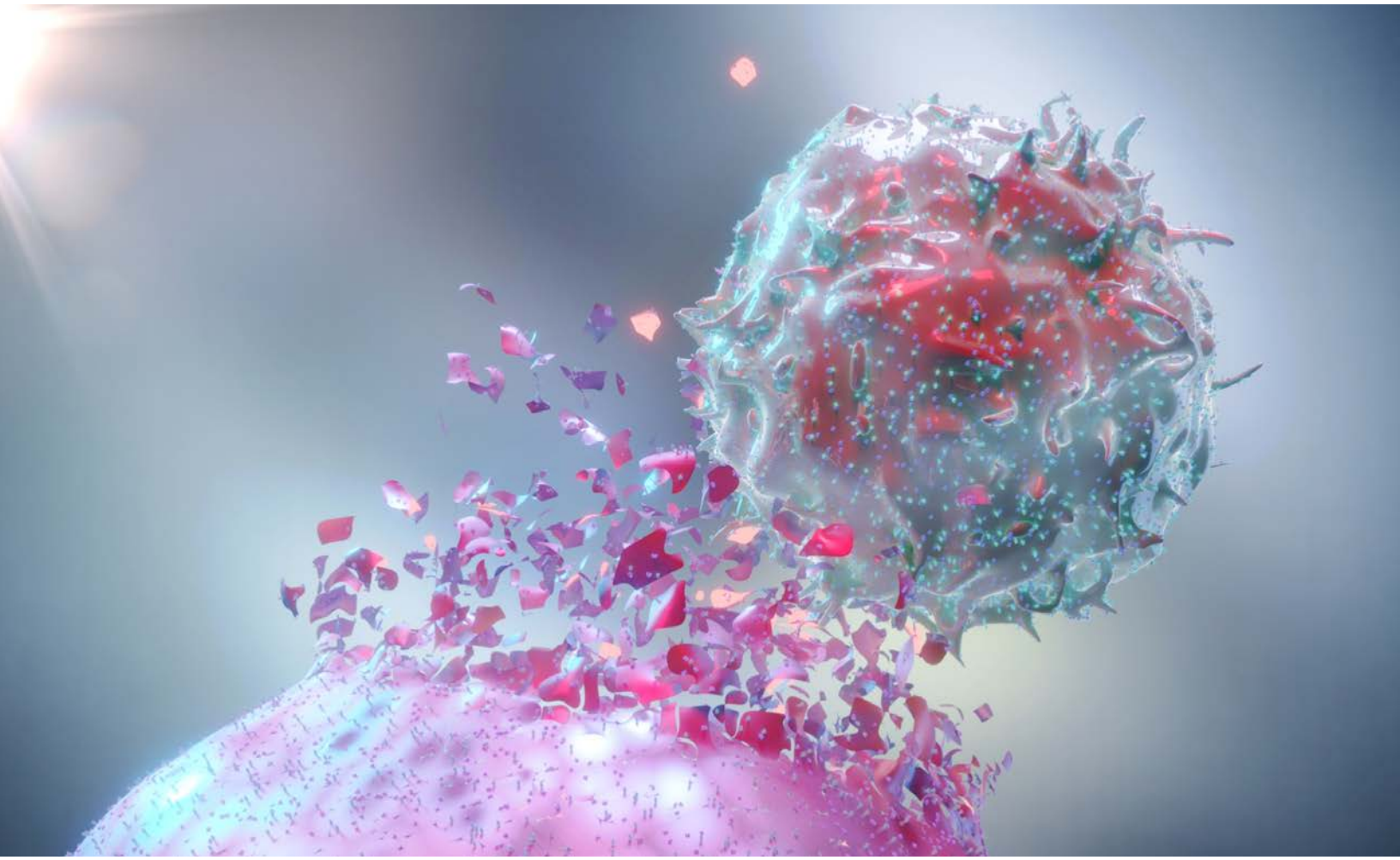
IO360®

Immuno-Oncology 360°

February 7 - 10, 2023

New York Marriott at the Brooklyn Bridge, Brooklyn, NY



Lead Sponsor

Featured Executive Sponsors

IMAGING ENDPOINTS
CONNECTING IMAGING TO THE CURE

Invicro

www.io360summit.com

#IO360nyc

DAY ONE - Tuesday, February 7th

IO Cell Therapy 360

7:30 am

Registration

8:10 am

IO Cell Therapy 360° Director's Welcome

Axel Hoos, MD, PhD
CEO, **Scorpion Therapeutics**

8:15 am

Opening Remarks: What Do We Need to Do To Make Cell Therapy Work Better Moving Forward

We begin with opening remarks from our IO Cell Therapy 360° lead advisors who address the issues with cell therapy that are impacting the field, what we have learned, where we need to go from here and prepare for the challenges ahead.

- Cost of goods
- Cost of time
- Efficacy
- Difficulty with doing clinical trials
- Limitations for solid tumors

Teri Foy, PhD
SVP, Immuno-Oncology and Cellular Therapy, **BMS**

Michael Kalos, PhD
Managing Director, **Next Pillar Consulting**

Ramy Ibrahim, MD
Oncology Drug Developer, **Stealth Co**

8:30 am

OPENING KEYNOTE

Mechanisms Driving CAR T Cells Activity and Failure

CART clinical trials have been ongoing for more than 15 years. Despite the remarkable successes, there is still much to be understood and solved for this approach to be generally applied. We will explore some of the principles and mechanisms that drive success and failure of this exciting treatment modality.

Marcela Maus, MD, PhD
Director, Cellular Therapy Program and Associate Professor of Medicine, **Harvard Medical School, Massachusetts General Hospital**

8:55 am

BUSINESS KEYNOTE

Investor Perspective on the State of the Current Market and Impact on the IO Cell Therapy Field

Expert investor Dr Arjun Goyal, Co-founder and Managing Director, Vida Ventures provides an overview of the state of the current market, future outlook and the impact on the IO cell therapy field. Additional topics include:

- What are the fundamental concerns and hesitations that VCs have in this space when they look at opportunities?
- What would they like to see companies bring forward as opportunities that they would be more excited to invest in?
- Are there any issues they foresee?

