4TH ANNUAL

IO COMBINATIONS 360°

June 20 -21, 2019
Wyndham Philadelphia Historic District, Philadelphia, PA

Organized by the Conference Forum  |  www.theconferenceforum.org  |  #IOCombos360
DAY ONE - THURSDAY, JUNE 20, 2019

7:45 am
Registration and Morning Coffee/Tea

8:15 am
Co-Chair’s Opening Remarks
Ian McCaffery, PhD
VP and Head of Oncology Translational Research, Janssen Research and Development

Omid Hamid, MD
Chief, Translational Research and Immunotherapy / Director, Melanoma Therapeutics, The Angeles Clinic and Research Institute

8:30 am
Opening Keynote: Hubble’s Constant for the Expanding Universe of Immunotherapy
Drew Pardoll, MD, PhD
Director, Bloomberg-Kimmel Institute for Cancer Immunotherapy, Professor of Oncology, Johns Hopkins University School of Medicine

Dis discovery, Preclinical Science and Bispecifics
Plenary Chair:
Omid Hamid, MD
Chief, Translational Research and Immunotherapy / Director, Melanoma Therapeutics, The Angeles Clinic and Research Institute

9:00 am
Preclinical Combinations with Bispecific T-cell engager (BiTE®) Immune-therapy and Translation to the Clinic
This talk will focus on PD1 combinations including an update on Blincyto/Keytruda combination.
Julie Bailis, PhD
Principal Scientist, Oncology Research, Amgen

9:20 am
Recombinant MVA an Immunotherapy for Cancer: More Than a Vaccine
This talk will include preclinical data on Bavarian Nordic’s vaccine platform as a tool to modify the global immune response by encoding target antigens, encoding costimulatory molecules, and encoding cytokines. This allows one agent to be used that can solve many problems that otherwise are being addressed, clinically, by multiple agents. Instead of combining vaccine + cytokine + checkpoint, in turn may be able to repurpose vectors to give them either intravenously or intratumorally (or both) to modify the TME, active innate immune responses including NK cells, generate T cell activation peripherally and locally. Then, combine with checkpoint inhibitors and ADCC-inducing antibodies to drive potent anti-tumor effect. These findings will be translated into various clinical trials in the next 6-18 months.
Hubertus Hochrein, PhD
VP, Head of Research, Bavarian Nordic

9:40 am
Grand Opening of the Exhibit, Networking Café & Breakfast

10:25 am
Updates on Bintrafusp alfa/M7824 Clinical Data
This talk will provide an overview of the molecule Bintrafusp alfa/M7824 - an innovative, first-in-class bifunctional fusion protein composed of an anti-PD-L1 mAb fused with 2 extracellular domains of TGF-βRII (a TGF-β “trap”). The mechanism of action, pre-clinical and phase 1 studies of this molecule will be discussed as well as an overview of the next wave of clinical development.
Laureen Ojalvo, MD, PhD
Medical Director, EMD Serono

10:45 am
Leveraging the Tumor Microenvironment for IO Therapy
This talk will address agonistic strategies, T and NK cell redirection and the use of genetic/phenotypic associations to identify novel target space in IO.
Kenneth Hance, PhD
Senior Director, Head of Immune Biology, Immuno-Oncology & Combinations DPU, Oncology R&D, GSK

11:05 am
Panel: Advancing Bispecifics for Combination Immunotherapy
• What are the types of bispecifics and what are the limitations?
• What are the toxicity related side effects?
• What are the next steps/levels for bispecifics?
• What does the future hold for bispecifics?
Moderated by:
Daniel Chen, MD, PhD
Chief Medical Officer, IGM Biosciences

Panelists:
Julie Bailis, PhD
Principal Scientist, Oncology Research, Amgen

Rajkumar Ganesan, PhD
Director, Bispecifics and CAR-T, Janssen Research & Development

