtable Experts

Kimberley Freeman
Vice President, Commercial Planning
Adaptimmune

Claudia Zylberberg
Chief Executive Officer
Akron Biotech

Barbra Sasu
Chief Scientific Officer
Allogene Therapeutics

Gwendolyn Binder
Executive Vice President, Science & Technology
Cabaletta Bio

Ariane Hamaide
Vice President Corporate Development
Cellectis

Katy Rezvani
Professor, Melanoma Medical Oncology, Chief of Section Cellular Therapy
MD Anderson Cancer Center

Isabelle Rivière
Director, Michael G. Harris Cell Therapy and Cell Engineering Facility
Memorial Sloan Kettering Cancer Center

> “This meeting is increasingly becoming the venue for significant breaking news in the field”
>
> **Tmunity Therapeutics**

Expert Speaker Faculty | Strategic Dives

Eric von Hofe
President
AffyImmune Therapeutics

Blake Aftab
Vice President of Translational Science
Atara Biotherapeutics

Doug Danison
Vice President, Market Access, Value & Evidence Strategy
bluebird bio

Loren Wagner
Head, CAR-T Manufacturing Operations
Celgene

Claire White
Nurse Navigator for the Cancer Immunotherapy Program
The Children's Hospital of Philadelphia

Chris Baldwin
Director, Supply Chain, Cell Gene Therapy
GlaxoSmithKline

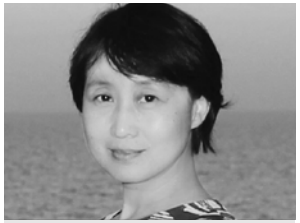
Andrew Hobbs
Managing Director
Huron

Mark Perrott
Senior Director
Huron

Santanu Das
Managing Director
Huron

Yannick Bulliard
Director, Translational Development
Immatics

John Rossi
Director, Translational Medicine
Kite, a Gilead Company



Dong Geng
Senior Director of Non-clinical Development
Legend Biotech

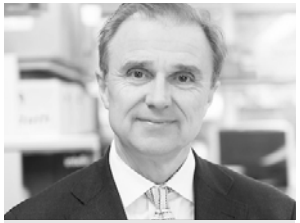
Yuhong Qiu,
Vice President of Global Regulatory Affairs
Legend Biotech

Knut Niss
Chief Technology Officer
Mustang Bio

Clark Eid
Director of Project Management Therapeutics Production
St. Jude Children's Research Hospital

Thomas Andresen
Chief Scientific Officer
Torque Therapeutics

Geoff Hodge
Chief Technical Officer
Unum Therapeutics



Laurence Cooper
Chief Executive Officer
Ziopharm Oncology

> "The CAR-TCR Summit is one of the most progressive meetings I attend with relevant content, interesting opinions and challenges, up to the minute technology and all done in a sincerely warm and collaborative atmosphere."
>
> **Ori Biotech Ltd.**

Expert Speaker Faculty | Summit Days

Hanspeter Gerber
Senior Vice President & Chief Scientific Officer
3T Biosciences

Bala Manian
Executive Chairman
Accelix

James Noble
Chief Executive Officer
Adaptimmune

John Lunger
Senior Vice President, Manufacturing & Supply Chain
Adaptimmune

Mark Dudley
Senior Vice President, Product Development
Adaptimmune

Mark Klinger
Head of TCR Discovery,
Adaptive Biotech

Claudia Zylberberg
Chief Executive Officer
Akron Biotech

Paul Rennert
Chief Scientific Officer
Aleta Biotherapeutics

Janet Lynch Lambert
Chief Executive Officer
Alliance for Regenerative Medicine

Michael Werner
Founder & Senior Policy Counsel
Alliance for Regenerative Medicine

Michael Lehmicke
Director, Science & Industry Affairs
Alliance for Regenerative Medicine

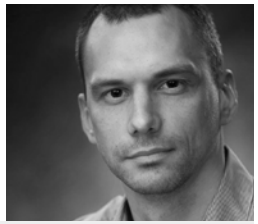
Barbra Sasu
Chief Scientific Officer
Allogene Therapeutics

Debiprasad Roy
Senior Director & Global Head of Programming & Clinical Systems
Allogene Therapeutics

Chris Haqq
Chief Scientific Office
Atara Biotherapeutics

Dan Maziasz
Vice President & Head of Business Development & Strategic Alliances
Atara Biotherapeutics

Derrell Porter
Senior Vice President, Global Commercial Head
Atara Biotherapeutics



Maksim Mamonkin
Assistant Professor
Baylor College of Medicine

Jamie Margolis
Director of Cell & Gene Therapy Operations
Be The Match BioTherapies

Sean Kevlahan
Senior Director, Cell & Gene Therapy
Bio-Techne

Alireza Abazari
Scientific Applications Director
BioLife Solutions, Inc.

Peter Olagunju
Vice President of Patient Operations
bluebird bio

Colleen Dansereau
Director of Clinical Operations, Gene Therapy Program
Dana Farber Boston Children's Center for Cancer and Blood Disorders

Shawn Foley
Attorney, Intellectual Property
Burns & Levinson

Gwendolyn Binder
Executive Vice President, Science & Technology
Cabaletta Bio

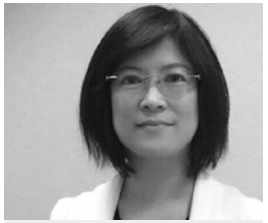
Expert Speaker Faculty | Summit Days

Steven Kanner
Chief Scientific Officer
Caribou Bio

Zonghai Li
Chief Executive Officer
CARsgen Therapeutics

Christopher Wiwi
Senior Director, CAR T Technical Commercialization Lead
Celgene

Deborah Liben
Executive Director
Celgene



Li Ren
Director, Chimeric Antigen Receptor T Cell, Chemistry, Manufacturing, Control & Technology Development
Celgene

Stefanos Theoharis
Senior Vice President, Corporate Development & Partnering
Cell Medica

André Choulika
Chief Executive Officer,
Cellectis

David Sourdive
Executive Vice President, Technical Operations
Cellectis

Elsy Boglioli
Chief Operating Officer
Cellectis

Tony Liu
Chief Executive Officer
Cellular Biomedicine Group

Elena Spanjaard
Global Head of Regulatory Affairs
Celyad

Frederic Lehmann
Head & Vice President Oncology Franchise
Celyad

Jean-Pierre Latere
Chief Operations Officer
Celyad

Katherine Szarama
Evidence Development Division, Coverage & Analysis Group
Centers for Medicare & Medicaid Services

Robert Ott
Director Quality Assurance & Regulatory
Children's GMP, LLC

David Barrett
Pediatric Oncologist
The Children's Hospital of Philadelphia

Bradley Wolff
Head of West Coast Life Sciences
Citi Corporate Investment Banking

Mark Sawicki
Chief Commercial Officer
Cryoport

Amy Emmert
Vice President HSCT & Cellular Therapy Service Line Operations
Dana-Farber Cancer Institute

Kathleen McDermott
Research Nurse
Dana-Farber Cancer Institute

Sarah Nikiforow
Assistant Medical Director, Cell Manipulation Core Facility
Dana-Farber Cancer Institute

Sanjay Srivastava
Senior Manager
Deloitte Consulting LLP

Hussain Mooraj
Next Gen Therapy Practice Lead, Principal
Deloitte Consulting LLP

Jenna Balestrini
Cell Bioprocessing & Program Manager
Draper

Expert Speaker Faculty | Summit Days

June Lu
Director, Translational Research
Endocyte

Cheng Liu
Founder & Chief Executive Officer
Eureka Therapeutics

Bob Valamehr
Chief Development Officer & Vice President, Cancer Immunotherapy
Fate Therapeutics

Jim Beitel
Senior Vice President, Corporate Development
Fate Therapeutics

Nina Bauer
Chief Commercial Officer
FloDesign Sonics Inc

Dobri Kiprov
Medical Director & Senior Vice President
Fresenius Apheresis Services

Philip Vanek
GM Cell Therapy Growth Strategy
GE Healthcare

Michael DeRidder
Head of Commercial Strategy & Oncology Cell Therapy
GlaxoSmithKline

John Sweetenham
Associate Director, Clinical Affairs, Harold C Simmons Comprehensive Cancer Center
UT Southwestern

David Smith
Head of Innovation and Engineering
Hitachi Chemical Advanced Therapeutics Solutions

