

FINAL DAYS TO REGISTER!

CAMBRIDGE HEALTHTECH INSTITUTE'S 13th ANNUAL

BIOMARKERS & IMMUNO-ONCOLOGY

WORLD CONGRESS 2017

The Leading Annual Meeting Where
Big Pharma and Biotech
Drive Innovation and Collaboration in
Biomarkers, Diagnostics and Immunotherapy

MAY 2 - 4, 2017 | PHILADELPHIA, PA | PHILADELPHIA MARRIOTT DOWNTOWN

2017 CONFERENCE PROGRAMS

MAY 2-3

- Clinical and Translational Biomarkers
- Immuno-Oncology Biomarkers
- Personalized Immunotherapy

MAY 3-4

- Biomarkers for Patient Selection
- Immune Profiling in Cancer
- Combination Immunotherapy

COURSES & WORKSHOPS

- Biomarker Assay Development and Validation
- Executive ThinkTank: Complementary Diagnostics
- Liquid Biopsy for Immuno-Oncology and Precision Medicine
- Next-Generation Sequencing as a Clinical Test
- PD-L1 Assays for Biomarkers and Companion Diagnostics
- Immune Monitoring in Cancer
- Preparing for Companion Dx Studies and FDA Submissions

DISTINGUISHED SPEAKERS



Robert Iannone
SVP & Head, Immuno-Oncology, AstraZeneca



Roy D. Baynes
SVP & Head, Global Clinical Development, Merck



George Poste
Chief Scientist, Complex Adaptive Systems
Arizona State Univ.



Nicholas C. Dracopoli
VP, Oncology Diagnostics, Janssen R&D



Lawrence J. Lesko
Clinical Professor, Systems Pharmacology
Univ. of Florida



Stefan Scherer
VP & Global Head, Correlative Science
Novartis



Marc Ladanyi
Chair, Molecular Oncology,
Memorial Sloan-Kettering Cancer Center



Zhen Su
VP & Head, Oncology
EMD Serono



Ignacio I. Wistuba
Chair, Translational Molecular Pathology
The Univ. of Texas MD, Anderson Cancer Center



Koustubh Ranade
Vice President, Translational Medicine
Medimmune



Jeff Fill
Director, Diagnostic Pathology
Eli Lilly and Company



Marielena Mata
Program Director,
Precision Medicine GlaxoSmithKline

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Short Courses

Clinical and Translational
Biomarkers

Immuno-Oncology Biomarkers

Personalized Immunotherapy

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CONFERENCE AT-A-GLANCE

MONDAY, MAY 1

12:00-5:00 pm	Short Course registration and Conference Pre-Registration		
1:00-4:00	Short Course* (SC1): Fit for Purpose Biomarker Assay Development and Validation (*Separate registration required)		
5:00-8:00	Dinner Workshop* (SC2): Liquid Biopsy for Immuno-Oncology and Precision Medicine		
5:00-8:00	Dinner Short Course* (SC3): Preparing for Companion Diagnostic Device Studies and Submissions to FDA		
	Clinical and Translational Biomarkers	Immuno-Oncology Biomarkers	Personalized Immunotherapy

TUESDAY, MAY 2

7:00 AM	Conference Registration and Morning Coffee		
8:00-9:25	Companion Diagnostic Development in Immuno-Oncology		
9:25-10:10	Coffee Break in the Exhibit Hall with Poster Viewing		
10:10-12:00 pm	Companion Diagnostic Development in Immuno-Oncology (Cont.)	Neoantigen-Targeted Therapies	
12:00-1:30	Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own		
1:30-5:00	Clinical Utility of Liquid Biopsy	Biomarkers to Predict Response to Immunotherapy	Personalized Cancer Vaccines
5:00-6:00	Welcome Reception in the Exhibit Hall with Poster Viewing		
5:30	Short Course Registration		
6:00-9:00	Dinner Short Course* (SC4): Next-Generation Sequencing as a Clinical Test (*Separate registration required)		
6:00-9:00	Dinner ThinkTank* (SC5): PD-L1 Assays for Biomarkers and Companion Diagnostics		

