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 Immuno-oncology
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 immune-modulatory 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 immune-modulating 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, **Torreya 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