David Schaer, PhD
Director, Translational Oncology Lead, Pfizer

11:50 am
IO Novel Technologies
This session showcases companies that have technologies and solutions that will help stakeholders in the IO field advance developments that provide treatment for cancer patients.
Plenary Chair:
Daniel Chen, MD, PhD
Chief Medical Officer, IGM Biosciences

QuartzBio, part of Precision for Medicine
Renée Deehan-Kenney, PhD
VP, Computational Biology

Invicro
Ohad Ilovich, PhD
Director, Translational Research

Advaxis
Joel R Hecht, MD
Professor of Clinical Medicine, David Geffen School of Medicine / Director, Gastrointestinal Oncology Program, University of California Los Angeles (UCLA) (on behalf of Advaxis)
12:30 pm
Networking Lunch and Partnering Meetings

Translational Science & Emerging Biomarkers
Plenary Chair:
Ian McCaffery, PhD
VP and Head of Oncology Translational Research, Janssen Research and Development

1:30 pm
Panel: How AI, Machine Learning and Big Data are Used to Inform Combinations
Led by:
Matthew Albert, MD, PhD
VP, Immunology & Infectious Diseases, Insitro

Panelists:
Edward Bowen
VP, AI & Machine Learning, GSK
Ryan Fukushima
Chief Operating Officer, Tempus
Renée Deehan-Kenney, PhD
VP, Computational Biology, QuartzBio, part of Precision for Medicine

2:15 pm
The Functional Capacity of Immune Cells as Measured by Single Cell Proteomics Predicts Clinical Outcome Across IO Therapies
Using single cell proteomics to measure the functional capacity or ‘fitness’ of immune cells has correlated with and been predictive of clinical outcome in CAR-T, TIL, Cancer Vaccine and Checkpoint Inhibitor therapy. This talk will review several of these data sets and discuss applications of IsoPlexis’ single cell technology.
Will Singleterry, PhD
Director, Business Development, IsoPlexis

2:35 pm
Molecular Correlates of Response and Resistance to Atezolizumab +/- Bevacizumab in Untreated Metastatic RCC
Mahrukh Huseni
Scientific Manager, Genentech

2:55 pm
Profiling the effect of Single Agent CPI versus Combinations Through Diverse Sampling and Personalized Tumor Histoculture
This presentation will address how Mitra Biotech’s personalized, fully human, ex-vivo histoculture platform technology (CANScriptTM), which uses patient material (tumor, autologous ligands and PBMC) to explore the mechanism of action for novel agents and combinations, focusing on molecular and phenotypic effects was used to model the effect of immune-modulating drugs on the tumor microenvironment. The focus will be how quality control of experimental conditions can result in the generation of biological insights.
Mark Paris, PhD
Associate Director, Translational Applications, Mitra Biotech

3:15 pm
Maximizing Immunotherapy Biomarker Discovery with a Multidimensional Tumor Immunogenomics Platform
More accurate, predictive biomarker analysis may assist in the selection of effective combinatorial immunotherapy treatments for patients. Additionally, the complexity of both the tumor and tumor microenvironment suggests a comprehensive approach is needed for robust characterization of the cancer ecosystem. The ImmunoID NeXT platform investigates key aspects of immunology; from elucidating mechanisms of tumor escape and detecting neoantigens, to identifying novel biomarker signatures and characterizing the immune repertoire. This presentation will focus on the current challenges facing investigators in immunoncological translational research including maximizing data generation from a single sample and the analysis of complex data.
Erin Newburn, MS, PhD
Associate Director, Field Applications Scientist, Personalis, Inc

3:35 pm
Afternoon Networking Break and Partnering Meetings

4:20 pm
Updates on PARP Inhibition
Darren Hodgson, PhD
Senior Principal Translational Scientist, Oncology iMED, AstraZeneca

