

Reporting on Rapid Advancements of Clinical, Scientific and Business Developments in IO

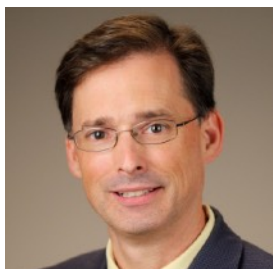
IO360 IMMUNO-ONCOLOGY 360°

FEBRUARY 6-8, 2019 | CROWNE PLAZA TIMES SQUARE, NEW YORK CITY, NY

Featured Speakers



Axel Hoos, MD, PhD
GlaxoSmithKline



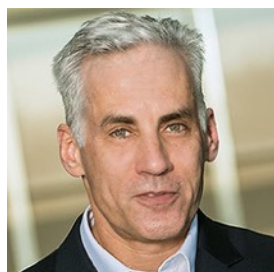
James Gulley, MD, PhD
National Cancer Institute



Andrew Baum, MD
Citi



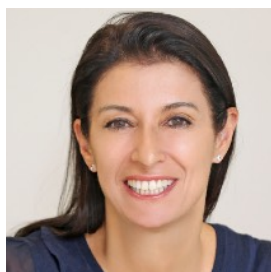
Priti Hegde, PhD
Genentech



Eric Rubin, MD
Merck Research Labs



Michael Kalos, PhD
Janssen Oncology



Jacqueline Karmel
Roche



Ronald Herbst, PhD
MedImmune



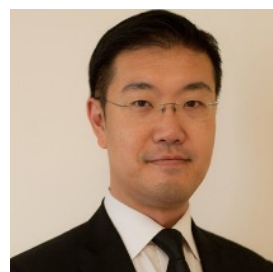
Andrea van Elsas, PhD
ADURO



Tara Arvedson, PhD
Amgen



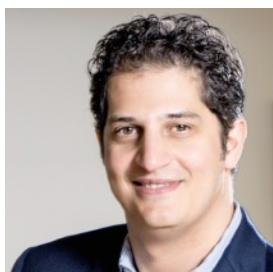
Aung Naing, MD, FACP
MD Anderson Cancer Center



David Leung, MD, PhD
BMS



Jonathan Zalevsky, PhD
Nektar



Tahamtan Ahmadi, MD, PhD
GenMab



Ian Pyrah, PhD
Seattle Genetics



Marco Ruella, MD
UPenn

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DAY ONE - WEDNESDAY, FEBRUARY 6, 2019**7:30 am****Registration****8:15 am****Co-chairs' Opening Remarks****James Gulley, MD, PhD**

Head, Immunotherapy Section, Director, Medical Oncology Service, Office of the Clinical Director, Center for Cancer Research, **National Cancer Institute**

Axel Hoos, MD, PhD

SVP, Oncology R&D, **GlaxoSmithKline**

Andrew Baum, MD

Head of Global Healthcare, Managing Director, Equity Research, **Citi**

8:30 am - 11:20 am**DISCOVERY & PRECLINICAL SCIENCE PLENARY**

This plenary includes talks focused on tumor microenvironment changing technologies, pegylated cytokines and additional discovery and preclinical data.

Tumor Microenvironment Changing Technologies**IDO Inhibition Preclinical Updates****Blockade of the Adenosine Pathway: Preclinical, Translational and Clinical studies with CPI-444, an A2A Receptor Antagonist for Cancer Treatment****Stephen B Willingham, PhD**

Senior Scientist, **Corvus Pharmaceuticals**

Update on Anti-CD73**Ronald Herbst, PhD**

VP R&D, Head Oncology Research, **Medimmune**

Pegylated Cytokines**Update on IL-10****Aung Naing, MD, FACP**

Associate Professor, Department of Investigational Cancer Therapeutics, Division of Cancer Medicine, **MD Anderson Cancer Center**

Martin Oft, MD

VP, Preclinical and Clinical Research, **ARMO**

NKTR-214: Accessing the IL-2 Pathway for Immune Oncology

- Nektar's polymer chemistry technology was used to create NKTR-214, a CD122-biased cytokine that targets the IL-2 pathway
- NKTR-214 has drug-like properties far improved over the native IL-2 cytokine
- Nonclinical studies validate NKTR-214 as an immune stimulating agent

- Clinical results demonstrate systemic and intratumoral immune activation, and the ability to drive increased TIL and convert tumors from PD-L1 negative to positive
- In combination with anti-PD-1, NKTR-214 shows broad activity across multiple tumor types, including PD-L1 negative and PD-L1 positive tumors

Jonathan Zalevsky, PhD

SVP, Research & Chief Scientific Officer, **Nektar**

11:20 am - 3:30 pm**TRANSLATIONAL SCIENCE AND EMERGING BIOMARKERS PLENARY PART I**

This plenary reports on translational data, biomarkers, companion diagnostics and additional applications to help predict responses to cancer immunotherapy.