Arjun Goyal, MD, MPhil, MBA
Co-founder and Managing Director, **Vida Ventures**

9:15 am

FDA Update on IO Cell Therapy and What they Want from Industry

- IO Cell therapy regulatory updates to include data of volume
- How to optimize engagement with the FDA at the right level
- What industry can do better as they bring forward new and innovative cell therapy programs
- 3 things the FDA would like to see in cell therapy to move towards democratizing access and affordability

Peter Marks, MD, PhD
Director, Center for Biologics Evaluation and Research (CBER), **FDA**

9:35 am

GRAND OPENING OF THE IO360° NETWORKING CAFE

- Breakfast
- Networking
- Meet the Exhibitors

MANUFACTURING AND NEW BUSINESS MODELS CONTRIBUTING TO ADVANCING THERAPY AND REDUCING COSTS OF GOODS

10:15 am

KEYNOTE:

Cell Therapy Manufacturing Progress Report and Novel Manufacturing Paradigms

Dr Isabelle Rivière provides a progress report on manufacturing platforms for cell therapy including Autologous, Allogeneic, In-vivo and Point of Care. She will address critical issues related to these novel manufacturing paradigms including sourcing, cost of goods and time, and supply chain logistics.

Isabelle Rivière, PhD
Director, Cell Therapy and Cell Engineering Laboratory, **Memorial Sloan Kettering Cancer Center (MSKCC)**

10:35 am

IO Cell Therapy 360° Manufacturing Showcase

In this session, manufacturing companies showcase their engineering capabilities to accelerate the process and development of cancer cell-based immunotherapies.

Led by:

Bruce Levine, PhD
Barbara and Edward Netter Professor in Cancer Gene Therapy, **University of Pennsylvania**

Presenting Companies:

Patrick Lucy
President & CEO

LYKAN BIOSCIENCE

John Lee, PhD, MBA
VP & Head, Cell Therapy

Center for Breakthrough Medicines

11:15 pm

New Kids on the Block: In Vivo and Point-of-Care Cell Therapies

In Vivo CAR-T and Point of Care point-of-care based approaches can potentially become disruptive platforms that effectively address supply chain, COG and COT and clinical operational issues. This panel will address both the promise and the barriers to progress for these new approaches:

- What do each solve for?
- What key problems do each need to address?
- How are companies addressing those problems?

Moderated by:

Bruce Levine, PhD
Barbara and Edward Netter Professor in Cancer Gene Therapy, **University of Pennsylvania**

Panelists:

Adrian Bot, MD, PhD
EVP, R&D and Founding CSO, **Capstan Therapeutics**

Robert Mabry, PhD
CSO, **oRNA Therapeutics**

David Peritt, PhD
Chief Scientific Officer and Co-Founder, **Lupagen**

Andrew Scharenberg, MD
Co-founder & CEO, **Umoja Biopharma**

12:00 pm

LUNCH & PARTNERING MEETINGS BEGIN

- Lunch
- Partnering Tables
- Networking
- "Charge-up" at the IO360° Charging Stations

12:20 pm

Optional Luncheon Roundtable Discussions

Roundtable #1: Addressing the Translational Research Paradigm And Generating the Right Information From your Translational Studies to Have Greater Impact
Roundtable #2: What's Unique to Cell Therapy Clinical Development That Can Help Solve Challenges the Industry May Face?
Roundtable #3: Cell Therapy Combinations: Key Questions, Challenges and Progress
Roundtable #4: CAR-T Development in China: What we Need to Know, Regulatory Considerations and Impact on the Field

Roundtable #1: Addressing the Translational Research Paradigm And Generating the Right Information From your Translational Studies to Have Greater Impact

The complexity of how translational science is conducted continues to be an operational and logistic challenge in cell therapy R&D. This roundtable will address how to practically establish translational infrastructure that can generate actionable and informative data to support clinical trials. More specifically, we will focus on the overlapping concepts of hypothesis -generating and -testing translational research, to enable more complete and actionable understanding of cell therapy activity, safety, and mechanism of action and inform empiric and rational program and pipeline development.

Led by:

Shari Kaiser, PhD
Senior Director, Immuno-Oncology and Cellular Therapy Translational Research, **BMS**

Michael Kalos, PhD
Managing Director, **Next Pillar Consulting**

Roundtable #2: What's Unique to Cell Therapy Clinical Development That Can Help Solve Challenges the Industry May Face?

- What are the appropriate endpoints to use when thinking about cell therapy?
- Clinical trial designs as contribution of components, single agent activity and/or developing multi-arm trials to address combinations
- How are we addressing the continued issue of safety management?
- Best practices to comply with long term followup requirements

Led by:

Ramy Ibrahim, MD
Oncology Drug Developer, **Stealth Co**

Rosanna Ricafort, MD
VP and Head, Cellular Therapy Clinical Development, **BMS**

Roundtable #3: Cell Therapy Combinations: Key Questions, Challenges and Progress

Cell therapy combinations present many challenges due to risk and costs. In this roundtable, we provide an update on key questions, challenges and progress.

- Will there ever be a place for 2 types of cells?
- Will there ever be a place for two different modalities together, such as oncolytics and CAR-Ts?
- How do we get the t-cell redirecting field, it could be CART or bispecifics, working effectively with adaptive immune modulators?
- What would trials look like and how were going to get those done?

Led by:

Barbra Sasu, PhD
CSO, **Allogene Therapeutics**

Teri Foy, PhD
SVP, Immuno-Oncology and Cellular Therapy, **BMS**

Roundtable #4: CAR-T Development in China: What we Need to Know, Regulatory Considerations and Impact on the Field

More US companies are shifting resources and doing early development work out of China to advance cancer treatments for patients. This roundtable addresses:

- How China is approaching cell therapy development, impact on the industry and what we can do to leverage this
- Will development in China continue and if so, how do we harmonize that with what we need to be able to develop CAR-Ts in the US and EU?
- What are the regulatory implications of shifting resources and development and doing trials in China but using the data in the US?
- Navigating through complexities of two different geographies for development and trials

Led by:

Leon 'Jun' Tang, PhD
Founder / Advisor, **InScienceWeTrust BioAdvisory / BioSpark Group**

Samuel Zhang, PhD, MBA
CBO, **Gracell Biotechnologies**

1:00 pm DISTINGUISHED LECTURE

High-Throughput Approaches to Discover Novel Gene Functions in T-Cells

This presentation will focus on a platform approach to drive the discovery of novel gene functions in T-cells or other immune cells that enhance cell function to drive enhanced persistence and enhance anti-tumor activity.