4:40 pm
How Biomarker Combinations are as Rational as IO Combinations
The design of successful clinical strategies for therapeutic combinations has been hindered by the inability of single analyte biomarkers to deliver a comprehensive view of the immune system. Combination therapies require advanced methods for interrogating tumor immune composition and patient's immune response. Early results with multidimensional biomarkers, driven by predictive immune modeling, are enabling higher predictive accuracy for better patient selection and more robust treatment decisions.
Jon Armstrong
Chief Scientific Officer, Cofactor Genomics

5:00 pm
Panel: Next Generation Biomarkers
• What’s the cutting edge thinking on biomarkers?
• Predictive markers and what are they telling us about the biology
• What are the mechanisms of resistance/action?
• How do you measure them like PD1 expression and PDL1 expression?
• How much do you need to see in order to have confidence that that combination is going to work? With other agents that target other receptors, biomarkers could be a way to drive a patient stratification. Is that evolving in a positive way? Are we seeing novel things?
• Beyond that are there emerging technologies? Can we detect from blood, biomarkers that will be able to enable clinical desire?
• How are we using machine learning and AI to find additional insights?

Moderated by:
Ian McCaffery, PhD
VP and Head of Oncology Translational Research, Janssen Research and Development
Panelists:
- Paul Beresford, PhD  
  Chief Business Officer, Biodesix
- Daniel Chen, MD, PhD  
  Chief Medical Officer, IGM Biosciences
- Ohad Ilovich, PhD  
  Director, Translational Research, Invicro
- Ruslan Novosiadly, MD, PhD  
  Oncology Translational Medicine Team Lead, BMS
- Matthew Onsum, PhD  
  Director, Head of Diagnostics, Analytics, and Biomarkers, Seattle Genetics

5:45 pm
PD1 Resistance with a Multi-Omic Approach
Antti-PD-1 therapy has transformed cancer care but most patients do not respond. It is increasingly clear that there will be no single biomarker of response to aPD-1, and that a multi-omic approach will be required. This talk will address:
- Orthogonality and correlation of response biomarkers across histologies
- Integration of multi-omic data sets for mechanistic insights into tumor immunobiology
- The translational approaches to PD1 resistance program at the Parker Institute
The focus throughout will be on leveraging molecular data for translational impact.
Danny Wells, PhD  
Senior Data Scientist, Parker Institute for Cancer Immunotherapy

6:05 pm
Annual Networking Reception

DAY TWO - FRIDAY, JUNE 21, 2019

8:00 am
Morning Coffee/Tea

8:20 am
Co-Chair's Opening Remarks
Ian McCaffery, PhD  
VP and Head of Oncology Translational Research, Janssen Research and Development

9:00 am
Opening Keynote: Clinical Trials of Double Chimeric Antigen Receptor (CAR) T Cells and Engineered T Cell Combination Therapies
Bruce Levine, PhD  
Barbara and Edward Netter Professor in Cancer Gene Therapy, Perelman School of Medicine, University of Pennsylvania

9:20 am
Combination Strategies for CAR-T Therapies
Cell therapy has revolutionized the field of oncology by presenting an alternate paradigm to engineer the immune system to target and eradicate cancer. While cell therapy has shown dramatic success in certain hematologic malignancies, considerable obstacles still remain for it’s full potential to be realized. In this presentation, we will provide overview strategies and approaches that have the potential to enhance the activity of cell-based therapies and lead to enhanced anti-tumor activity.
Michael Kalos, PhD  
VP, Immuno-Oncology and Oncology Cellular Therapies, Janssen Oncology

9:40 am
Networking Café, Morning Break, Breakfast and Partnering Meetings

10:20 am
Multimodal T Cell Combinations for Cancer Therapy
Dmitry Pankov, MD  
Head, Non-Clinical Combinations Oncology Cell Therapy, GSK