WEDNESDAY, MAY 3

7:30 AM	Breakfast Presentations (Sponsorship Opportunities Available) or Morning Coffee		
8:25-9:45	Translational Biomarkers in Drug Development	Immune Monitoring: Biomarkers of Response to Immunotherapy	
9:45-10:45	Coffee Break in the Exhibit Hall with Poster Viewing		
10:45-12:30 pm	Translational Biomarkers in Drug Development (Cont.)	Genomic Biomarkers for Immunotherapy Patient Selection	Personalized Cell Therapy
12:30	Close of Conference		
	Biomarkers for Patient Selection	Immune Profiling in Cancer	Combination Immunotherapy
11:00 AM	Conference Registration		
12:30	Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own		
1:30	Dessert Break in the Exhibit Hall with Poster Viewing		
2:00-3:20	Plenary Keynotes		
3:20-4:10	Refreshment Break in the Exhibit Hall with Poster Viewing		
4:10-5:45	Companion Diagnostics Assays: Biomarker Translation from Assay to Clinic	Immunophenotyping: Biomarker Discovery and Validation for Immuno-Oncology	Biomarkers for Combination Immunotherapy
5:45	Short Course Registration		
6:00-9:00	Dinner Executive ThinkTank* (SC6): Complementary Diagnostics (*Separate registration required)		
6:00-9:00	Dinner Short Course* (SC7): Immune Monitoring in Cancer		

THURSDAY, MAY 4

7:30 AM	Breakfast Presentations (Sponsorship Opportunities Available) or Morning Coffee		
8:25-10:15	Implementing Precision Medicine: Patient Stratification Strategies	Immunosequencing and Immune Cell Infiltration Profiling	Strategies for Immunotherapy Combinations
10:15-10:45	Networking Coffee Break		
10:45-12:25	Genomic Biomarkers for Personalized Therapy	Immunosequencing and Immune Cell Infiltration Profiling (Cont.)	Immune Modulators and Combinations
12:25-1:40	Enjoy Lunch on Your Own		
1:40-3:00	Biomarker-Driven Clinical Trials	Profiling the Tumor Microenvironment	Combining Immunotherapy with Other Modalities
3:00	Close of Conference		



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Robert Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins University

Philip M. Arlen, M.D., President & CEO, Precision Biologics

Sunita Badola, MS, Director, Functional Genomics, Takeda

Lourdes Barrera, Ph.D., Global Capability Director, Diagnostics, AstraZeneca

Roy D. Baynes, M.D., Ph.D., Senior Vice President and Head, Global Clinical Development, CMO, Merck Research Laboratories

Marijo Bilusic, M.D., Ph.D., Associate Research Physician, National Cancer Institute, National Institutes of Health

Joshua Brody, M.D., Director, Lymphoma Immunotherapy Program, Icahn School of Medicine at Mount Sinai

Jean-Marie Bruey, Ph.D., Companion Diagnostics Group Leader, Genentech

Michael E. (Ted) Burczynski, Ph.D., PPM Expert, Director, Personalized & Predictive Medicine, Analytics & Big Data, Teva Pharmaceuticals

Juliann Chmielecki, Ph.D., Associate Director, Translational Sciences, AstraZeneca

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Daniel Edelman, Ph.D., Core Manager, Clinical Molecular Profiling Core, National Cancer Institute, NIH

Olivier Elemento, Ph.D., Associate Professor & Associate Director, Institute for Computational Biomedicine, Department of Physiology and Biophysics, Weill Cornell Medicine

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Koustubh Ranade, Ph.D., Vice President, Translational Medicine, MedImmune

Adrian E. Rice, Ph.D., Senior Scientist, Immunology, Etubics Corporation

David B. Roth, M.D., Ph.D., Simon Flexner Professor & Chair, Pathology and Laboratory Medicine; Director, Penn Center for Precision Medicine, Perelman School of Medicine, University of Pennsylvania