Neville Sanjana, PhD
Core Faculty Member / Associate Professor of Biology / Associate Professor of Neuroscience and Physiology,
New York Genome Center / New York University / NYU Grossman School of Medicine

1:20 pm

Soup to Nuts: Key Learnings from the Clinical Development Path of The Approved Cell Therapy Products

This session will focus on key learnings cleaned from the full clinical development pathway- from first-in-human through launch to commercialization for each of the to-date approved autologous cell therapy products. We will explore and discuss what worked, what didn't work and what could be done differently in future trials to enable and drive the more efficient and effective development of future cell therapies.

Moderated by:

Michael Kalos, PhD
Managing Director, **Next Pillar Consulting**

Panelists:

Amir Hefni, PhD, MBA
Global Head, Cell & Gene Therapy, **Novartis**

Jonathan Jazayeri, PharmD
Executive Director, Global Regulatory Affairs, **Kite, a Gilead Company**

Jordan Schecter, MD
VP, Cellular Therapy, **Janssen Pharmaceuticals**

Shivani Srivastava, MD
VP, Development Program Lead, Cell Therapy Development, **BMS**

2:00 pm IO CELL THERAPY 360° DEBATE

NK Cells vs Gamma Delta

- Why NK Cells?
- Why Gamma Delta Cells?
- Which will have the most impact on the field?

Blake Aftab, PhD
CSO, **Adicet Bio, Inc.**

vs:

Kanya Rajangam, MD, PhD
Chief Medical and Development Officer, **Senti Bio**

Debate Moderated:
Daniel S Chen, MD, PhD
Founder, **Engenuity Life Sciences**

2:30 pm

AFTERNOON BREAK IN THE EXHIBIT CAFE & PARTNERING MEETINGS

- Refreshments
- Partnering Tables
- Networking
- Meet the Exhibitors
- "Charge-up" at the IO360° Charging Stations

3:10 pm

Overcome the Limitations of Cell Therapy

The four major areas of cell therapy moving forward include autologous, allogeneic, point of care and invivo CAR-T. They all bring tremendous potential, challenges and limitations. This rapid-style session features updates from companies specializing in CAR-T modifications on progress, challenges and next steps.

TRACK A: IPSCs	TRACK B: MODIFIED TCRs; SYNTHETIC CIRCUITS	TRACK C: HARNESSING THE FULL POTENTIAL OF TUMOR REACTIVE LYMPHOCYTES
3:10 pm - 3:20 pm **David Main, MBA** *President & CEO,* **Notch Therapeutics**	**3:10 pm - 3:20 pm** **Garry Menzel, PhD, MBA** *President & CEO,* **TCR2 Therapeutics**	**3:10 pm - 3:20 pm** **Mark Dudley, PhD** *CSO,* **Instil Bio**
3:25 pm - 3:35 pm **Bob Valamehr, PhD, MBA** *Chief R&D Officer,* **Fate Therapeutics**	**3:25 pm - 3:35 pm** **Kanya Rajangam, MD, PhD** *Chief Medical and Development Officer,* **Senti Bio**	**3:25 pm - 3:35 pm** **Shana Kelley, PhD** *President, CTO & Co-founder,* **CTRL Therapeutics**
3:40 pm - 3:50 pm **Wei Li, PhD** *CSO,* **Cytovia Therapeutics**	**3:40 pm - 3:50 pm** **Marc Lajoie, PhD** *Co-founder & CEO,* **Outpace Bio**	**3:40 pm - 3:50 pm** **Jan ter Meulen, MD, PhD** *CSO,* **Obsidian Therapeutics**
	3:55 pm - 4:05 pm **Leah Sibener, PhD** *Co-founder, VP, Head of Therapeutic Discovery,* **3T Biosciences**	**3:55 pm - 4:05 pm** **Micah Benson, PhD** *CSO,* **KSQ Therapeutics**
	4:10 pm - 4:20 pm **François Gaudet, PhD** *CSO,* **Mnemo Therapeutics**	**4:10 pm - 4:20 pm** **Stewart Abbot, PhD** *CSO,* **Turnstone Biologics**

4:25 pm
Advancements in Cell Therapy
Three track choices covering new cell type approaches, neoantigen targeting approaches and clinical advancements.

TRACK A: NOVEL ENGINEERED CELL THERAPIES AND CONCEPTS	TRACK B: NEOANTIGEN & SHARED TARGETING APPROACHES	TRACK C: CLINICAL ADVANCEMENTS
4:25 pm - 4:40 pm **Anish Suri, PhD** *President & CSO,* **CUE Biopharma**	**4:25 pm - 4:40 pm** **Loïc Vincent, PhD** *CSO,* **Affini-T**	**4:25 pm - 4:40 pm** **Stephen Santoro, PhD** *Senior Director, ICT Development,* **Arsenal Bio**
4:45 pm - 5:00 pm **Krishnan Viswanadhan, PharmD** *President & CEO,* **Be Bio**	**4:45 pm - 5:00 pm** **Reagan Jarvis, PhD** *CEO & Scientific Founder,* **Anocca**	**4:45 pm - 5:00 pm** **Oliver Nussbaumer, MD, PhD** *R&D Distinguished Fellow (Executive Scientific Director), Cell Therapy Innovations,* **Takeda Pharmaceuticals**
5:05 pm - 5:20 pm **Michael Klichinsky, PharmD, PhD** *Co-founder & CSO,* **Carisma Therapeutics**	**5:05 pm - 5:20 pm** **Gavin MacBeath, PhD** *CSO & COO,* **TScan Therapeutics**	**5:05 pm - 5:20 pm** **Sharon Benzeno, PhD, MBA** *Chief Commercial Officer, Immune Medicine,* **Adaptive Biotechnologies**
5:25 pm - 5:40 pm **Moutih Rafei, PhD** *VP, R&D, Director,* **Defence Therapeutics Inc**	**5:25 pm - 5:40 pm** **Kevin Pojasek, PhD** *President & CEO,* **Enara Bio Limited**	**5:25 pm - 5:40 pm** **Rachel Haurwitz, PhD** *President & CEO,* **Caribou Biosciences**
5:45 pm - 6:00 pm **Laura Johnson, PhD** *CSO,* **Verismo Therapeutics**		**5:45 pm - 6:00 pm** **William Ho, MBA** *Director, President, CEO & Co-founder,* **In8bio**
6:00 pm **End of Day One**		

6:30 pm
Brooklyn Heights Historical Walk
Join us for an hour and fifteen minute guided walking tour to explore New York City's **first Landmark District**– Brooklyn Heights. Brooklyn Heights is a neighborhood with more than 500 Antebellum homes and buildings. On this walk we will discuss the neighborhood's agricultural roots, its emergence as the country's first suburb, and its 20th century decline and dramatic regeneration. On this outing, we will also stop along the **Brooklyn Heights Promenade** for truly breathtaking views of lower Manhattan, New York Harbor and the **Brooklyn Bridge.**

To RSVP, please email **Efrosini at efrosini@tcfllc.org** to reserve your spot.