Brian Burke
Head of Strategy
Horizon Discovery Group

Martin Lachs
Vice President Project Management Oncology
ICON PLC

Ali Mohamed
Vice President of CMC
Immatics

William Ho
Chief Executive Officer
Incysus Therapeutics

Lawrence Lamb
Chief Scientific Officer
Incysus Therapeutics

Xiao Lei
Chief Executive Officer
Innovative Cellular Therapeutics

Sean Mackay
Chief Executive Officer
IsoPlexis

Kristen Sudol
Director, Vein to Vein Supply Chain & Chimeric Antigen Receptor
The Janssen Pharmaceutical Companies of Johnson & Johnson

Adrian Bot
Vice President of Translation
Kite, a Gilead Company

Jian Irish
Global Head of Manufacturing
Kite, a Gilead Company

Peter Emtage
Senior Vice President & Global Head of Cell Therapy Research
Kite, a Gilead Company

Sadik Kassim
Executive Director
Kite, a Gilead Company

Jeff Mayhew
Chief Development Officer
LabConnect

Qiong Wang
Senior Director of R&D
Legend Biotech

Expert Speaker Faculty | Summit Days

Matthew Hewitt
Head of Clinical Development, Personalized Medicine
Lonza

Matthew Frigault
Instructor in Medicine
Massachusetts General Hospital

Katy Rezvani
Professor, Melanoma Medical Oncology, Chief of Section Cellular Therapy
MD Anderson Cancer Center

Allison Matthews
Service Designer
Mayo Clinic Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery

Boro Dropulic
Chief Scientific Officer
Lentigen, a Miltenyi Company

Isabelle Rivière
Director, Michael G. Harris Cell Therapy and Cell Engineering Facility
Memorial Sloan Kettering Cancer Center

Junxia Wang
Director of Analytical Development
Mustang Bio

Mario Marcondes
Senior Director, Clinical Development
Nektar Therapeutics

Srujana Cherukuri
Chief Exectuive Officer
Noble Life Sciences, Inc

Kirstin Powel
Director, Product Quality
Novartis

Pascal Touchon
Senior Vice President & Global Head of Cell & Gene
Novartis

Steve Shamah
Head of Research
Obsidian Therapeutics

Steven Lynum
President
PHC Corporation of North America

Eric Ostertag
Chief Executive Officer
Poseida Therapeutics

Matthew Spear
Chief Medical Officer
Poseida Therapeutics

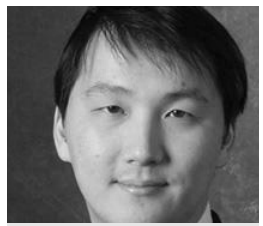
Vita Golubovskaya
Director R&D & Business Development
Promab Biotechnologies

Peter Jensen
Chief Executive Officer
Protect Therapeutics

Kent Thorup
Regional Vice President
Quick Group of Companies

Jim Freeth
Co-managing Director
Retrogenix

George O'Sullivan
Head of Supply Chain
Rubius Therapeutics



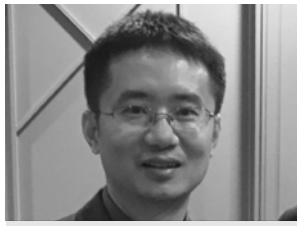
Tim Lu
Chief Executive Officer
Senti Biosciences

Jerome Zeldis
Chief Medical Officer
Sorrento Therapeutics

Steven Feldman
Director, Manufacturing & Development
Stanford School of Medicine

Qiong Xue
Associate Director, Analytical Development & Cell Therapies
Takeda

Expert Speaker Faculty | Summit Days



Lan Cao
Senior Director & Head of Product Development, Clinical Manufacturing, Cell Therapy & Pharmaceutical Science
Takeda

Angela Scott
Chief Operating Officer
TCBiopharm

Jason Krentz
Chief Technology Officer
Tmunity Therapeutics

Andrea Moore
Director of Analytical Development
Tmunity Therapeutics

Kristian Elverum
Senior Vice President, Corporate Development
Turnstone Biologics

Joseph McGuirk
Division Director, Hematologic Malignancies & Cellular Therapeutics
University of Kansas Medical Center

Bruce Levine
Founding Director, Clinical Cell, Vaccine Production Facility
University of Pennsylvania

Elizabeth Olson Hexner
Associate Professor of Medicine
The University Of Pennsylvania

Joseph Fraietta
Director, Solid Tumor Immunotherapy Research Laboratory
University of Pennsylvania

Marco Ruella
Assistant Professor of Medicine
University of Pennsylvania

Ann Ranger
Senior Director of Translational Medicine
Unum Therapeutics

Heidi Hagen
Chief Strategy Officer
Vineti

Expert Speaker Faculty | Focus Day

Shon Green
Director, Clinical Translation
Altius Institute for Biomedical Sciences

Scott Shoemaker
Senior Director of Operations
bluebird bio

Alexandre Juillerat
US Laboratory Head
Cellectis

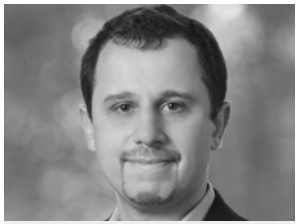
Tony Ho
Executive Vice President, Head of Research & Development
CRISPR Therapeutics

Michael Klichinsky
Co-Founder & Vice President, Discovery Research
Carisma Therapeutics

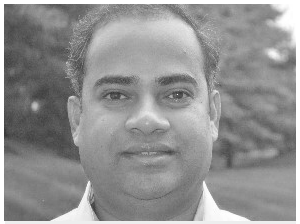
Saul Priceman
Assistant Professor, Dept. of Hematology & Hematopoietic Cell Transplantation
City of Hope National Medical Center

Rick Morgan
Senior Vice President of Immunogenetics
Editas Medicine

Aiman Shalabi
Vice President R&D
GlaxoSmithKline



Roman Yelensky
Chief Technology Officer
Gritstone Oncology



Rajkumar Ganesan
Director
The Janssen Pharmaceutical Companies of Johnson & Johnson

Stephanie Astrow
Senior Director, Translational Medicine
Kite, a Gilead Company

Peter Hoang
Chief Executive Officer
Marker Therapeutics

Slavoljub Milosevic
Head of Technology & Innovation
Medigene

Devon Shedlock
Vice President, Preclinical Development
Poseida Therapeutics

Franco Marincola
Chief Science Officer
Refuge Biotechnologies

Alfonso Quintas-Cardama
Chief Medical Officer
TCR2 Therapeutics

Sabine Chlosta
Chief Medical Officer
Triumvera Immunologics

Miguel Forte
Chief Executive Officer
Zelluna Immunotherapy

> "The CAR-TCR Summit gives a fresh and extensive update on what's going on in the field and the opportunity to establish new networks and consolidate established ones"
> **MolMed S.p.A**

9.00

Discovery

A Armoured CAR & TCR Constructs to Create Better Killers

- Explore novel gene engineered CAR-T and TCR constructs which enhance potency and overcome the suppressive nature of the tumor microenvironment
- Review the effect of stripping inhibitory receptors to create anti-T-cell CAR-T
- Identify accessory proteins which help enhance efficacy

Thomas Andresen, Chief Scientific Officer, **Torque Therapeutics**

Translation

B T Cell Fitness, a Major Product Attribute Influencing Clinical Performance of CAR-T Cells

- Understand how product T cell fitness, defined by CAR-T cell expansion capability and polyfunctionality, have major impact on clinical outcome
- Explore how the pharmacokinetics profile of CAR-T cells is linked to the intrinsic CAR-T cell expansion capability
- Learn how T cell fitness shows heterogeneity across normal subjects and patients, with substantial impact on design and optimization of both autologous and allogeneic products

John Rossi, Director, Translational Medicine, **Kite, a Gilead Company**

Manufacturing

C Facility Design Considerations for Autologous Cell Therapies

- Categorize higher risk vs. lower risk operations to allocate classified spaces optimally
- Review the need to organize manufacturing suites based on process considerations
- Ensure that supporting functions are not underestimated during the design process

Loren Wagner, Head, CAR-T Manufacturing Operations, **Celgene Corporation**

Logistics

D Managing Leukapheresis for Autologous Cell Therapies

- Overview of leukapheresis instruments and operating parameters
- Discuss the variability in operating procedures and current efforts to standardize them
- Understand the impact of controlling leukapheresis on cell therapy processes

Geoff Hodge, Chief Technical Officer, **Unum Therapeutics**

Commercialization

E Develop & Execute a Successful Cross-Functional Strategy to Optimize Commercial Success

- Review the value chain for the product, looking at the motivations of the different stakeholders
- Discuss the challenges and engagement opportunities associated with each stakeholder group
- Brainstorm and cluster potential solutions through three lenses: regulatory, market access and commercialization
- Pull these solutions together into a high-level, cross-functional plan

Andrew Hobbs, Managing Director, **Huron**, **Mark Perrott**, Senior Director, **Huron**, & **Santanu Das**, Managing Director, **Huron**

11.00 Morning Refreshments & Debrief

Join the networking session and hear a 5 minute review of the key take away points from each of the workshop leaders.