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Janaki Veeraraghavan, Ph.D., Biologist, Office of *In Vitro* Diagnostics & Radiological Health, CDRH, FDA

Jeffrey Wallin, Ph.D., Group Leader/Senior Scientist, Oncology Biomarker Development, Genentech

William Watt, Ph.D., President & CEO, EpiThany

Glen J. Weiss, M.D., MBA, Director of Clinical Research and Phase I & II Clinical Trials at Cancer Treatment Centers of America, Goodyear, AZ

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Roman Yelensky, Ph.D., EVP Sequencing and Bioinformatics, Gritstone Oncology

Hua Yu, Ph.D., Professor & Co-Chair, Immuno-Oncology, Beckman Research Institute at City of Hope Comprehensive Cancer Center

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- Reception style
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MONDAY AFTERNOON, MAY 1 | 1:00 – 4:00 PM

Short Course

SC1: FIT-FOR-PURPOSE BIOMARKER ASSAY DEVELOPMENT AND VALIDATION

Instructors:

John L. Allinson, FIBMS, Head, Biomarker Strategy, Drug Development Services, LGC Group

Viswanath Devanarayan, Ph.D., Global Head & Senior Research Fellow, Exploratory Statistics & Bioinformatics, AbbVie, Inc.

MONDAY EVENING, MAY 1 | 5:00 – 8:00 PM

Dinner Workshop

SC2: LIQUID BIOPSY FOR IMMUNO-ONCOLOGY AND PRECISION MEDICINE

Characterizing the Cancer Genome from the Circulation

Rebecca Leary, Ph.D., Senior Investigator, Next Generation Diagnostics, Oncology Research, Novartis Institutes for BioMedical Research

The Prognostic Potential of Tumor-Derived Exosomes Isolated from Plasma of Patients with Cancer

Theresa L. Whiteside, Ph.D., Professor, Pathology, Immunology and Otolaryngology, University of Pittsburgh Cancer Institute

Tumor-Specific and PD-L1 Subtype CTC Capture/Detection in Relevance of Clinical Utility

Shulin Li, Ph.D., WT & Louise Jarrett Moran Distinguished Chair & Professor, Pediatrics – Research, The University of Texas MD Anderson Cancer Center

Dinner Short Course

SC3: PREPARING FOR COMPANION DIAGNOSTIC DEVICE STUDIES AND SUBMISSIONS TO FDA

Instructor:

Kate Simon, Ph.D., Senior Consultant, Biologics Consulting

TUESDAY EVENING, MAY 2 | 6:00 – 9:00 PM

Dinner Short Course

SC4: NEXT-GENERATION SEQUENCING AS A CLINICAL TEST

Instructors:

Seth Crosby, M.D., Director, Partnerships & Alliances, Washington University School of Medicine

Avni Santani, Ph.D., Director, Division of Genomic Diagnostics, Children's Hospital of Philadelphia; Assistant Professor, Clinical Pathology, Perelman School of Medicine, University of Pennsylvania

Dinner ThinkTank

SC5: PD-L1 ASSAYS FOR BIOMARKERS AND COMPANION DIAGNOSTICS

Developing an Immunohistochemistry Test for “Programmed Cell Death 1 Ligand” (PD-L1) as a Companion Diagnostic for Pembrolizumab

Kenneth Emancipator, M.D., Executive Medical Director and Head of Companion Diagnostics, Merck & Co.

Regulatory Update on PD-L1 Assays

Janaki Veeraraghavan, Ph.D., Biologist, Office of In Vitro Diagnostics & Radiological Health, CDRH, FDA

PD-L1 as a Biomarker: Opportunities and Challenges

Kurt A. Schalper, M.D., Ph.D., Assistant Professor, Pathology and Medicine (Medical Oncology), Yale School of Medicine

Panel Discussion with Speakers

Moderator: Kenneth Emancipator, M.D., Executive Medical Director and Head of Companion Diagnostics, Merck & Co.