DAY TWO - Wednesday, February 8th

7:30 am
Registration

8:10 am
IO360° Opening Remarks

Axel Hoos, MD, PhD
CEO, **Scorpion Therapeutics**

James Gulley, MD, PhD
Co-Director, Center for Cancer Research, Acting Director, **National Cancer Institute**

8:25 am
KEYNOTE

Oncology 2.0: Transformational Medicines & The Next Wave of IO

The industry is at a turning point where the next wave of IO is eagerly expected but has not come yet. However, adjacent areas, such as ADCs, precision oncology, etc, have made more progress. This talk will provide a deep dive into the evolving Oncology landscape with a focus on the next wave of IO and its modalities.

Axel Hoos, MD, PhD
CEO, **Scorpion Therapeutics**

8:45 am
NOBEL LAUREATE KEYNOTE

Bioorthogonal and Click Chemistries Impact on Advancing Cancer Immunotherapy

IO360° is pleased to welcome newly minted Nobel Laureate Dr Carolyn Bertozzi who will share how her work in bioorthogonal and click chemistry is being applied to help advance cancer immunotherapy research.

Carolyn Bertozzi, PhD
Baker Family Director of Stanford ChEM-H, Anne T and Robert M Bass Professor in the School of Humanities and Sciences and Professor, by courtesy, of Chemical and Systems Biology and of Radiology, **Stanford University**

**Dr Carolyn Bertozzi was awarded the Nobel Prize in chemistry for her development of bioorthogonal reactions, which allow scientists to explore cells and track biological processes without disrupting the normal chemistry of the cell.*

DISCOVERY/PRECLINICAL PLENARY SESSION

Plenary Chair:

James Gulley, MD, PhD
Co-Director, Center for Cancer Research, Acting Director, **National Cancer Institute**

9:10 am
Identification of New Targets through Ultra Focus Microscopy

Roy Baynes, MD, PhD
EVP & CMO, **Eikon Therapeutics**

9:30 am

MORNING NETWORKING CAFE, EXHIBITS & PARTNERING MEETINGS

- Breakfast
- Networking
- Meet the Exhibitors
- IO360° Giveaways

10:10 am

Applying Proteogenomics to Identify Cancers Non-Canonical Alternative Neoantigens and the Development of Immunotherapies Targeting Those Antigens

Bernard Fox, PhD
Harder Family Chair for Cancer Research and Member and Chief, Laboratory of Molecular and Tumor Immunology at the Robert W. Franz Cancer Center, **Earle A. Chiles Research Institute, a division of Providence Cancer Institute**

10:30 am

Updates on Pfizer's R&D IO Pipeline

Robert Rickert, PhD
SVP and Head, Cancer Immunology Discovery, Oncology R&D, Worldwide Medical, Research and Development, **Pfizer iNC.**

10:50 am

Unlocking Immune Response in Solid Tumors

This talk will provide an update on Amgen's preclinical T-cell engager program and insights on what is coming down the pipeline.

Julie Bailis, PhD
Executive Director, Oncology Research, **Amgen**

IO NOVEL TECHNOLOGIES SHOWCASE TRACKS

11:10 am – 12:00 pm

This session showcases ten companies that have technologies and solutions that will help stakeholders in the IO field advance developments that provide treatment for cancer patients.

Participating Companies to Date:

TRACK A	TRACK B
Gareth Smith, PhD *VP, Business Strategy,* **ImaginAB**	**Spencer Schwarz** *Product Manager, ChipCytometry,* **Canopy**
Michael Boice, PhD *VP, Scientific Engagement,* **TD2**	**Moutih Rafei, PhD** *VP, R&D,* **Defence Therapeutics**
Axiom	**Median**
Rich Klinghoffer, PhD *CEO,* **Presage Biosciences**	**Wim Vos** *CEO,* **Radiomics**
Ramji Srinivasan *CEO,* **Teiko.bio**	

12:05 pm

LUNCH & PARTNERING MEETINGS BEGIN

- Partnering Tables
- Networking
- Meet the Exhibitors
- IO360° Giveaways
- "Charge-up" at the IO360° Charging Stations

Women Leaders in IO Luncheon & Panel Discussion - *Pre-Registration with Ticket Required*

IO360º is proud to present the Women Leaders in IO luncheon. The luncheon will include a panel that addresses both the challenges and opportunities for women working in immuno-oncology, such as unconscious bias, negotiation skills and provide career advice. Open Q&A to follow.

Co - Moderators:

Katie McCarthy
Chief Innovation Officer, **Halloran Consulting Group**

Jill O'Donnell-Tormey, PhD
CEO & Director, Scientific Affairs, **Cancer Research Institute (CRI)**

Panelists:

Lisa Butterfield, PhD
Adjunct Professor of Microbiology and Immunology, **University of California San Francisco (UCSF)**

Priti Hegde, PhD
CSO, **Foundation Medicine**

Rosanna Ricafort, MD
VP and Head, Cellular Therapy Clinical Development, BMS

Raluca Verona, PhD
Head, Heme Malignancies, Translational Research, **Janssen R&D**

1:05 pm Two Track Choices

TRACK A ADVANCEMENTS IN IO IMAGING	TRACK B CLINICAL OPERATIONS
Track Chair: **Charles Glaus, PhD** *Sr Director, Oncology Precision Medicine,* **Bayer**	**Plenary Chair:** **Andy Lee** *SVP & Head, Global Clinical Trial Operations,* **Merck**
1:05 pm – 1:25 pm **Using Imaging as a Decision Making Tool to Guide Treatments & What that Means for IO** **Michael Postow, MD** *Chief, Melanoma Service, Co-Director, Melanoma Disease Management Team, Medical Oncologist,* **Memorial Sloan Kettering Cancer Center (MSKCC)**	**1:05 pm – 1:15 pm** **Addressing IO Clinical Trial Operations Challenges** **Andy Lee** *SVP & Head, Global Clinical Trial Operations,* **Merck**

TRACK A

1:25 pm – 1:45 pm

How Radiomics is Being Used to Generate Value

Charles Glaus, PhD
Sr Director, Oncology Precision Medicine, **Bayer**

1:45 pm – 2:00 pm

PSMA Theranostics to Transform Prostate Cancer Therapy (e.g., Augments IO)

2:00 pm - 2:15 pm

Imaging Biomarkers for Assessment of IO Response – CD8 and Beyond

- What new imaging agents are available for the evaluation of IO treatment response?
- When is the optimal use of these agents in a trial or routine clinical practice?
- What imaging metrics can be employed, and what information do they provide?