10:40 am
High-Throughput Identification of Neoantigen-specific TCRs for Therapeutic Development
The Adaptive Biotechnologies TruTCR™ discovery technology enables the screening and identification of naturally-occurring TCRs at extraordinary throughput and scale. The TruTCR approach leverages a novel, highly sensitive, multiplex approach, known as MIRA™(Multiplexed Identification of T-cell Receptor Antigen specificity), which combines deep sequencing with...
cellular immunology techniques to assess TCR specificity to large numbers of query antigens. More than 400 antigens are routinely and simultaneously queried using MIRA, and antigen-specific TCRs at frequencies as low as 1 in 10 million are identified. TCRs are then reconstructed by accurate high-throughput pairing of TCRA with TCRB chains using Adaptive’s pairSEQÒ technology. Select candidate TCRs undergo further profiling and characterization, including functional avidity, cytokine release, cytotoxicity and safety evaluations. Adaptive has identified and characterized several high avidity TCRs against clinically relevant cancer antigens and shared neoantigens. These TCRs demonstrate differentiated therapeutic potential that includes promising cytolytic activity and safety profile.

Sharon Benzeno, PhD, MBA
SVP, Business Development, Adaptive Biotechnologies

10:55 am

New Opportunities for Cell Therapy Combinations:
- What are the new opportunities in cell therapy for combinations?
- What the challenges are going to be with the microenvironment?
- What is being done to engineer cell therapy?
- How do you develop CARs and TCRs that deliver payloads?
- How do you manufacture all of this beyond mouse models to figure out how to effectively do this in patients?
- How do you actually go about designing trials and testing hypothesis?
- How do you create the regulatory framework to do these types of studies?
- How do you engage with regulatory agencies to get these things moving?

Moderated by:
Michael Kalos, PhD
VP, Immuno-Oncology and Oncology Cellular Therapies, Janssen Oncology

Panelists:
Sharon Benzeno, PhD, MBA
SVP, Business Development, Adaptive Biotechnologies
Chaohong Fan, MD, PhD
Medical Officer, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research (CBER), FDA
Bruce Levine, PhD
Barbara and Edward Netter Professor in Cancer Gene Therapy, Perelman School of Medicine, University of Pennsylvania
Mark Stewart, PhD
VP, Science Policy, Friends of Cancer Research
Bahram (Bob) Valamehr, PhD
Chief Development Officer, Fate Therapeutics

Business Aspects for IO Combinations
Plenary Chair:
Asthika Goonewardene, MBA
Senior Biotech Analyst, Bloomberg Intelligence

11:40 am

Approaches to IO Combination Collaborations and Building on Existing Partnerships
- How do you think about partnering strategically?
- What are the innovative approaches?
- How can partnerships evolve between pharma and biotech?
- How can we as an industry consider those and improve on the process?
- If we look beyond checkpoint inhibitors, where is the next wave and how does that influence approaches to collaborations?

Moderated by:
Anton Xavier, MSc, MBA
Assistant Director, Technology and Business Development, New York State Center for Biotechnology

Panelists:
Madee Gooriah, PharmD
Director of Oncology Search & Evaluation for Business Development, BMS
Paul Stead, PhD
VP, Business Development, Adaptimmune
Loïc VINCENT, PhD
VP, Immuno-Oncology & Cell Therapy Discovery, and Research Partnerships, Takeda
Michael Woo, PharmD
Head, Search & Evaluation, Immuno-Oncology; Business Development & Licensing, Novartis Institutes for BioMedical Research

12:20 pm

Evaluating and Investing in IO Combinations
This fireside chat brings together perspectives from VCs, Crossover and Public Market investors on the following:
- How to evaluate the science and how to figure out who the winners are?
- From an investment perspective, what are the technologies right now and what needs to develop to make them happen?
- What science aspects and how much of it do investors at each stage require for decision making?