Additional Panelists:

Jean-Marie Bruey, Ph.D., Companion Diagnostics Group Leader, Genentech

Morganna Freeman, D.O., Medical Oncologist, Immunotherapeutics, The Angeles Clinic and Research Institute

Arnold B. Gelb, M.D., MS, FASCP, FCAP, Senior Director, Global Clinical Biomarkers and Companion Diagnostics, EMD Serono

WEDNESDAY EVENING, MAY 3 | 6:15 – 9:15 PM

Dinner Executive ThinkTank

SC6: COMPLEMENTARY DIAGNOSTICS

Opportunities and Challenges in Developing and Commercializing Complementary Diagnostics

Peter Hoehn, JD, Global Business Leader, Janssen Diagnostics

Diagnostics: What's in a Label?

Marielena Mata, Ph.D., Program Director, Precision Medicine & Companion Diagnostics, GlaxoSmithKline

Supporting Therapeutic Outcomes: Complementary Diagnostics in Immuno-Oncology

George A. Green IV, Ph.D., Group Director, Pharmacodiagnostic Center of Excellence, Bristol-Myers Squibb

Companion vs. Complementary from Clinical and Regulatory Perspectives

Abdel B. Halim, Pharm.D., Ph.D., DABCC-CC, DABCC-MD, DABCC-Tox, Vice President, Translational Medicine, Biomarkers & Diagnostics, Celldex Therapeutics

Complementary vs. Companion Diagnostics: Two Sides of the Same Coin?

Victoria H. Brophy, Ph.D., Director, Genomics & Oncology Research, Roche Molecular Systems, Inc.

Dinner Short Course

SC7: IMMUNE MONITORING IN CANCER

Instructor:

Sacha Gnjatic, Ph.D., Associate Professor, Tisch Cancer Institute, Hematology/Oncology, Immunology, Icahn School of Medicine at Mount Sinai

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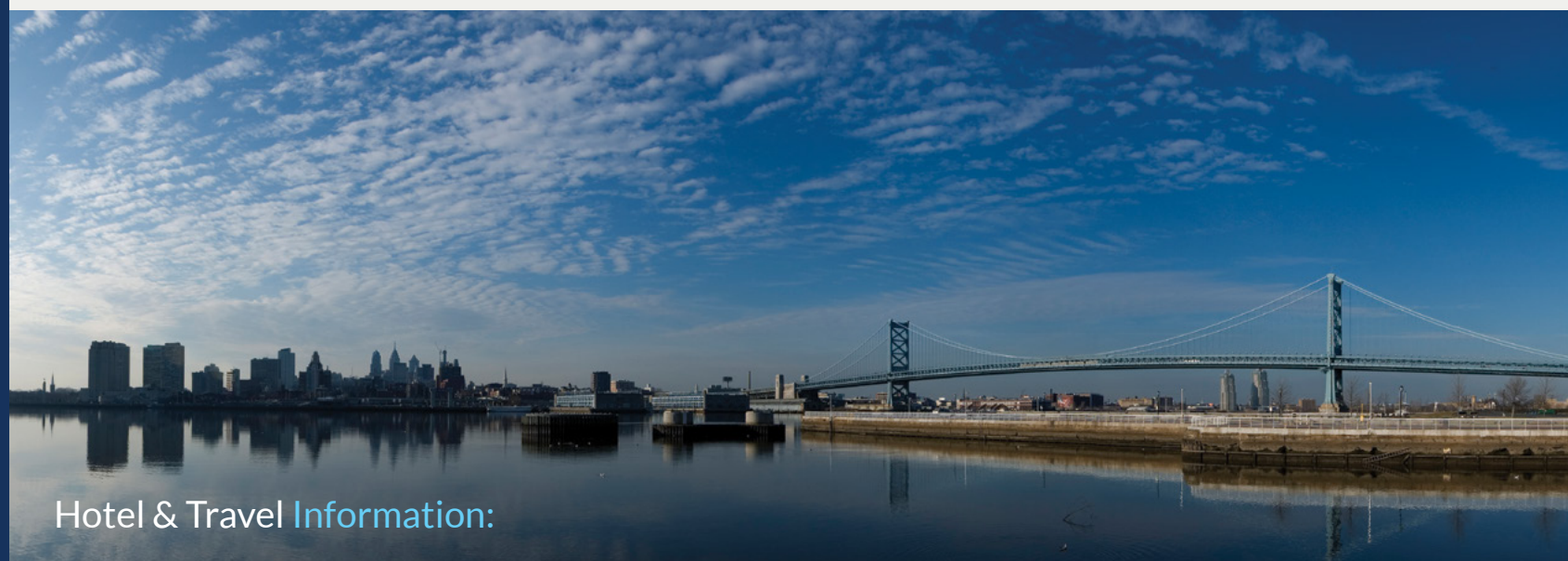
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Conference Venue & Hotel:
Philadelphia Marriott Downtown
1201 Market Street
Philadelphia, PA 19107
Phone: 215-625-2900