12.00

Discovery

F Antigen Identification for Clean Targets

- Review potential approaches to minimize off-target toxicity by identifying tumor-specific antigens at which to target CAR T cells
- Discuss strategies to identify antigens found primarily or exclusively on tumor cells that could be targets for CAR T therapy

Blake Aftab, Vice President of Translational Science, **Atara Biotherapeutics**

Translation

G Strategies & Considerations of IND Submission for CAR-T Cell Therapies

- Understand current FDA and EMEA requirements for preclinical assessment of cell therapies
- Review nonclinical *in vitro* and *in vivo* data that have received IND approval. Gain clarity on the preclinical studies which are necessary for IND submission
- Discuss regulatory strategies in IND submission of CAR-T products

Dong Geng, Senior Director of Non-clinical Development, **Legend Biotech**

Yuhong Qiu, Vice President of Global Regulatory Affairs, **Legend Biotech**

Manufacturing

H Scaling Out Within GMP Facilities

- Optimize manufacturing operations of multiple individual projects for higher throughput
- Learn from experience in experience in running a quality system that can permit multiple patient products
- Advice on how to ensure manufacturing capacity matches clinical capacity

Knut Niss, Chief Technology Officer, **Mustang Bio**

Logistics

I Labelling to Secure Tracking & Monitor Movement

- Understand the need for a standardized labelling process for academic and commercial entities to support chain of identity
- Discuss moving all manufacturing of cell therapy products to a standardized labelling system, to identify products in a universal information system ensuring directional traceability of these products

Chris Baldwin, Director, Supply Chain, Cell & Gene Therapy, **GlaxoSmithKline**

Commercialization

J Capturing Product Strategy in a Target Product Profile

- Use the TPP to capture labeling goals during project initiation to save costs, reduce time to market and improve performance
- Unite diverse stakeholder opinions, stabilize product development and provideaccurate communication with regulatory officials
- Define the TPP structure for cellular and gene therapy products and its re-use as a source document for IND submissions

Clark Eid, Director of Project Management, Therapeutics Production, **St. Jude Children's Research Hospital**

2.00 Afternoon Refreshments & Debrief

Join the networking session and hear a 5 minute review of the key take away points from each of the workshop leaders.

3.00

K Density Selective Target Binding to Improve Specificity & CAR T Cell Function

- Detail how increased selectivity by affinity tuning the targeting moiety can result in desired CAR T cell function
- Review partial CAR T cell signalling to amplify natural T cell activity
- Discuss how affinity and signalling selection can enhance solid tumor activity

Eric von Hofe, President, **AffyImmune Therapeutics**

L En Route to the Off-the-Shelf Future of Cellular Therapy

- Evaluate the balance between tolerability and durable clinical response via persistence, which is paramount to the success of allogeneic cell therapy
- Discuss how commercial viability will depend on large-scale expansion processes that preserve product fitness and potency, with minimal product heterogeneity
- Review how first-generation modalities entering the clinic will shed light on some of these pressing questions

Yannick Bulliard, Director Translational Development, **Immatics**

M Scaling Gene Therapy Using Sleeping Beauty System to Express CARs & TCRs to Target Hematologic Malignancies & Solid Tumors

- Outline the Sleeping Beauty system which is a non-viral approach to genetically modifying clinical grade T cells
- Understand how the Sleeping Beauty system can express chimeric antigen receptor (CARs) and T-cell receptor (TCRs)
- Review how the Sleeping Beauty system can address inter- and intra-tumor heterogeneity of antigen expression to broaden distribution and prevent relapse

Laurence Cooper, Chief Executive Officer, **Ziopharm Oncology**

N Bridge the Gap between Patient Support & Marketing Programs

- Explore the strategy and operations behind managing a CAR-T program that is an industry first
- Discuss strategies to manage patient support when coordinating with different teams
- Outline the need for market education to prepare and quantify an appropriate patient

Claire White, Nurse Navigator for the Cancer Immunotherapy Program, **The Children's Hospital of Philadelphia**

O Explore Payment Systems for Next Generation CAR & TCR Therapies

- Explore how to design and support patient centric or outcome based contracts
- How to design the operating frameworks and develop financial models to support the contract
- Understand how to operationalize and administer this contract internally and externally

Doug Danison, Vice President, Market Access, Value & Evidence Strategy, **bluebird bio**

5.00 Evening Refreshments & Debrief

Join the networking session and hear a 5 minute review of the key take away points from each of the workshop leaders.

6.00 Ambassador Reception, Hosted by Bio-Rad, Attendance by Invitation Only

BIO-RAD

6.00 Women of CAR-TCR Round Table Discussion, Separate registration required

> "Excellent meeting, a great event for gaining an up-to-date understanding of the field and for ability to engage directly with market and scientific leaders"
>
> **Immunocore**

Summit Day One | Wednesday, September 11th 2019

CAR-TCR Summit

7.20 **Registration & Morning Coffee Refreshments**

8.20 **Welcome Remarks**

Jade Wallace
Program Director
Hanson Wade

8.30 **Chairman's Opening Remarks**

9.00 **Industry Leader's Fireside Chat**

With two approved CAR-T therapies seeking global approval, what are the next steps? Where do we go now? With the excitement in allogeneic therapy, will autologous therapy become a thing of the past?
How can we enhance the efficacy when targeting solid tumors and meet this unmet need?

Take this opportunity to ask the leaders what their future plans are and what we can expect from the CAR-TCR space over the next few years.

James Noble
Chief Executive Officer
Adaptimmune

Laurence Cooper
Chief Executive Officer
Ziopharm Oncology

André Choulika
Chief Executive Officer
Cellectis

Peter Emtage
Senior Vice President & Global Head of Cell Therapy Research
Kite, a Gilead Company

10.00 MACS Miltenyi Biotec

10.30 **Speed Networking & Morning Refreshments**

This session is fast paced aiming to provide brief introductions to as many participants at the CAR-TCR Summit as early on in the meeting as possible. The renowned speed networking session will be one of the most valuable hours you spend at this summit.

11.30 - 12.00

Discovery	Translation	Clinical Management	Manufacturing	Logistics	Commercialization
Improving Tumor Targeting	**Reducing Toxicity**	**Institutional Readiness**	**Automation**	**Supply Chain Optimization**	**Realities of Commercializing Products**
Innovative TCR Cell Design • Explore the importance of affinity, specificity and target validation • Next generation strategies to overcome the tumor microenvironment and enhance persistence **James Noble**, Chief Executive Officer, **Adaptimmune**	**Overcoming Treatment Resistance to T Cell Therapy** • YESCARTA® clinical performance is influenced by the TME, T cell fitness and dose • Toxicities are related to excess T and myeloid cell activity and trafficking • Optimizing CAR-T therapy to overcome primary and secondary treatment failures **Adrian Bot**, Vice President of Translation, **Kite, a Gilead Company**	**Institutional Preparation for CAR-T Cell Therapy** • Prepare institution infrastructure and resource utilization to support safe and efficient CAR-T therapy • Development of SOPs for taking the patient through the CAR-T journey • Development of standardized algorithms of care, Quality Assurance program and outcomes reporting **Joseph McGuirk**, Division Director, Hematologic Malignancies & Cellular Therapeutics, **University of Kansas Medical Center**	**Strategies to Automate Autologous Therapy** • Experience being among the first to launch a commercially-approved cellular therapy treatment • Scaling cellular therapy manufacturing from single-site to a decentralized network of global sites • Applying Industry 4.0 and automation opportunities in autologous cellular therapy manufacturing **Jian Irish**, Global Head of Manufacturing, **Kite Pharma**	**Challenges in Global Apheresis Supply** • Gain an overview of apheresis supply chain • Discuss the regulatory landscape for apheresis and cell supply • Outline a standardized process for qualification of cells **Kirstin Powel**, Director, Product Quality, **Novartis**	**Implementing the First Ever Global Launch of CAR-T with Kymriah** Successfully managing regulatory submissions for EU, Canada, Australia and Japan • Building a commercial infrastructure that supports efficient delivery of autologous CAR-T globally • Value based pricing and reimbursement in various countries

Summit Day One | Wednesday, September 11th 2019

CAR-TCR Summit

12.02 - 12.32

Identification of Novel Shared Targets in Solid Tumors

- Yeast display technology to define peptide MHC complexes binding to a lead TCR
- Defining all peptide MHC complexes that bind to a given T- cell receptor
- Peptide MHC profiling of clinical TCRs to improve safety while maintaining activity