Sean Carlin, PhD, *Principal Scientist, Scientific and Medical Services,* **Invicro**

2:15 pm – 2:30 pm

Radiomics and Automated Image Analyses for Drug Development and Internal Decision Making

In this talk, BMS shares case examples where radiomics have been applied such as NSCLC along with additional examples in Glioblastoma and NSCLC of where automated image analyses are being explored in support of drug development, decision making and stratification.

Diederik Grootendorst, PhD, *Director, Global Oncology Imaging,* **Bristol Myers Squibb**

TRACK B

1:15 pm – 2:00 pm

Addressing Saturation of Clinical Trials and Building New Capabilities in Community-based Centers

The top cancer centers are totally saturated with clinical trials and are increasingly unable to accommodate more studies that need to get done. Especially as more patients become available for these trials, including specialized trials with select patient populations. Additionally, trials that require a niche patient group also require expertise in bio assays and special lab testing. This is quite often esoteric testing that is not available outside of certain academic centers. This panel will discuss how we can go into community based centers that are research naive and build the new capabilities required to support these trials and patients.

Led by:

Tracy Vanderslice, *VP & Head, Clinical Operations-Oncology,* **Gilead Sciences**

Panelists:

Dana Dornsife, *Founder, Chief Mission & Strategy Officer,* **Lazarex Cancer Foundation**

Julie Martin, MBA, *CEO & Co-owner,* **Scimega**

Kelly Clark, *Head of US Partnerships and Global Site Development,* **Merck**

Emily Barnhill, *Director, Strategic Industry Ventures,* **MD Anderson Cancer Center**

2:00 pm – 2:40 pm

Global Clinical Trials: The Impact of Ukraine/Russia Crisis on Managing Patients and Solving for What has Been Disrupted

In some areas of the world where resources are extremely limited and where there is not a lot of standard of care, clinical trials become a really attractive option for patients. However, getting patients is a big problem to solve operationally as we try to navigate through war and political unrest. This session will address:

- What has been disrupted in global clinical trial operations and considerations to overcome them?
- How are patients being managed in global trials during the Ukraine/Russia Crisis?
- What are the ethics of shifting patients to neighboring countries and will regulators accept that data?

Led by:

Andy Lee, *SVP & Head, Global Clinical Trial Operations,* **Merck**

Serhiy Mykhaylov, MD, MBA, *Clinical Research Director Ukraine, Georgia & CIS,Global Clinical Trial Operations (GCTO),* **MSD Ukraine, LLC**

TRACK A

2:30 pm – 2:45 pm

Adding Advanced Imaging Analysis to Standard Response Assessments in Lymphoma Patients Treated with Immunotherapy

Ron Korn, MD, PhD, *Founder, Chairman & Chief Medical Officer,* **Imaging Endpoints**

2:45 pm – 3:30 pm

Panel: Novel Imaging Targets to Impact Immuno-Oncology

This panel addresses imaging targets and upcoming probes impactful for IO therapy. These include PSMA, Granzyme B, FAP and others.

Led by:

David Leung, MD, PhD
VP, Discovery & Translational Medicine, **RefleXion**

Panelists:

Colin Hayward, MD
Group Chief Medical Officer, **Telix Pharmaceuticals**

Benjamin Larimer, PhD
Co-founder, **CytoSite Bio**

Elaine Long, PhD
Scientific Leader, Immuno-Oncology Franchise, **GE Healthcare Pharmaceutical Diagnostics**

Kevin Maresca, PhD
Senior Director, PET Imaging, **Pfizer**

Sean Carlin, PhD
Principal Scientist, Scientific and Medical Services, **Invicro**

TRACK B

2:40 pm – 3:30 pm

Developing a Strategic Diversity and Inclusion Plan and Practical Execution in Clinical Trials (50)

The FDA guidance for diversity in clinical trials requires that a diversity plan be created and shared up front reflecting a certain percentage of diverse populations. However, recruiting diverse populations in trials is still difficult. Having a plan that requires a certain percentage of diverse populations and actually achieving this continues to be an operational challenge. Key topics include:

- Updates on the FDA Guidance and requirements for diversity plans
- How do we translate the requirements in these development plans?
- What do those development elements look like?
- What is the practical execution for this?
- How to partner with community hospitals to help recruit diverse populations

Led by:

Adrelia Allen, PharmD
Director, Clinical Trial Patient Diversity, Global Clinical Trial Operations, **Merck Research Labs**

Panelists:

Ana Rosa Sáez Ibáñez, PhD
Research Analyst, Clinical Accelerator and Venture Fund, **Cancer Research Institute (CRI)**

Caroline Owen
Senior Site Activation Manager, **Catalyst Clinical Research**

3:30 pm

AFTERNOON BREAK IN THE EXHIBIT CAFE & PARTNERING MEETINGS

- Refreshments including chocolate samples
- Partnering Tables
- Meet the Exhibitors
- Networking
- IO360° Giveaways
- "Charge-up" at the IO360° Charging Stations

TRANSLATIONAL SCIENCE & BIOMARKERS PLENARY SESSION PART 1

Plenary Chair:

Lisa Butterfield, PhD
Adjunct Professor of Microbiology and Immunology, **University of California San Francisco (UCSF)**

4:10 pm

The Untapped Power of the Innate Immune System: Novel Translational Approaches to Outsmart Cancer's Evasion Strategies

- What is innate immunity, and what potential does it hold for treating cancer?
- What makes this approach unique? How can leveraging innate immunity introduce new classes of immunotherapies?
- What novel innate immune mechanisms and corresponding translational biomarker approaches are currently being investigated?