Biomarker Signaling: Turning Cold Tumors Hot**Priti Hegde, PhD**

Global Franchise Lead, Cancer Immunotherapy Biomarkers, **Genentech**

Prostvac and Lessons Learned About Therapeutic Cancer Vaccines**James Gulley, MD, PhD**

Head, Immunotherapy Section, Director, Medical Oncology Service, Office of the Clinical Director, Center for Cancer Research, **National Cancer Institute**

Oncolytic Viruses: Promises, Problems & Solutions

Oncolytic viruses (OV) are live viruses used as drugs. They can be many drugs in one because they stimulate multiple pathways leading to activation of innate and adaptive immunity in tumors and can be engineered to deliver multiple biological drugs like antibodies, cytokines, etc. However, unlike small molecules and biologics, the immune system is very good at clearing viruses. This session will provide data demonstrating how BeneVir's OV hide from innate and adaptive immunity to enhance therapeutic efficacy.

Matthew Mulvey, PhD

CEO, **BeneVir**, a **Janssen Pharmaceuticals Company**

Key Central Laboratory Capabilities to Enable Successful Immuno-Oncology Clinical Development

This talk will provide an overview of central laboratory capabilities that deliver mechanistic and predictive biomarker data to support decision making for Immuno-Oncology Clinical Development.

Patrice Hugo, PhD

Chief Scientific Officer, **Q² Solutions**

Data-Driven Case Studies by:**Imaging Endpoints****Ron Korn, MD, PhD**

Founder, Chairman and Chief Medical Officer

Neogenomics Laboratories**Maher Albitar, MD**

SVP, Chief Medical Officer and Director of Research and Development

Immunosequencing: Expanding Beyond MRD and Immunooncology

This talk will briefly review the use of immunosequencing as a clinical diagnostic for monitoring patients with lymphoid malignancies and as an adjunct in the evaluation of cancer patients who might benefit or have benefited from immunomodulatory therapy. It will then describe new advances in the ability to define the target of a B- or T-cell based on knowledge of the primary nucleotide sequence(s) of its immune receptors. It will conclude with a description of current efforts to create a comprehensive “immunome” for any individual as a general assessment of health and disease status.

Lanny Kirsch, MD

SVP Translational Medicine, Adaptive Biotechnologies

Modeling the Effect of Checkpoint Inhibition on the Tumor Microenvironment Using A Personalized Ex Vivo Histoculture Approach

Delineation of the intra-tumor microenvironment in a dynamic, spatio-temporal setting is critical for investigating the activity and efficacy of candidate oncology drugs. The majority of solid cancers contain unorganized, highly-complex microenvironment wherein a dysregulated phenotypic impacts treatment outcomes at a personalized level. Mitra Biotech developed and validated a personalized, fully human ex-vivo histoculture platform technology (CANscript™) using patient material (tumor, autologous ligands and immune cells) to explore the effect of a variety of drug classes on individual tumor compartments and across the phenotype of the sample (Nat Comm., 6:6169:1-14 2015). With respect to immunomodulating agents, we have investigated the effect of innate and adaptive targets on immune contexture. This session will review Mitra's strategy for histoculture and explore data from internal and client studies as a means of understanding the strengths and weaknesses of our approach.

Mark Paris, PhD

Associate Director, Translational Applications, Mitra Biotech

Panel: Next Generation Biomarker and Companion Diagnostics for Predicting Response

- How can biomarkers act as a tool for understanding the biology at a level that is sufficient for making decisions around combinations?
- What are the potential biomarkers that can help predict if a patient will respond to combinations?
- Once a biomarker is identified in terms of biology, been measured and the technology platform identified to meet those measures, how is the biomarker developed to the level of clinical grade that meets approval?
- How do we validate diagnostics in IO/combinations?
- How do you satisfy regulators?
- Are there other biomarkers in development?
- What are the implications for intervention?