Hanspeter Gerber, Senior Vice President & Chief Scientific Officer, **3T Biosciences**

Strategies to Reduce Toxicity

- Dosing strategies based on tumor bulk and early intervention at Grade 2
- Dual signaling CAR Ts to enhance specificity of targeting
- AlloEBV CAR Ts and next generation costimulation domains
- Management strategies to mitigate toxicity and minimize risk of impact on therapeutic efficacy

Christopher Haqq, Chief Scientific Officer, **Atara Biotherapeutics**

Institutional Readiness: A Multidisciplinary Approach to CAR-T Cell Delivery Models

- Outline a multidiscipline needs assessment approach
- Explore the importance of communication, education and collaboration
- Review the continuous quality improvement model to optimize operations

Colleen Dansereau, Director of Clinical Operations, Gene Therapy Program, **Dana Farber Boston Children's Center for Cancer and Blood Disorders**

Automated CAR-T Cell Production Compatible with Lentiviral & Gammaretroviral Vector Platforms

- Focus on CliniMACS Prodigy for automated cell production
- Review lentiviral vector encoding an anti-CD19/22 bispecific loop CAR
- Analyze a gammaretroviral vector encoding an anti-GD2 CAR
- Highlight process data, product attributes and clinical trial updates

Steven Feldman, Director, Manufacturing & Development, **Stanford School of Medicine**

Establishing Scalable Supply & Logistics

- Transitioning programs from an early development partner to expand to multi-center trials
- Leverage early investments in technology and strategic partnerships
- Review process design, performance monitoring, and continuous improvement

Jason Krentz, Chief Technology Officer, **Tmunity Therapeutics**

Bringing an Off-the-Shelf Therapy Through to Commercialization

- CAR T innovation is moving toward off-the-shelf allogeneic CAR T cells
- Optimize the therapy delivery process whilst streamlining the HLA matching process
- Building commercial infrastructure prior to potential launch of allogeneic T cell product, tab-cel®
- Discuss Atara's approach preparing to commercialise tab-cel®

Derrell Porter, SVP, Global Commercial Head, **Atara Biotherapeutics**

12.34 - 13.04

Novel CAR-T Cells

- Novel CAR-T cells will be presented against haematological and solid cancers

Vita Golubovskaya, Director R&D & Business Development, **Promab Biotechnologies**

Accellix

Operationalizing a Successful CAR T Clinical Trial

- On-boarding sites
- Managing Logistics
- Data currency planning

Martin Lachs, Vice President of Project Management Oncology, **ICON**

Automation & Decentralization of CAR-T Manufacture

Boro Dropulic, Chief Scientific Officer, **Lentigen, a Miltenyi Company**

Mitigating Risk Through Standardization in the Cell Therapy Supply Chain & Beyond

- Solutions to standardize processes and mitigate risk across the supply chain
- Opportunities to efficiently develop and deliver innovative therapies to patients

Jamie Margolis, Director of Cell & Gene Therapy Operations, **Be The Match BioTherapies**

The Role of Apheresis in the Evolving Field of Cellular Immunotherapy

- Issues with current apheresis technology used to collect cells for immunotherapy
- Logistical issues related to providing apheresis services for cellular immunotherapy
- How to overcome these challenges

Dobri Kiprov, Medical Director & Senior Vice President, **Fresenius Apheresis Services**

13.04 **Lunch & Networking**

13.04 **Rising Stars of CAR-TCR Private Lunch** - Exclusively for registered PhD and Post Doc attendees

NEW THIS YEAR!

13.04 **Private Lunch Hosted by KBI** - Attendance by Invitation Only KBI BIOPHARMA

Summit Day One | Wednesday, September 11th 2019

CAR-TCR Summit

14.00 - 14.30

Panel: TCR vs CAR

- Discuss the strengths and weaknesses of each cell product
- Challenges faced in bringing engineered TCRs successfully through clinic

Qiong Wang, Senior Director of R&D, **Legend Biotech**

Stefanos Theoharis, Senior Vice President, Corporate Development and Partnering, **Cell Medica**

Brian Burke, Head of Strategy, **Horizon Discovery Group**

Barbra Sasu, Chief Scientific Officer, **Allogene Therapeutics**

Tackling Persistence

Panel: What is the Optimal T Cell from Clinical Experience?

- Clinical trial experience identifying attributes of a functioning T cell
- Monitor persistence and exhaustion to improve selection

Sean Mackay, CEO, **Isoplexis**

Dong Geng, Senior Director of Non-clinical Development, **Legend Biotech**

Qiong Xue, Head of Analytical Development for Cell Therapies, **Takeda**

Panel: What Do You Need to Run a Successful CAR-T Trial?

- Infrastructure requirements for a successful CAR-T trial
- Outline what training and qualifications are required to support infrastructure
- Managing high risk patients
- How to prepare for and monitor toxicities

Bruce Levine, Founding Director, Clinical Cell, Vaccine Production Facility, **University of Pennsylvania**

Colleen Dansereau, Director of Clinical Operations, Gene Therapy Program, **Dana Farber Boston Children's Center for Cancer and Blood Disorders**

Managing Heterogeneity

Panel: Manufacturing Techniques to Support the Heterogeneous & Patient-Specific Material of Autologous Therapy?

- Review manufacturing practices to manage the heterogeneous starting material
- Optimize and streamline manufacturing processes to reduce turn-around time

Claudia Zylberberg, Chief Executive Officer, **Akron Biotech**

Sadik Kassim, Executive Director, **Kite, a Gilead Company**

Lan Cao, Senior Director & Head of Product Development, Clinical Manufacturing, Cell Therapy & Pharmaceutical Science, **Takeda**

Isabelle Rivière, Director, Michael G. Harris Cell Therapy and Cell Engineering Facility, **Memorial Sloan Kettering Cancer Center**

Managing Supply Chain Ecosystems

Panel: Logistical Considerations of Autologous Vs Allogeneic Therapy

- Challenges in transporting patient specific therapies
- The importance of chain of identity
- Challenges in bulk expansion and storage of allogeneic therapy
- Consider conditions for cell viability

Mark Dudley, Senior Vice President, Product Development, **Adaptimmune**

World Courier
AmerisourceBergen

Panel: Ensuring CAR-TCR Therapies are Accessible to Patients

- Discuss the challenges faced when finalizing CAR-T reimbursement models
- How will future allogeneic therapies compare in reimbursement strategies?
- Discuss the need to increase CAR-T sites to allow greater accessibility to care

Janet Lynch Lambert, Chief Executive Officer, **Alliance for Regenerative Medicine**

John Sweetenham, Associate Director, Clinical Affairs, Harold C Simmons Comprehensive Cancer Center, **UT Southwestern**

14.32 - 15.02

Robust Technology for Targeting Multiple Tumor Antigens with a Single CAR T Cell

- Bridging protein technology to create CAR19 T cells targeted to multiple different tumor antigens
- Target multiple antigens, simultaneously, for solid tumors, B cell cancers, and AML
- *In vitro* and *in vivo* data from AML and solid tumor programs

Paul Rennert, Chief Scientific Officer, **Aleta Biotherapeutics**

CAR-Engineered NK Cells as an Off-the-Shelf Therapy for Cancer

- Human cord blood to produce CAR-NK cells, redirecting specificity and enhancing persistence
- Engineering NK cells to express IL-15 to enhance *in vivo* proliferation and persistence
- Data from first-in-human Phase I/II study of CAR19/IL15-engineered NK cells

Katy Rezvani, Professor. Melanoma Medical Oncology, Chief of Section Cellular Therapy, **MD Anderson Cancer Center**

Clinical Drug Development Challenges for Cell & Gene Therapy in China

- Medical digitalization will fundamentally transform research, clinical, and healthcare as a whole
- How China can advance the progress in novel therapy modalities
- De-risking clinical trials by leveraging fast-track clinical studies

Tony Liu, Chief Executive Officer, **Cellular Biomedicine Group**

Challenges & Surprises in Autologous T Cell Manufacturing

- What you see is what you get, or not?
- What makes an acceptable or unacceptable product for T cell manufacture
- Dosing and viability for a cell product that is a living and dividing drug

Bruce Levine, Founding Director, Clinical Cell, Vaccine Production Facility, **University of Pennsylvania**

Optimize Supply Chain Coordination to Ensure Secure Chain of Custody

- Strategies to track personalized therapies throughout logistics to ensure control throughout product journey

Kristen Sudol, Director, Vein to Vein Supply Chain & Chimeric Antigen Receptor, **The Janssen Pharmaceutical Companies of Johnson & Johnson**

International Regulations & Best Practice

Navigating Regulatory Requirements for Early Phase CAR-T Clinical Studies

- Outline efficient US and global submission planning for initial clinical studies
- Define requirements for nonclinical, CMC and clinical sections of the IND
- List key considerations for autologous and allogeneic CAR-T therapies

Elena Spanjaard, Global Head of Regulatory Affairs, **Celyad**

15.04 - 15.34

Enhancing CAR-T Therapies with Regulated Immunomodulatory Factors

- Engineered CAR-T cells to produce IL15, IL12, or CD40L can enhance functional activity
- Report on Destabilizing Domain technology used to couple titratable regulation of immunomodulatory factors with CAR-T to support T cell proliferation and maintain stem cell-like activity

Steve Shamah, Head of Research, **Obsidian Therapeutics**

Explore Patient Clinical Data to Review *In Vivo* T Cell Persistence

- Manufacturing under cGMP conditions to meet safety and efficacy release criteria
- Present *in vivo* data on T cell persistence

Ali Mohamed, Vice President of CMC, **Immatics**

Patient Management

Challenges in Effective Patient Scheduling

- Risks associated with CAR therapies
- Outline which preconditioning methods can enhance the efficacy of the therapy
- Explore the operational challenges of scheduling a patient specific therapy with manufacturing timelines
- Should patients be waiting for this costly and toxic therapy?