Christine Ward, PhD
VP, Head, Oncology and Cell Therapy Precision and Translational Medicine, **Takeda**

4:30 pm

CD8 PET as a both a Predictive and Response Biomarker

Elaine Long, PhD
Scientific Leader, Immuno-Oncology Franchise,
GE Healthcare Pharmaceutical Diagnostics

4:45 pm

Biomarker Panel: Validating and Standardizing the Use of Multiplex as a Predictive Biomarker for Checkpoint Blockade Therapy

Moderated by:

Bernard Fox, PhD
Harder Family Chair for Cancer Research and Member and Chief, Laboratory of Molecular and Tumor Immunology at the Robert W. Franz Cancer Center, **Earle A. Chiles Research Institute, a division of Providence Cancer Institute**

Panelists:

Janis Taube, MD
Director, Division of Dermatopathology, Professor of Dermatology, **Johns Hopkins University**

David Rimm, MD, PhD
Professor of Pathology, Director of Pathology Tissue Services & Director of Translational Pathology,
Yale School of Medicine

Andy Beck, MD, PhD
CEO & Co-founder, **PathAi**

Jérôme Galon, PhD
Research Director / SVP and Scientific Executive Director, **Inserm France / Veracyte**

5:30 pm

IO360° CANCER IMMUNOTHERAPY DEBATE

Neoadjuvant vs Adjuvant: Is Neoadjuvant for Immunotherapy Better, Worse or the Same as Adjuvant Therapy for Immunotherapy?

- From a commercial point of view, neoadjuvant isn't where the money is at, so what are we interested in it for? Is it the mechanistic point of view and its relevance to the broader rational setting?
- Do you need some level of tumor mass to be there for the immune system to respond to so that you get a rip roaring, nice response that then protects you over time?
- How is neoadjuvant data going to inform clinical practice? Is it going to or not?
- How is neoadjuvant going to really shape patient management?

Naiyer Rizvi, MD
CMO, **Synthekine**

vs

Charles Drake, MD, PhD
VP, Immuno-Oncology, **Janssen**

Debate Moderator:

Daniel S Chen, MD, PhD
Founder, **Engenuity Life Sciences**

6:00 pm

9th Annual Networking Reception & Partnering Meetings

Meet with fellow attendees, visit the exhibiting companies and take part in partnering meetings.

DAY THREE - Thursday, February 9th

7:30 am

Registration

8:10 am

IO360° Day Three Welcome

8:20 am

ANALYST KEYNOTE

What's Next on the IO Radar? Top 10 Recommendations from Citi's Expert Analyst, Dr Andrew Baum

Andrew Baum, MD
Managing Director, Equity Research, **Citi**

BUSINESS & FINANCIAL DEVELOPMENTS PLENARY SESSION

8:40 am

Panel: Addressing the Current Market and Investment Trends in Immuno-Oncology

Moderated by:

Axel Hoos, MD, PhD
CEO, **Scorpion Therapeutics**

Panelists:

Irina Margine, PhD
Principal, Biotech Private Equity, **Wellington Management**

Albert Hwang, MD, MBA
Managing Director, Co-Head of US Healthcare Investment Banking, **Morgan Stanley**

Rajiv Kaul
Portfolio Manager, Equity Division,
Fidelity Investments

9:20 am

MORNING NETWORKING CAFE, EXHIBITS & PARTNERING MEETINGS

- Breakfast
- Partnering Tables
- Networking
- Meet the Exhibitors
- IO360° Givaways

10:00 am

Independent Action Models for Strategic Planning and Investment Decision Making in Early Stage Oncology Drug Development

In this talk, Merck's Dr Emmett Schmidt shares how Independent Action Models can be applied to understand and predict combination treatment effects and help facilitate strategic planning, decision making and investment strategies in early stage oncology drug development. Key topics addressed:

- Overview of what Independent Action is
- How Independent Action explains results from PD-1 combination experiments, and might inform prioritization of combinations most likely to succeed in continued development
- Lessons learned from the last 12 years of IO development that are important to consider for combination partnerships

Emmett Schmidt, MD, PhD
VP, Clinical Oncology, External Collaborations, **Merck**

10:20 am

From the Science to Investing: What Biotechs

Need to Know on Sourcing Innovation, Investing and Partnering in IO in Today's Current Market

This panel will address what new and emerging biotech's need to know and prepare for in order to rise above the noise in the IO biotech space when sourcing investments and partnerships. Biopharma business leaders address key questions biotechs have including:

- What is our preclinical and early clinical development strategy that will get the biggest bang for the buck where the runways and cash available may be constrained?
- How do we stand out in the noise of IO where there are thousands of biotechs saturating this space?
- What does it take to get a Series A and/or a partnership in this current investing environment?

Moderated by:

Jeff Bockman, PhD
EVP, Head of Oncology, **Lumanity**

Panelists:

Axel Hoos, MD, PhD
CEO, **Scorpion Therapeutics**

Sharon Benzeno, PhD
Chief Commercial Officer, Immune Medicine,
Adaptive Biotechnologies

Asthika Goonewardene, MBA
Managing Director, Senior Biotech Analyst,
Truist Securities

11:00 am

VIP FIRESIDE PATIENT PERSPECTIVE CHAT

We are honored to welcome Oswald Peterson, a stage IV lung cancer survivor and accomplished Carnival Dancer, who shares his incredible immunotherapy story that has given him back his life.

VIP Patients Guest:

Oswald Peterson
Patient Advocate

Moderated by:

Cindy Geoghegan
Patient Advocate

11:20 am

IO360° BIOTECH SHOWCASE

This session features small to mid-size private biotech companies to showcase their promising immuno-oncology science and innovations to help advance IO.

Participating Companies:

David Feltquate, MD, PhD
CMO, **Palleon**

Jack Elands, PhD
CEO, **Emergence Therapeutics**

Sumayah Jamal, MD, PhD
Co-founder, President & CSO, **ENB Therapeutics**

Henry Yu, PhD
CEO, **Canwell**

12:10 pm

LUNCH & PARTNERING MEETINGS

- Partnering Tables
- Networking
- Meet the Exhibitors
- IO360° Giveaways
- "Charge-up" at the IO360° Charging Stations

TRANSLATIONAL SCIENCE & BIOMARKERS PLENARY SESSION PART II

Plenary Chair:
Alexandra Snyder, MD
CMO, **Generate Biomedicine**

1:10 pm

Translational Learnings from Enhertu for Metastatic HER2-Low Breast Cancer

AstraZeneca tells the Enhertu story from a translational point of view, how they pivoted from assays that were in high her2 patients to assays that can detect low her2 and how they built that into the program.

Maurizio Scaltriti, PhD
VP, Translational Medicine, Early Oncology, Oncology R&D, **AstraZeneca**

1:30 pm

Engineered Cytokines & Lessons Learned from Bempegaldesleukin

This talk will present findings from phase I through III including translational data, insights on the mechanistic hypothesis and why the expectation was different from what the result was, along with lessons learned that can help the industry understand the downfall so that it can be built upon in the future.