- Are biomarkers and companion diagnostics crucial for rational combination success?

Moderator:

Priti Hegde, PhD

Global Franchise Lead, Cancer Immunotherapy Biomarkers, Genentech

Panelists:

Theresa LaVallee, PhD

Head of Translational Medicine and Regulatory Affairs, Parker Institute for Cancer Immunotherapy

Daniel Chen, MD, PhD

Chief Medical Officer, IGM Biosciences

Ian McCaffery, PhD

VP and Head of Oncology Translational Research, Janssen Research and Development

4:10 pm - 5:10 pm

IO NOVEL TECHNOLOGIES AND INNOVATIVE SOLUTIONS PLENARY

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

5:10 pm - 6:30 pm

FINANCIAL AND COMMERCIAL IMPLICATIONS PLENARY

This plenary features talks by VCs, Investors and Analysts on the IO landscape and delves deeper into the financial implications of the IPO Process for IO biotechs.

Financial Plenary Keynote Address

Investor Perspective on the IO Landscape

This talk will provide a perspective on how long term investors in IO are looking at and evaluating the space including approaches and areas to concentrate on when funding innovation.

Khalil Barrage

Managing Director, Public Equity, Invus

Monetizing Science: Turning an Asset into Value through IPOs

This panel, moderated by Dr Andrew Baum, Citi, delves into discussion on the preparation of an IPO, straight licensing with the transition to a public company and decision making on prioritization within portfolios.

Moderator:

Andrew Baum, MD

Head of Global Healthcare, Managing Director, Equity Research, Citi

with

David Epstein, MBA

Executive Partner, Flagship Pioneering

Dan Passeri, MSc, JD

President and Chief Executive Officer, Cue Biopharma

DAY TWO - THURSDAY, FEBRUARY 7, 2019

7:30 am
Registration

8:20 am
Co-chairs' Opening Remarks

James Gulley, MD, PhD

Head, Immunotherapy Section, Director, Medical Oncology Service, Office of the Clinical Director, Center for Cancer Research, National Cancer Institute

Axel Hoos, MD, PhD

SVP, Oncology R&D, GlaxoSmithKline

Andrew Baum, MD

Head of Global Healthcare, Managing Director, Equity Research, Citi

8:30 am - 9:30 am

TRENDS AND COLLABORATIONS PLENARY

This plenary features reports from three major publications on the IO field including new innovations, trends, partnerships and the impact of investments driving collaborations.

BioCentury Report

The BioCentury report will cover how companies and academic investigators are driving innovations within immuno-oncology, including new targets, modalities and technologies, to address some of the field's biggest challenges.

Simone Fishburn, PhD

VP and Executive Editor, BioCentury & BioCentury Innovations

Bloomberg Intelligence Report

Asthika Goonewardene, MBA

Senior Biotech Analyst, Bloomberg Intelligence

Endpoints News Report

The Endpoints News Report will review the build up of immuno-oncology over the past few years. With the large amount of money and the extraordinary numbers we have seen invested in the space, this talk will discuss what impact this may have on collaborations.

John D Carroll

Editor-in-Chief, Endpoints News

10:10 am - 12:30 pm

BUSINESS DEVELOPMENT PLENARY HOSTED BY SOLEBURY TROUT

This plenary provides a recap of recent IO deal-making and includes perspectives from pharma and biotech along with investors on raising capital and other investment decision-making aspects throughout the development lifecycle.

Insights from Deal Trends: Betting on Tumor Immunology

Jeffrey Bockman, PhD

EVP, Oncology Practice, Defined Health

IO Partnering Strategies In an Increasingly Complex Environment

In this panel, large pharma and biotech business development leads discuss decision-making when it comes to partnering and collaborations in today's IO environment.

- What is the current nature and types of partnerships being done in IO?
- Is dealmaking and partnerships evolving due to the need for IO combinations? How so?
- What is the balance between in house R&D and external innovation in IO?
- What is the decision making regarding exclusive licensing and "no strings attached" partnerships?