Jerome Zeldis, Chief Medical Officer, **Sorrento Therapeutics**

Adapting to Variance in T Cell Starting Material for CAR Manufacture in Pediatrics

- Discuss T cell starting material variance depending on prior therapy
- Metabolic assessments may not correlate with phenotype
- Outline possibilities for adaptive manufacture

David Barrett, Pediatric Oncologist, **Children's Hospital of Philadelphia**

Managing an Ecosystem for Clinical & Commercial Products

Sarah Nikiforow, Assistant Medical Director, Cell Manipulation Core Facility, **Dana-Farber Cancer Institute**

Challenges of Initiating Global Clinical Trials with an Autologous CAR-T Product

- Understand the clinical supply models of initiating trials in US, EU and Japan
- Outline the CMC challenges: oversea technology transfer, comparability, viral vector, raw materials
- Analyze the regulatory and logistic challenges

Li Ren, Director, Chimeric Antigen Receptors T Cell, Chemistry, Manufacturing, Control & Technology Development, **Celgene**

15.36 - 16.06

MaxCyte

Session details to be confirmed

Vineti

Microfluidic Systems to Enable the Manufacture of Next Generation Cell Therapies

Jenna Balestrini, Cell Bioprocessing & Program Manager, **Draper**

Overcoming Complexities of the Personalized Medicine Supply Chain

- Temperature requirements
- Identify Cold Chain packaging
- Identify manufacturing and clinical site locations
- Route mapping
- Risk mitigation
- Chain of Custody Scalability
- Synchronized data and connectivity – IT integration

Kent Thorup, Regional Vice President, **Quick Group of Companies**

Implementation of Biopreservation Best Practices in Cell & Gene Therapy Manufacturing

- Discuss cryopreservation stress and delayed onset cell death
- Formulation considerations for cryopreservation of cellular therapies
- Outline critical process parameters of cryopreservation

Alireza Abazari, MSc, PhD, Scientific Applications Director, **BioLife Solutions, Inc**

16.06 **Tech Slam @ Innovation Hub** IrvineScientific NanoCool A Cool Revolution. OVIZIO Promega

16.46 **Afternoon Refreshments & Poster Session with Rising Stars of CAR-TCR**

Share your work with the pioneers of CAR-TCR therapeutic development! Bring a poster and gain feedback on your latest research with this expert community. Growing through popular demand, this exciting session brings you hot new data highlighting innovating research, and new for this year we will be showcasing the **Rising Stars of CAR-TCR** by displaying a hand chosen group of PhD and Post Doc posters too!

NEW THIS YEAR!

17.46 - 18.16

Adaptive biotechnologies®

Incorporating Novel Tools to Enhance *Ex Vivo* Cell Manufacturing Workflows

Sean Kevlahan, Senior Director, Cell & Gene Therapy, **Bio-Techne**

LABCONNECT

MARKEN a UPS Company

ekkoTM: Acoustics Cell Processing Changing Cell & Gene Manufacturing

- How can we achieve commercially viable routines in manufacturing?
- How acoustophoresis and the ekko platform is changing the cell processing paradigm
- Case studies on concentrate and wash where ekko is solving processing challenges

Nina Bauer, Chief Commercial Officer, **FloDesign Sonics Inc**

Chain of Compliance™: The Standardization of Precision Medicine Logistics

- Increasing regulatory requirements supporting precision medicine distribution are emerging
- Chain of Compliance™ adherence will be a basic requirement for managing distribution
- How does this standardization impact clinical and commercial logistics strategies?

Mark Sawici, Chief Commercial Officer, **Cryoport**

Session details to be confirmed

Overcoming Rejection

Enhancing Efficacy with Combinations

Product Characterization

Allogeneic Considerations

Accessibility to CAR-TCR Therapies

18.18 - 18.48

Rejection-Resistant Off-the-Shelf T Cell Platform

- Allogeneic T cell activity is limited by immune rejection by host T- and NK-cells
- Alloimmune Defense Receptors (ADR) selectively recognize and eliminate alloreactive lymphocytes, sparing resting cells
- ADRs enable CAR T cells to resist T- and NK-cell rejection *in vitro* and *in vivo*

Maksim Mamonkin, Assistant Professor, **Baylor College of Medicine**

Utilizing Next Generation Cytokines to Enhance Efficacy & Durability of CAR-Ts

- Optimize CAR T-cell efficacy via next generation cytokines
- Enhance CAR-T pro-survival effect and/or disrupt an Immunosuppressive tumor micro-environment
- Characterization of FDA approved CD19 CAR-T products with next generation cytokines

Mario Marcondes, Senior Director, Clinical Development, **Nektar Therapeutics**

Management of Patients & Care Givers

- Best practice for managing patients in the community
- Information which should be provided for care givers
- Review a detailed site management plan

Kathleen McDermott, Research Nurse, **Dana-Faber Cancer Institute**

CAR-T Product Characterization & Function

- Explore product composition, stability, and characterization
- Determine key attributes to assess product efficacy
- Define strategies for determining CAR-T potency

Andrea Moore, Director of Analytical Development, **Tmunity Therapeutics**

Stepwise Translation to Allogeneic CAR-T: A Pragmatic Clinical Approach

- Define the benefits of gamma-delta T cells
- Characterize the conditions required to store allogeneic cells in banks
- Consider operational challenges around long term viability conditions

Angela Scott, Chief Operating Officer, **TCBiopharm**

Improving Access to Autologous Cell Therapy for a Future Beyond B-cell Malignancies

- Summarize structural challenges to widespread adoption of cell therapies
- Address reimbursement challenges for single-administration treatments to provide long term disease control or cure
- Discuss barriers to access, such as geography, facility and provider capacity

Michael DeRidder, Head of Commercial Strategy & Oncology Cell Therapy, **GlaxoSmithKline**

18.50 - 19.20

Prospects for Off-the-Shelf CAR Therapy

- Unique approach to create a master pluripotent stem cell line
- Continuous conversion of master cell line into uniform populations of off-the-shelf CART
- Genetic editing includes complete elimination of TCR expression and TRAC locus
- Targeting antigen escape through a secondary non-CAR mechanism

Bob Valamehr, Chief Development Officer & Vice President, Cancer Immunotherapy, **Fate Therapeutics**

The Combination of Radiotherapy with CAR-T Cell Therapy

- Radiotherapy to enhance antitumor activities of CAR T cell therapy
- Radiotherapy to enhance infiltration of CAR T cells in the tumor tissue
- Other immune cells involved in the increased antitumor activities imposed by combined therapy

Zonghai Li, Chief Executive Officer, **CARsgen Therapeutics**

Enrolment to Infusion: Key Considerations in Delivering C> Products

- What is Therapy Services
- Potential challenges in the treatment pathway
- Success factors for commercial success

Peter Olagunju, Vice President of Patient Operations, **bluebird bio**

Analytical Challenges for Method Transfer to Clinical Manufacturing Sites

- Transfer analytical methods with limited assay qualification studies and batch testing experience
- Discuss the different approaches to meet these regulatory requirements
- Early and late stage of process development, complexity of comparability studies, prior experience from recent analytical transfers

Junxia Wang, Director of Analytical Development, **Mustang Bio**

Infrastructure Readiness for Allogeneic Therapies

- Outline the infrastructure required to support the transport of cryogenic material
- Detail storage conditions to support allogeneic banking

George O'Sullivan, Head of Supply Chain, **Rubius Therapeutics**

Access & Capacity Management for CAR-T Clinical Delivery

- Identify financial authorization challenges and solutions
- Meet demand through dynamic governance blending clinical trials and commercial patient work flows

Amy Emmert, Vice President, HSCT & Cellular Therapy Service Line Operations, **Dana-Farber Cancer Institute**

19.20

The Cell-ebration of CAR-TCR!