Moderated by:
Asthika Goonewardene, MBA
Senior Biotech Analyst, Bloomberg Intelligence

Fireside Guests:
Christiana Bardon, MD
Managing Director, Burrage Capital / MPM Capital Oncology Impact Fund
Carlo Rizzuto, PhD
Partner, Versant Ventures

1:00 pm

Networking Lunch and Partnering Meetings
2:00 pm
Addressing Operational Challenges of Multi-Therapy Combination Studies
This panel, led by Andy Lee, SVP, Head of Global Clinical Trial Operations, Merck will address the philosophy and pragmatics of synergistic therapies in combination trials. Key talking points include:
- How do you source the material, manage the expiry dates and acquire them in different countries?
- How do you set up a trial?
- What's the difference between doing your own combinations vs doing a study with an external collaborator?
- How do you go about contracting, deciding systems and processes, etc.
- Insourcing vs outsourcing: How do you work with two different sponsor's drugs and products?
- How do you set up your workforce that you firewall?
- Once the study is going, how do you manage the safety when you have two different combinations?
- How do you report the safety to different sponsors?
- How do you update and manage the informed consent?
- How do you run two studies together with competing sites and firewalling, etc?
Moderated by:
Andy Lee
SVP, Head of Global Clinical Trial Operations, Merck
Panelists:
Carol Haddad
Executive Director, CSSM Oncology, GCTO, Merck
Gretchen Hurst
Director, Oncology Project Leadership, IQVIA
Ron Korn, MD, PhD
Founder, Chairman and CMO, Imaging Endpoints
Beth Metzheiser
Head of Clinical Operations, Hematology and CRO Collaborations, BMS

3:00 pm
Emerging Results in the IO Field on PD1 Checkpoint Inhibitor Combination Therapy
In this talk, Dr Emmett Schmidt will share data he has compiled based on 300 clinical trials that include emerging response data. As a result of this analysis, Dr Schmidt found that most clinical combinations are showing combination activity above the equivalent monotherapy activity of the PD-1 combination agent. He will offer an approach to the analysis of “synergy” based on a recent review article. At this time, this analysis does not detect evidence for mathematical synergy in current PD-1 pathway inhibitor combination trials.
Emmett Schmidt, MD, PhD
Scientific Associate, VP of Clinical Oncology & Lead, External Collaborations Project Team, Merck Research Labs

3:15 pm
Pembrolizumab as a Foundational Partner for Combination Immune-Oncology Drug Development
There are quite a number of evolving data sets which help inform the direction of combination therapy. This talk addresses:
- The foundational nature of PD-1 antibodies as combination partners
- The utility of precision based tools for suggesting potential combinations
- Emerging data which are exemplars of the approach including:
  - Chemo-combinations
  - TKI-combinations
  - IO-IO combinations
Roy Baynes, MD, PhD
SVP & Head, Global Clinical Development, Chief Medical Officer, Merck Research Laboratories

3:35 pm
Bempegaldesleukin (NKTR-214): Harnessing the IL-2 Pathway in Combination Immunotherapies
- Bempegaldesleukin: Structure and function of an engineered IL-2 cytokine prodrug providing sustained IL-2Rβγ-biased signaling
- Preclinical PK, PD, MOA and combination with PD-1 checkpoint inhibition
- Clinical PK, PD, clinical response data and biomarkers in patients with melanoma and bladder cancer
- Combinations under investigation
Willem Overwijk, PhD
VP, Oncology Research, Nektar Therapeutics

4:15 pm
Taking a “Toll” on Cancer: Combination Strategies with TLR9 to Overcome Immunotherapy Resistance
- Tilsotolimod: Creating a beneficial tumor microenvironment by engaging innate immune pathways
- Clinical translation of the MOA in patients with melanoma and refractory solid tumors
- Improving clinical outcomes in PD-1 refractory metastatic melanoma
- Combination strategies beyond melanoma
Srinivas K Chunduru, PhD
VP, Translational Medicine, Idera Pharmaceuticals

4:35 pm
Clinical Updates on Vemurafenib + Cobimetinib + Anti-PDL1
Justine Cohen, DO
Oncologist, Center for Melanoma, Massachusetts General Hospital

4:55 pm
Conference Concludes