Anton Xavier, MBA

Assistant Director, Technology and Business Development, New York State Center for Biotechnology

Fund Raising in the Current IO Space

This panel, designed for small and emerging biotechs, will address the following questions on fund raising in today's competitive market.

- How do you raise capital?
- How do you interact with your shareholders?
- How do you maintain visibility in the market?
- How do you entice investors and such to be part of your IPO
- How do you move forward if you have a short term investor rather than a long term investor?
- How do you differentiate yourself from other IO companies?

The Rational Investor: Understanding IO Investment Decisions

- To what extent are big rounds of financing sustainable in the future?
- What is the trigger for why it is sustainable or not?
- How do you decide who to put new funds towards?

Executive Fireside Chat

This fireside chat, presented by Solebury Trout, includes a spotlight discussion with an IO Biotech CEO who will share how the company got where they are today along with the steps and lessons learned from the IPO journey.

1:20 pm - 3:40 pm

Afternoon Breakout Sessions

Track 1A: Translational Science & Emerging Biomarkers Part II

This session continues to focus on the biology and applications to help predict responses to immunotherapy.

1:20 pm **HexaBody Technology To Enhance Antibody Therapeutics for a Broad Range of Applications in Cancer**

Tahamtan Ahmadi, MD, PhD

SVP, Oncology and Translational Medicine, Genmab

ADC Mechanisms of Action Used to Inform Combinations

Ian Pyrah, PhD

VP Translational Sciences, Seattle Genetics

Novel CARs for Solid Tumors: IL-13

Sadik Kassim, PhD

Chief Scientific Officer, Mustang Bio

Track 1B: Clinical Operations

This session is designed for clinical trial operation executives who want to learn what it takes to execute an IO clinical trial. This is an excellent opportunity to walk through the building blocks of IO clinical trial operations and discuss pitfalls and lessons learned.

1:20 pm **Genentech: An End-to-End Clinical Trial Operations Case Study**

In this talk, Genentech will walk the audience through their clinical trial operations strategy using case examples, identifying pitfalls that have been avoided and those that have been experienced and overcome in order to provide key learnings and help organizations both large and small navigate the operational minefield.

Karen Dimick, *Operations Program Leader – Cancer Immunotherapy Combinations Development- Oncology Global Product Development, Genentech*

Multi-Dimensional Computation Analysis for IO

This talk will address bringing together the data from the patient including their immune profile, imaging of the immune cells, genetic modifications, and applying AI and machine learning into multi-dimensional analytics and visualization. Applying multi-dimensional analytics could really inform where you need to be going next with the data, with the molecules and with IO combinations.

Operational Collaborations and Data Management Between Multi-stakeholders

This panel will address the operational challenges with obtaining IO data and the utilization of IO data to advance science. Key discussion points include:

- Aggregating data across trials and centers
- Obtaining associated clinical data from academic studies and combine it with data from other studies
- Obtaining secondary data analysis which brings in new channels of research on top of the primary analysis
- How to best to leverage all the operational data to drive the types of activities required to start trials, to know where we are and to be able to manage risks

Adriana Comprelli, *Head, Clinical Operations, Early Assets & Clinical Pharmacology, BMS*

Jacqueline Karmel, *Principal Director Scientific Collaborations, Roche*

4:20 pm - 6:15 pm

IO IMAGING ASPECTS PLENARY

This plenary includes imaging data and methods to further monitor the immune system and provides informative approaches that can assist in the assessments of IO therapies.

Whole Body PDL1 PET

David Leung, MD, PhD

Medical Director, Oncology Imaging, Exploratory Clinical & Translational Research, BMS

Radiomics as a Tool to Look for Trends and Predictive Features for Efficacy in Trials

Lawrence Schwartz, MD

Chief, Radiology Service, Columbia University Medical Center

Regulatory Perspective: Imaging and Immuno-Oncology Trends

Imaging Evaluation for Immuno-oncology Protocols at the Site Level

This joint presentation addresses how site performs clinical trials from a radiology and PI perspective and the challenges.