After a jam packed day of learning and networking, unwind with your new colleagues over some cocktails and nibbles... with the live band in full swing, dancing is strongly encouraged!

> "We are all working towards one goal, to save patients' lives with this new technology related to CAR-TCR"
>
> **bluebird bio**

Summit Day Two | Thursday, September 12th 2019

CAR-TCR Summit

7.00 **Emily Whitehead Foundation Charity 5k Virtual Run**

8.30 **Registration & Coffee**

9.00 **Chair's Opening Remarks**

9.30 GE Healthcare

Philip Vanek
GM Cell Therapy Growth Strategy
GE Healthcare

10.00 **Late Breaking Abstracts**

Key companies will present new data for the first time at the CAR-TCR Summit.
Be sure not to miss the session of the year and be the first to hear these new clinical trial read outs.
An update Eureka's ongoing liver cancer solid tumor study.

UNPUBLISHED DATA

Cheng Liu
Founder and Chief Executive Officer
Eureka Inc.

10.30 TERUMOBCT
Unlocking the Potential of Blood

11.00 PHC
Healthcare with Precision

Steven Lynum
President
PHC Corporation of North America

11.30 **Networking & Refreshments**

11.35 **Tech Slam @ The Innovation Hub**

Key stakeholders will give you a demonstration and the low down on innovations and show you how they can be integrated into your strategies. Take part to improve, support and revolutionize current processes in this field.

GenScript Make Research Easy | Berkeley Lights | ThermoGenesis

12.30 - 13.00

Discovery

Panel: Next Generation CAR-TCR Engineering to Enhance Trafficking & Persistence

- Next generation construct design for a potent, targeted and safer therapy
- Understand how these advances can improve the efficacy in solid tumors

Tim Lu, Chief Executive Officer, **Senti Biosciences**

Peter Jensen, Chief Executive Officer, **Protect Therapeutics**

William Ho, Chief Executive Officer, **Incysus Therapeutics**

Translation

Panel: Discuss Disruptive Gene Editing Technology that will Create the Next Generation CAR-TCR

- Discuss the ethics of genetic engineering in clinical research
- Review current viral and non-viral gene editing platforms to overcome manufacturing bottlenecks

Eric Ostertag, Chief Executive Officer, **Poseida Therapeutics**

TSCAN THERAPEUTICS

Clinical Management

Panel: CAR-T Therapy to Replace Transplants

- Potential of CAR-T replacing the need for stem cell transplants
- CAR-T can be a better alternative to socio economic burden of transplant
- Thought process change for CAR-T to be a first line treatment

Matthew Frigault, Instructor in Medicine, **Massachusetts General Hospital**

Manufacturing

Panel: Streamline Manufacture to Reduce CoG & Ensure Timely Delivery

- Reduce the current turn-around time and laborious manufacture processes
- Is the future in off-the-shelf manufacture?
- Challenges in genetically engineering an allogeneic product to reduce rejection

Christopher Wiwi, Senior Director, CAR T Technical Commercialization Lead, **Celgene Corporation**

Jian Irish, Global Head of Manufacturing, **Kite Pharma**

David Sourdive, Executive Vice President Technical Operations, **Cellectis**

Logistics

Panel: Optimize Supply Chain Coordination to Ensure Control & Security of Products

- Methods to improve communication between different areas of logistics to meet timeframes
- Ensure the chain of custody is clear for personalized therapies

Commercialization

Panel: How Partnerships Can Accelerate Product Development & Commercialization

- What types of partnerships are being done and their value drivers?
- How are partnerships in the cell therapy field different?

Jim Beitel, Senior Vice President- Corporate Development, **Fate Therapeutics**

Bradley Wolff, Head of West Coast Life Sciences, **Citi Corporate and Investment Banking**

Elsy Boglioli, Chief Operating Officer, **Cellectis**

Dan Maziasz, Vice President & Head of Business Development & Strategic Alliances, **Atara Biotherapeutics**

Summit Day Two | Thursday, September 12th 2019

CAR-TCR Summit

	CAR for Autoimmune Disorders	Enhancing Efficacy with Combinations	Managing Adverse Events	Define Manufacturing Standards	Supply Chain Digitalization	Ethical Reimbursement & Pricing
13.02 - 13.32	**Chimeric Auto Antigen Receptors (CAARs) for B Cell Mediated Autoimmune Disease** • Review the CAAR platform and their capabilities • Discuss Pemphigus vulgaris as the first clinical proof of concept • Outline current progress and future plans **Gwendolyn Binder**, PhD, EVP of Science & Technology, **Cabaletta Bio**	**Clinical Pharmacology of a Unique Antibody Coupled T Cell (ACTR) Therapy Combination Product** • ACTR platform, a universal engineered T cell therapy developed to mediate anti-tumor activity • Demonstrate ACTR's T cell activity in Phase I studies • Review the correlation between ACTR T cell activity and ACTR T cell and host attributes **Ann Ranger**, Senior Director of Translational Medicine, **Unum Therapeutics**	**Clinical Challenges in the Assessment of CAR-T Trials** • CAR-T biomarkers in patient characterization and stratification • Strategies to measure and apply MRD in clinical trials **Matthew Spear**, Chief Medical Officer, **Poseida Therapeutics**	**Cross-Sector Efforts to Advance Gene & Cell Therapy Manufacturing** • Define and drive best cell and gene therapy manufacturing practices • Update CMC related regulatory guidance • Evolve appropriate standards for the field **Michael Lehmicke**, Director, Science & Industry Affairs, **Alliance for Regenerative Medicine**	**Digital Platforms to Support an Efficient Operation System** • Optimize order intake through digital platforms to ensure customer journey is seamless and easy to manage • Review digital analytics that can be used to track and control movement and delivery of specific products **Debiprasad Roy**, Head of Clinical Systems & Programming, **Allogene Therapeutics**	**Market Access Innovations for CAR-T Therapies** • US and European public payors address reimbursement for new CAR-T therapies • Insight into the latest sector-wide proposals and efforts to ensure CAR-T access **Michael Werner**, ARM Founder & Senior Policy Counsel, **Alliance for Regenerative Medicine**
13.34 - 14.04	**Controlling Safety** **Target Specificity Screening for Safety Assessment of Novel Cell Therapies** **Jim Freeth**, Co-managing Director, **Retrogenix**	ACEA Biosciences, Inc.	**Session details to be confirmed**	**The CocoonTM Platform, a Kaleidoscope Approach to Cell Therapy Manufacturing** • Cocoon platform overview, a closed, automated cell therapy manufacturing platform • Development update on the Cocoon platform's current and future capabilities • Summary of Cocoon platform scalability to address bottlenecks in commercial-scale cell therapy manufacturing **Matthew Hewitt**, Head of Clinical Development, Personalized Medicine, **Lonza**	savsu TECHNOLOGIES	**Optimizing Clinical Development of CAR-T Therapies** • Robust IT infrastructure, data analytics and stakeholder engagement tools to orchestrate cell journeys • Clinical supply chain considerations to help drive error-free, end-to-end patient and cell journeys **Hussain Mooraj**, Next Gen Therapy Practice Lead, Principal, **Deloitte Consulting LLP** **Sanjay Srivastava**, PhD, Senior Manager, **Deloitte Consulting LLP**
14.04	**Lunch & Networking**					
15.00 - 15.30	BECKMAN COULTER	BIO-RAD	**Session details to be confirmed**	**Automation: Enough Talking About It, Now It's Time to Deliver** **David Smith**, Head of Innovation and Engineering, **Hitachi Chemical Advanced Therapeutics Solutions**	**Leveraging Manufacturing IT Systems to Boost Productivity, Scalability & Compliance in Autologous Engineered T-Cell Therapy** **John Lunger**, Senioqr Vice President, Manufacturing & Supply Chain, **Adaptimmune Limited**	**Session details to be confirmed**

Summit Day Two | Thursday, September 12th 2019

CAR-TCR Summit

15.32 - 16.02

Development of Antibody-TCR (AbTCR) Expressing T Cells Against Solid & Hematological Malignancies

- Review major barriers of current CAR-T: CRS and neurotoxicity risks
- ARTEMIS AbTCR T-cell receptor platform
- Safety validation of ARTEMIS platform in CD19+ NHL
- Eureka built a versatile structure to go after both hem and solid tumor with ARTEMIS Plus
- Safety and efficacy validation in AFP+ HCC and CD19 programs are achieved
- Future directions on expanding ARTEMIS platform