Adi Diab, MD
Associate Professor, Department of Melanoma Medical Oncology, Division of Cancer Medicine,
The University of Texas, MD Anderson Cancer Center

1:50 pm

Panel: Optimizing Dosing for Immunotherapy through Translational Data and Biomarkers

The FDA is hyper-focused on dose-finding and requiring that companies define their dose of the drugs and define a rationale for their dose. This relates to translational data and biomarkers because a big part of determining dose is looking at your selected population, in some cases, your unselected population, PK, etc. It's more about translational data than just efficacy data. This panel will discuss:

- Who are your patients who are benefiting?
- What are the characteristics you are seeing?
- What does your PK look like?

- What do your anti drug antibodies look like?
- How do you determine what the dose is to move forward with cell therapies?
- How do you identify a dose and PK in solid tumors with cell therapy?

Moderated by:

Priti Hegde, PhD
CSO, **Foundation Medicine**

Panelists:

David Shames, PhD
Executive Director and Senior Research Fellow, Oncology Biomarker Development, **Genentech**

John Simmons, PhD
Global VP, Biopharma Partnerships, **Natera**

2:35 pm

AFTERNOON BREAK IN THE EXHIBIT CAFE & PARTNERING MEETINGS

- Ice Cream
- Partnering Tables
- Meet the Exhibitors
- Networking
- "Charge-up" at the IO360° Charging Stations

3:15 pm TRANSLATIONAL SCIENCE & BIOMARKER TRACK CHOICES

TRACK A	TRACK B
3:15 pm – 3:35 pm **Longitudinal Monitoring and Understanding Clonal Evolution with Checkpoint Inhibitors** **Priti Hegde, PhD** *CSO,* **Foundation Medicine**	**3:15 pm – 3:35 pm** **IO Dark Matter: Sialoglycans As An Important Missing Piece in the IO Resistance Puzzle** • Review evidence that glycan biology plays a role in immuno-regulation • Discuss therapeutic approaches to target sialoglycan mediated resistance • Discuss translational data in support of sialidase-based therapeutics **David Feltquate, MD, PhD** *CMO,* **Palleon Pharmaceuticals**
3:40 pm – 3:55 pm **Addressing Translational Challenges in Biomarker-driven Oncology Drug Development** This talk will present the key challenges in designing and executing precision immuno-oncology clinical trials and share our learnings and solutions to address these challenges: • What are the unique barriers in precision immuno-oncology clinical trial space? • How to leverage innovative approaches including data-driven solutions to conquer them? • What are our learnings from executing real-world oncology trials that lead to successful biomarker and drug co-development? **Angela Qu, MD, PhD** *SVP, Biomarker Genomic Medicine,* **Parexel**	**3:40 pm – 3:55 pm** **Key Challenges and Solutions: Comprehensive Platforms for Both Tissue and Liquid Biopsy** Currently, oncology tissue profiling platforms focus on mutational changes in a small panel of genes and provide limited data to support multidimensional biomarkers for predicting immunotherapy. Additionally, while circulating tumor-derived DNA is an emerging biomarker for many cancers, the limited sensitivity of detection methods reduces its utility for determining Molecular Residual Disease (MRD) across clinical trial settings. Data will be shared that demonstrates how the Personalis NeXT platform leverages expansive tissue-derived molecular features with an ultrasensitive approach designed to detect MRD at the earliest timepoints, with simultaneous variant tracking for insight into disease progression. **Christelle Johnson, PhD** *Manager, Field Applications Scientist,* **Personalis, Inc**

TRACK A	TRACK B
4:00 pm – 4:20 pm **Progress Report on Friends of Cancer Research ctMoniTR Project and Utilizing ctDNA in Drug Development** The ctDNA to Monitor Treatment Response (ctMoniTR) Project is a unique partnership led by Friends of Cancer Research to answer the important question: Do changes in ctDNA reflect response to treatment? This public-private partnership brings together stakeholders from academia, government, industry, and patient advocacy groups to establish an approach to evaluate ctDNA levels and leverages cross-sector data sharing towards using ctDNA as a treatment monitoring tool for drug development. The project is helping develop the necessary evidence to establish ctDNA as a reliable monitoring tool for treatment response and align data across numerous clinical trials to evaluate ctDNA as a potential surrogate biomarker. This session provides the most up to data analyses from the ctMoniTR Project and provides guidance on how to use ctDNA in drug development and best practices for working with regulators along the way. **Jeff Allen, PhD** *CEO & President,* **Friends of Cancer Research (FOCR)**	**:00 pm – 4:20 pm** **REVOLUTION Platform Trial Progress and Impact on the Treatment Landscape for Pancreatic Cancer** This talk consists of a broad swath of translational science on high throughput analysis and hypothesis generating data in PICI's REVOLUTION pancreatic study. **Eileen O'Reilly, MD** *Winthrop Rockefeller Endowed Chair in Medical Oncology; Co-Director, Medical Initiatives, David M Rubenstein Center for Pancreatic Cancer Research; Section Head, Hepatopancreaticobilary & Neuroendocrine Cancers,* **Memorial Sloan Kettering Cancer Center**
4:25 pm – 4:45 pm **Partnership for Accelerating Cancer Therapies Progress on Biomarker Harmonization** This talk will update on the Partnership for Accelerating Cancer Therapies (PACT) project, a Cancer Moonshot 1.0 project, and its next steps. Specifically, it will provide progress on the biomarker harmonization across laboratories within the network and their sharing of the validation and harmonization process with the entire immunotherapy field. **Stacey Adam** *AVP, Research Partnerships,* **Foundation for the National Institutes of Health (FNIH)**	**4:25 pm – 4:45 pm** **Predicting Efficacy and Toxicities Prior to Immune Checkpoint Inhibitor Treatment** Responses to immune checkpoint inhibitor treatments in oncology are still heterogeneous and not fully predictable for an individual patient. Some patients develop significant and possibly life-threatening immune-related toxicities. In this talk, GE Healthcare (GEHC) and Vanderbilt University Medical Center (VUMC) report on the progress of their co-developed predictive models to predict efficacy of IO treatment and the likelihood of some of the most common toxicities. **Jan Wolber, PhD** *Global Product Leader Digital, Pharmaceutical Diagnostics,* **GE Healthcare** **Travis Osterman, DO, MS** *Assistant Professor, Department of Biomedical Informatics, Assistant Professor, Division of Hematology and Oncology / Director of Cancer Clinical Informatics,* **Vanderbilt University Medical Center / Vanderbilt-Ingram Cancer Center**