Kelie Luby

VP, Clinical Trials Software, Mint Medical

5th Annual Networking Reception**DAY THREE - FRIDAY, FEBRUARY 8, 2019**

7:45 am

Registration

8:20 am

Co-chairs' Opening Remarks

James Gulley, MD, PhD

Head, Immunotherapy Section, Director, Medical Oncology Service, Office of the Clinical Director, Center for Cancer Research, National Cancer Institute

Axel Hoos, MD, PhD

SVP, Oncology R&D, GlaxoSmithKline

Andrew Baum, MD

Head of Global Healthcare, Managing Director, Equity Research, Citi

8:30 am

Combining IO Modalities In a Cost Effective, Patient Beneficial Manner that Unfolds in Our Lifetime

The hardest thing to figure out now is what combinations make the most sense in which patients and how to combine all these emerging modalities in a way that is cost effective, benefits patients and unfolds in our lifetime. There are hypothesis on what technologies should be explored together. Very few companies

have all the relevant skills, reagents or product candidates in one setting, so it requires collaboration to generate the most powerful combinations. This overview talk, followed by a panel will delve into the following:

- What is the underlying pathobiology and how it is similar from patient to patient and how it is different in individuals?
- What interventions make the most sense and how to get the right patient into the studies to test your hypothesis?
- How do you connect modalities such as cell therapies and immune-module antibodies?
- How do you explore potential meaningful combinations before you have approved agents where you can tap into other products?

Moderator:

Robert Stein, MD, PhD

Senior R&D Advisor, Agenus

Panelists:

Jeffrey Bockman, PhD

EVP, Oncology Practice, Defined Health

Mark Simon, MBA

Partner and Co-founder, Torrey Partners

9:10 am - 12:45 pm

NEXT GENERATION CELL THERAPY PLENARY

This new plenary for 2018 features talks on emerging cell therapy approaches, optimization, manufacturing and engineering CAR-Ts and the future outlook of cell-based therapies.

CAR-T Therapy for Cancer: Optimization Through Engineering T-cells or Combinations

This talk will focus on the next steps for CAR-T therapy for cancer, discussing the novel approaches that are being developing in Dr Carl June's lab including CAR-T combinations with small molecules and gene-editing.

Marco Ruella, MD

Assistant Professor and Scientific Director Lymphoma Program, Division of Hematology and Oncology, Department of Medicine and Center for Cellular Immunotherapies (CCI), Perelman School of Medicine, University of Pennsylvania

Allogeneic Approaches in Cell Therapy

Update on NY-ESO

Cedrik Britten, MD

Head, Cell Therapy, GSK

CAR-T Cell Manufacturing

There is a debate between allogeneic and autologous approaches for manufacturing of CAR-T cells. It would be ideal to optimise the process and take the cells out of the patient but the turnaround time is over 4 weeks. This case study provides examples and data on how to effectively take the cells out of the patient with a quick turnaround that is beneficial.

CAR-T Clinical Developments

Michael Kalos, PhD

VP, Immuno-oncology & Oncology Cellular Therapies, Janssen Oncology

Next Generation CAR-T and Cell-Based Immunotherapies

This panel will address the scalability, challenges, emerging approaches and the future outlook of cell-based therapies.

- Can the adoptive cell therapy technology meet the high expectations?
- Are the toxicities telling us we are not ready?
- How do we scale T-cell therapy and what are the plans for getting the therapy into all the patients who need it?
- What combination therapy should be given with T-cell therapy?
- How is cell-based immunotherapies changing the industry?

Moderated by:

Morrie Ruffin

Founder and Managing Director, Alliance for Regenerative Medicine (ARM)

1:40 pm - 4:00 pm

IO CLINICAL DEVELOPMENTS PLENARY

This plenary provides progress reports on recent IO clinical data across indications.

MSI Case Study: Investigator/Industry Collaboration that led to the FDA's 1st Tumor Agnostic Label Approval

This multi-stakeholder talk will share the science of MSI and the journey of how MSI became the first tumor agnostic label approval. The objective is to demonstrate how effective the therapies are in MSI so it can help others design programs using tumor agnostics because the precedent is there.

Eric Rubin, MD

VP, Global Clinical Oncology, Merck Research Laboratories

Preclinical and Early Clinical Experience with ADU-S100/MIW815, a first-in-class STING Agonist for the Treatment of Cancer

Andrea van Elsas, PhD

Chief Scientific Officer, ADURO

Update on BCMA BiTE and AMG 330

Tara Arvedson, PhD

Director, Oncology Research, Amgen

Latest Clinical Data on T-Cell Bispecifics

Speaker TBA, ImmunoCore

Conference Concludes