Strategic Combinations of Chemotherapy, Gene-Modified γδ T Cells, & Immune Modulation for Eradication of Residual Malignancy

- Genetic modification of γδ T cells for chemotherapy resistance enables cytotoxic lymphocyte function
- Chemotherapy-rich environment supports tumor stress

Lawrence Lamb, Chief Scientific Officer, **Incysus Therapeutics**

Developing an Ideal CAR-T Cell Therapy Patient Experience through Human-Centered Design and Innovation

- Outline the development and implementation of a superior patient experience that provides patients with a sense of caring, supportive environment, timely knowledge, and realistic expectations
- Understand latent and unspoken needs in order to develop an ideal CAR-T therapy patient journey

Allison Matthews, Service Designer, **Mayo Clinic Robert D. and Patricia E. Kern Center for the Science of Health Care Delivery**

Overcoming Allogeneic Challenges

Exploiting NKG2D Receptor for Non-Gene Edited Allogeneic CAR T Cells

- NKG2D Receptor is a clinically validated target for autologous NKG2D CAR T cells
- Non-gene edited approaches to allogeneic CAR T cells
- Experience in manufacturing these allogeneic products

Jean-Pierre Latere, Chief Operations Officer, **Celyad**

Round Table Discussion: Effective Patient Scheduling to Ensure Streamlined Delivery

In groups review the communication pathway and how IT platforms can be optimized to build in the following: documentation, specifications, recollections, patient delays and contingency plans

Reimbursement & Payer Perspectives

- CMS will provide background information on the National Coverage Determination process
- Describe the final National Coverage Determination for CAR T-cell therapy in the Medicare population

Katherine Szarama, Evidence Development Division, Coverage & Analysis Group, **Center for Clinical Standards & Quality, Centers for Medicare & Medicaid Services**

16.04 - 16.34

Next-Generation Gene Editing Technology for Allogeneic Immune Cell Therapeutics

- Review next-generation CRISPR-Cas9 technology and its significantly enhanced editing specificity
- Editing in immune cells for generation of functionally tuned therapeutics

Steven Kanner, Chief Scientific Officer, **Caribou Bio**

Transformative Trials

Non-Gene Edited Allogeneic CAR-T Therapies

- Celyad NKG2D CAR-Ts: Autologous and Allogeneic comprehensive clinical development
- Celyad's technologies for non-genetically engineered CARs
- Data from fist-in-human Phase I study of CYAD-101 CAR-T to target refractory metastatic colo-rectal cancer

Frederic Lehmann, Head & Vice President Oncology Franchise, **Celyad**

Standardize CAR-T Cell Algorithms to Manage Toxicity

- Understand the different procedures for identifying and managing toxicity for CAR-T
- Discuss the need for standardization

Elizabeth Olson Hexner, Associate Professor Of Medicine, **The University Of Pennsylvania**

Manufacturing Hurdles for Off-the-Shelf CAR-T Therapies Using Invariant NKT Cells

- Development of the CAR-NKT platform against haematological and solid tumor malignancies
- Engineered products to secrete cytokines that further enhance persistence and solid tumor activity
- Explore strategies to overcome immunogenicity and enhance persistence and potency

Stefanos Theoharis, Senior Vice President, Corporate Development & Partnering, **Cell Medica**

Achieving Scale-up in Commercialization

- Systemic challenges in the patient and cell journey
- Achieving scale before and after cell manufacturing
- Considerations for biopharma companies

Kristian Elverum, Senior Vice President, Corporate Development, **Turnstone Biologics**

Novel Legal & Ethical Considerations for a Novel Therapy

- Game changing personalized CAR T therapies raise novel legal and ethical questions
- Handling orders for off label use
- Allocating manufacturing slots when supply is limited
- Providing medical support but not medical advice
- How to partner with in-house and outside counsel gaining efficient practical advice

Deborah Liben, Executive Director, **Celgene**

16.36 - 17.06

Tackling Solid Tumors with a Bispecific Adaptor Molecule-Controlled CAR T-cell Therapy Directed Against a Foreign Hapten

- Construct of a "universal" CAR-T cell specific for a foreign antigen (fluorescein)
- Design of CAMs (CAR-T Adaptor Molecules) and therapy across different tumor models
- Controlling sCRS through strategic CAM dosing and quick-acting rescue agents
- Future directions in solid tumors

June Lu, Director, Translational Research, **Endocyte**

Integrate New Technologies to Treat Solid Tumor by CAR-T Cell Therapy

- Discuss challenges treating solid tumor with CAR-T
- Evaluate promising new technologies
- Share preliminary clinical experience

Xiao Lei, Chief Executive Officer, **Innovative Cellular Therapeutics**

Biomarkers to Identify Patient Eligibility

- Outline biomarker and eligibility tests used for patient selection
- Optimize patient stratification to identify traits of patients responders

Joseph Fraietta, Director, Solid Tumor Immunotherapy Research Laboratory, **University of Pennsylvania**

Manufacturing Concepts for Gene-Edited Allogeneic CAR-T Cell Products

- Transforming CAR-T cell approaches with gene-editing
- Process development and supply chain concepts for universality in allogeneic CAR-T
- Analytical approaches and product characterization strategies for off-the-shelf CAR-T cell products

David Sourdive, Executive Vice President Technical Operations, **Cellectis**

CGT Product Scale-Up, Scale-Out, Scale-Deep: Best Practices, Challenges, & Opportunities

- Rationale for scale-up, scale-out, and scale-deep in the manufacturing of CGT products
- Compliance without compromise with cGMP, cGTP, and FACT standards
- Managing risk during multi-product processing in a single manufacturing suite

Robert Ott, Director Quality Assurance & Regulatory, **Children's GMP, LLC**

IP and Licensing: Navigating the Landscape

- Discuss the evolution of this field
- from the first generation patents to
- the current state of the field
- Licensing-related aspects of CAR-T
- IP from a practical perspective

Shawn Foley, Attorney, Intellectual Property, **Burns & Levinson**

17.10 **Putting Patients First: How Has the Face of Cancer Therapy Changed** emily whitehead foundation

17.40 **Chair's Closing Remarks**

17.50 **Close of 5th Annual CAR-TCR Summit**

8.30 Coffee & Registration

Targeting Solid Tumors

Tumor Microenvironment

9.00

CAR-T Cells & Solid Tumors: Few Sizes May Fit All

- Solid tumor biology is becoming predictable
- "One size" may not, but a few may fit all immune landscapes
- CAR-T cells can be programmed to react to the nuances of the tumor microenvironment

Franco Marincola, Chief Scientific Officer, **Refuge Biotechnologies**

9.30

Advancing CAR T Cells for Solid Tumors: Prostate Cancer & Beyond

- Developing PSCA-CAR T cells for bone metastatic prostate cancer
- Building preclinical models to evaluate tumor microenvironment
- Future combination strategies for effective immunotherapy

Saul Priceman, Assistant Professor, Dept. of Hematology & Hematopoietic Cell Transplantation , **City of Hope National Medical Center**

Gene Editing Technologies

Comparison of Current & Novel Platforms

Defining the Future of CAR-T Cells through Genetic Engineering

- Leading the genetic engineering of CAR T-cells with TALEN
- Discover how Cellectis is empowering its TALEN platform
- Beyond genetic knock-out, how to created smarter, safer more efficient CAR T-cells

Alexandre Juillerat, US Laboratory Head, **Cellectis**

Solve the Lentiviral Vector Bottleneck for Product Development, Commercialization and Supply

- Review examples of progress towards these ends and discuss continued opportunities
- LVV represents a significant fraction of the overall Cost Of Goods Sold for most LVV-based therapies and driving improved economics is critical to bring products to the patients that require them
- Progress towards driving improved costs through productivity enhancements will be reviewed, along with the ramifications of significant process changes after initial clinical experience

Scott Shoemaker, Senior Director of Operations, **bluebird bio**

TCR-T Cell Drug Development

Targeting to Overcome Evasion

Current & Next Generation TCR-engineered T Cells with Pleiotropic Anti-tumor Activity

- TCR-engineered T cells can target a broad range of tumor associated antigens such as cancer-testes and viral oncogenes, through recognition of epitopes derived from the intracellular proteome
- Genetic reprogramming of a broad category of T cells, comprising MHC class I and II-restricted TCRs onto both CD8 and CD4 T cells, may lead to co-deployment of a broader range of immune mechanisms to counteract tumor immune evasion
- Emerging evidence points to clinical activity of TCR-engineered T cells, as well as mechanisms of treatment evasion, leading to future treatment optimizations and next generation T cell products