TRACK A	TRACK B
4:50 pm – 5:05 pm **Elucidation of the Cellular and Molecular Features of the TME Underlying Immune Escape and IO Failure** **Michael Goldberg, PhD** *Director, Immunology,* **BostonGene**	**4:50 pm – 5:05 pm** **Single Cell and Spatial Approaches for Drug Discovery and Development** In this talk, 10x Genomic discusses how multiomic insights can help increase success and reduce risk of drug candidate failures, specifically by utilizing single cell and spatial tools with throughput, reproducibility, and multiomic capabilities. Additionally, actionable insights can be gained throughout program pipelines and can lead to enriched biomarker discovery and improved antibody discovery. **Andrew Allison** *Pharma Account Manager,* **10x Genomics**
5:10 pm – 5:30 pm **Translational Learnings from IO** **Leanne Peiser, PhD** *Executive Director, Translational Research,* **BMS**	**5:10 pm – 5:30 pm** **The Importance of Immune Fitness in Clinical Response to Bispecific Antibodies: Correlative Analyses from the MajecTEC-1 study in RRMM** • Data presented here are analyses of tumor and immune baseline correlatives from the MajesTEC-1 for Teclistamab, the first off-the-shelf BCMA × CD3 bispecific antibody approved in patients with heavily pretreated Relapsed Refractory Multiple Myeloma • Analysis of baseline correlatives suggests the importance of immune fitness in achieving clinical response with teclistamab • Non-responding patients had an unfavorable immune profile at baseline, associated with T cell dysfunction/ exhaustion and immune suppression **Raluca Verona, PhD** *Head, Heme Malignancies, Translational Research,* **Janssen R&D**
6:00 pm **End of Day Three**	

DAY FOUR - Friday, February 10th

8:15 am

Registration

8:45 am

IO360° Day Four Welcome

9:00 am

EXECUTIVE FIRESIDE CHAT

History of mRNA in Cancer and Next Steps

In this fireside chat, Dr Tal Zaks will discuss the history of mRNA use in cancer, ways companies may be underutilizing their capital, and where mRNA is likely to have the highest impact in oncology.

Tal Zaks, MD, PhD
Partner, Private Equity, **OrbiMed**

Moderated by:

Mark Simon, MBA
Co-founder and Advisor, **Torreya**

9:25 am

VIP Talk & Fireside Chat: Off-the-Shelf Allogeneic EBV T Cells - Ushering in the Next Wave of Innovation

Virus-specific allogeneic platforms hold the promise of effective, off-the-shelf treatments manufactured at scale, and rapidly delivered to patients within days. Following a recent European approval of the first ever allogeneic T-cell immunotherapy, Atara's EbvalloTM (tabelecleucel) represents a significant advance in the rapidly expanding cell-therapy field. Dr Jakob Dupont, Atara's EVP of Global R&D, will discuss the journey that led to this historic milestone and what it could mean for the broader cancer and autoimmune disease treatment landscape. A fireside chat will follow.

Jakob Dupont, MD
Head, Global Research & Development,
Atara Biosciences

Moderated by:

Axel Hoos, MD, PhD
CEO, **Scorpion Therapeutics**

9:50 am

MORNING IO360° NETWORKING CAFE, EXHIBITS & PARTNERING MEETINGS

- Breakfast
- Partnering Tables
- Networking
- Meet the Exhibitors
- IO360° Giveaways
- Charity Raffle Drawing
- "Charge-up" at the IO360° Charging Stations

ADVANCEMENTS IN RNA THERAPEUTICS FOR CANCER IMMUNOTHERAPY

New targets and even very old targets with a new modality can now be sought after by using RNA. COVID vaccines have paved the way for people to have more confidence in RNA treatments. In this section, companies report on the progress with RNA therapeutics.

10:35 am

Landscape Overview on the RNA Space and the Impact on Cancer Immunotherapy

Sandra Wolin, MD, PhD
Chief and Senior Investigator, RNA Biology Laboratory, **National Cancer Institute**

10:55 am

Epigenomic Programming for Precision Genomic Control: A Powerful New Paradigm in Cancer Treatment

Thomas McCauley, PhD
CSO, **Omega Therapeutics**

11:15 am

Addressing the Limitations of Current Immunotherapies with Circular RNA

Robert Mabry, PhD
CSO, **oRNA Therapeutics**

11:35 am

Revolutionizing Immunotherapy with mRNA Technology

Zach Taylor
VP, Corporate Development & Strategy,
BioNTech US

11:55 am

Pharma Case Study

12:15 pm
LUNCH & PARTNERING MEETINGS BEGIN

- Lunch on your own
- Networking
- IO360° Giveaways
- "Charge-up" at the IO360° Charging Stations

CLINICAL DEVELOPMENTS PLENARY SESSION

1:15 pm

Neoepitope-based Vaccines for Pancreatic Cancer

Vinod Balachandran, MD
Surgical Oncologist, Member Researcher, David M. Rubenstein Center for Pancreatic Cancer Research,
Memorial Sloan Kettering Cancer Center (MSKCC)

1:35 pm

PSMAxCD28 in Combo with Cemiplimab

Israel Lowy, MD, PhD
SVP, Clinical Sciences, Head, Translational Science and Oncology, **Regeneron Pharmaceuticals**

1:55 pm

Neoantigen Immunotherapy for Solid Tumors: Molecular Responses and Clinical Benefit in End-stage Patients

This talk addresses:

- Neoantigens can be delivered to solid tumor patients on an individualized or "off-the-shelf" immunotherapy product basis
- Phase 1/2 data in advanced disease shows clear evidence of immune response and associated clinical benefit
- Neoantigen immunotherapy is likely to drive even greater benefit in earlier-stage patients – these trials are starting

Andrew Allen, MD, PhD
President & CEO, **Gritstone bio, Inc.**

2:15 pm

Clinical Progress with TIGIT + PD1 Combination: Coherus Biosciences

- Present the latest activity and bringing it to the US
- Are all PD1s the same or do they have some differences based on their epitopes and mechanisms?
- How does that impact patients?
- What the field showing us and how that impacted their development and decision making

Theresa LaValle, PhD
Chief Development Officer, **Coherus Biosciences**

2:35 pm

Conditionally Active Antibodies in Immuno-Oncology: What VISTA Taught Us

Edward van der Horst, PhD
CSO, **Sensei Bio**

2:50 pm

Developing a New Class of Immunotherapies and Vaccines

Jeremy Graff, PhD
CSO, **IMV Inc**

3:35 pm

End of Conference