Stephanie Astrow, Senior Director, Translational Medicine, **Kite, a Gilead Company**

Identify Tumor-Specific Targets for Cancer Immunotherapy with a Deep Learning Antigen Prediction Model

- Generate a potent, therapeutic immune response in cancer patients by immunizing with viral vector based immunotherapies against tumor-specific targets identified using the company's proprietary antigen discovery platform called EDGE™
- Review development of EDGE™ using extensive immunopeptidomic data from hundreds of human tumor samples, the model was trained on this large dataset and enables prediction which tumor-specific peptides
- Targets identified by EDGE™ enable development of tumor-targeting therapeutic approaches such as personalized or off-the-shelf vaccines, T-cell receptor-directed cell therapies and bispecific antibody therapies

Roman Yelensky, Chief Technology Officer, **Gritstone Oncology**

10.00 Morning Refreshments & Networking

11.00

Session details to be confirmed

Session details to be confirmed

TSCAN THERAPEUTICS

Clinical Exploration

11.30

Key Considerations for Moving a Product into Development for Pivotal Registration

- Standard vs accelerated development
- Cross-functional alignment
- Trade-offs between speed and opportunity

Aiman Shalabi, Vice President R&D, **GlaxoSmithKline**

CRISPR Unlocks Genome Editing, Addresses Diverse Mutations & has a Rigorous Approach to Specificity

- Review how CRISPR's complex of nuclease and RNA can precisely locate and cut genomic sites with the ability to target multiple sites simultaneously
- Detail how non-homologous end joining typically disrupts a gene or eliminates a disease-causing mutation; whereas homology-directed repair and targeted insertion aims to promote expression of correct DNA sequences
- Enhancing specificity with computational screening, cellular and biochemical assays and targeted sequencing panels

Rick Morgan, Senior Vice President of Immunogenetics, **Editas Medicine**

i-TCR (inducible TCR): Controlled Cytotoxicity of Tumor-Specific TCR-modified T Cells with Improved Avidity Through Control of TCR Surface Expression

- Controlling the risk of off-tumor reactivity of tumor-specific TCR-modified T cells through tight control of TCR surface expression
- Engineering tumor-specific TCRs with higher avidity without interfering with complementarity determining regions (CDRs)
- Turning TCRs on and off conditionally

Slavoljub Milosevic, Head of Technology & Innovation, **Medigene**

Promising Targeting Strategies

12.00

CAR Macrophages: Tailor-Made for Solid Tumor Immunotherapy

- Current challenges in solid tumor cell therapy
- Overview of the Carisma CAR Macrophage platform
- The promise of CAR Macrophages in solid tumors

Michael Klichinsky, Co-Founder & VP, Discovery Research, **Carisma Therapeutics**

Liquid to Solid: CRISPR based Allogenic CAR-T

- Discuss using CRISPR to program allogenic CAR-T
- How to overcome tumor microenvironments and resist exhaustion?
- Bringing CRISPR based CAR-T to the clinic

Tony Ho, Executive Vice President, Head of Research & Development, **CRISPR Therapeutics**

Autologous & Allogeneic Payloads for TCR Targeting

- The opportunities and challenges of using TCRs as targeting approaches in solid tumors
- The role for TCR-T autologous ACT with differentiated TCRs
- TCR-NK as an opportunity for allogeneic ACT

Miguel Forte, Chief Executive Officer, **Zelluna Immunotherapy**

12.30 Lunch & Networking

14.00

Conduit CAR-T: A Decoupled Approach to Solid Tumor Targeting with a Modular Chimeric Antigen Receptor T Cells

- Molecular design strategies to overcome immune surveillance, heterogeneity and antigen escape in solid tumors
- Decoupled approach: Modular CAR-T and a tunable mono/multi-specificity for tumor targeting
- Flexible design ensures safety when adverse events are not-manageable.

Rajkumar Ganesan, Director of Antibody Engineering & Bispecifics, **The Janssen Pharmaceutical Companies of Johnson & Johnson**

Enhancing T Cell Therapies with Precision Epigenome Engineering

- The development of novel epigenetic effectors for controlling gene expression in engineered T cells without the risk of genotoxicity
- Assessing off target effects of epigenetic editing technologies
- Enhancing CAR-Ts with multiplexed epigenetic repression of immune checkpoint genes

Shon Green, Director, Clinical Translation, **Altius Institute for Biomedical Sciences**

Enhancing TCR Potential

TRuC ^tm Platform: Overcoming CAR-T & TCR Limitations

- Advantages of the TRuC Platform – using the full TCR complex without HLA matching
- TRuC-T cell's potential to address solid tumors and hematologic malignancies
- Phase 1/2 trial design for our lead solid tumor and hematologic malignancy candidates

Alfonso Quintas-Cardama, Chief Medical Officer, **TCR2 Therapeutics**

14.30

Breaching the Wall: Driving Potential Efficacy in Solid Tumors with a Multi-Antigen Targeted Approach to Cell Therapy

- TCR approaches in synovial sarcoma have yielded interesting initial results, but have delivered only transient responses to date
- Pancreatic cancer is considered one of the most difficult solid tumor indications for immuno-oncology, particularly cell therapies
- Review how a non-genetically modified, multi-antigen specific approach using MAST T cells may overcome these challenges in some of the most difficult solid tumors like pancreatic cancer

Peter Hoang, Chief Exectuive Officer, **Marker Therapeutics**

Non-viral piggyBac® DNA transposon & Cas-CLOVER® Gene Editing Systems for Development of Stem Cell Memory T Cell Autologous & Allogeneic CAR-T Product Candidates

- The piggyBac DNA Modification System is a DNA transposon, non-viral technology for stable transgene integration that is safer than virus, can accommodate a large cargo, is less costly to manufacture
- Cas-CLOVER gene editing technology is a fully dimeric site-specific gene editing system that produces low to no off-target cutting and efficiently edits resting T cells, thereby producing allogeneic CART product candidates with safety and efficacy advantages
- piggyBac and Cas-CLOVER can be used together to develop and manufacture both autologous and allogeneic stem cell memory CAR-T therapies

Devon Shedlock, Vice President, Preclinical Development, **Poseida Therapeutics**

TAC-T Cells Show Improved Safety & are Efficacious in Solid Tumors

- T cell Antigen Coupler (TAC) T-cells co-opt nature's T-cell receptor
- Demonstration of superiority compared to CAR-T cells in both preclinical liquid and solid tumor models
- Design of a safer and more effective T cell therapy

Sabine Chlosta, Chief Medical Officer, **Triumvera Immunologics**

15.00 End of Focus Day

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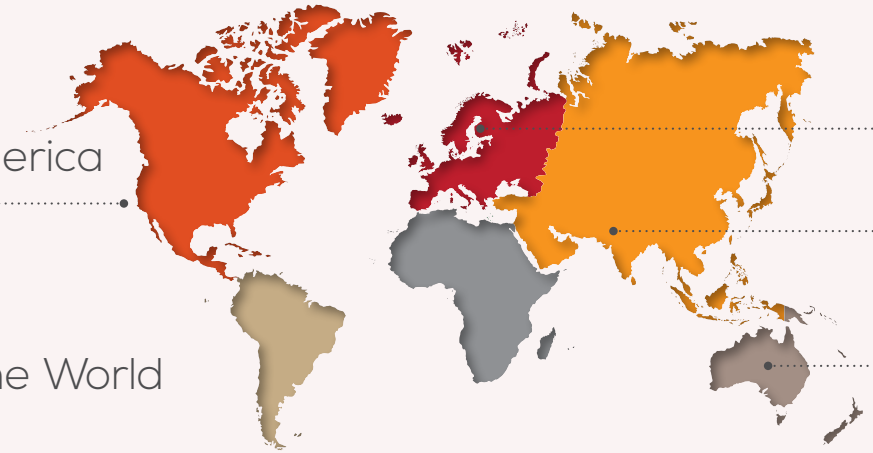

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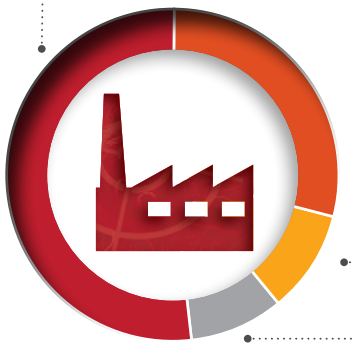

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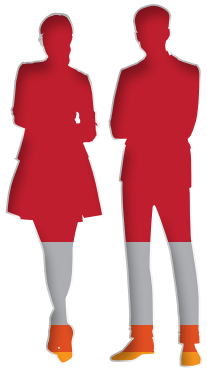

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