Discounted Room Rate: \$269 s/d
Discounted Room Rate Cut-off Date: April 4, 2017

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MONDAY, MAY 1

12:00 - 5:00 pm Short Course Registration and Conference Pre-Registration

1:00 - 4:00 Short Course*

SC1: Fit-for-Purpose Biomarker Assay Development and Validation

5:00 - 8:00 Dinner Workshop*

SC2: Liquid Biopsy for Immuno-Oncology and Precision Medicine

5:00 - 8:00 Dinner Short Course*

SC3: Preparing for Companion Diagnostic Device Studies and Submissions to FDA

**Separate registration required*

TUESDAY, MAY 2

7:00 am Conference Registration and Morning Coffee

COMPANION DIAGNOSTIC DEVELOPMENT IN IMMUNO-ONCOLOGY

8:00 Chairperson's Opening Remarks

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

8:10 Immuno-Oncology Companion Diagnostics Development: A Complex Systems Approach

Lourdes Barrera, Ph.D., Global Capability Director, Diagnostics, AstraZeneca

Development of companion diagnostics for emerging immunotherapies is more complicated because they are not dependent on driver mutations in the drug target. Consequently, we need to develop new biomarker strategies for the development of immunotherapies. During this review, we will give some examples of how a complex systems approach is supporting the development of new biomarkers and potentially companion and complementary diagnostic tests.

8:35 The Evolution of Oncology Companion Diagnostics from Signal Transduction to Immuno-Oncology

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

Companion diagnostic (CDx) tests for signal transduction inhibitors measure the activation status of the drug target. CDx tests for immune modulating drugs will be much more complicated and need to measure the immune status of tumors and differentiate those with a suppressed immune response from those with no prior immune response. These new CDx tests will drive the choice of therapeutic intervention with checkpoint inhibitors or alternative approaches to prime a new immune response.

9:00 An Industry Perspective on Clinical Biomarkers and Companion Diagnostics for Checkpoint Inhibitor Therapies

Arnold B. Gelb, M.D., MS, FASCP, FCAP, Senior Director, Global Clinical Biomarkers and Companion Diagnostics, EMD Serono

Ongoing trends in clinical oncology support the value proposition of using a precision medicine approach for patient selection and enrichment strategies when developing immuno-oncology therapeutics. This presentation will review aspects pertinent to checkpoint inhibitor therapies of exploratory analyses of clinical biomarkers to identify predictive/prognostic clinical biomarkers that may lead to co-development of a companion diagnostic or a complementary diagnostic. Examples will be drawn from the current status of approved PD-L1 assays, citing the limitations thereof, and other clinical biomarkers and candidate companion or complementary diagnostics, including characterizations of the tumor microenvironment, immune cell phenotyping, T cell repertoires, IFN-gamma gene signature, neoantigen burden/mutational load, microsatellite instability status, and potentially other "hot topics" such as liquid biopsies.

9:25 Coffee Break in the Exhibit Hall with Poster Viewing

COMPANION DIAGNOSTIC DEVELOPMENT IN IMMUNO-ONCOLOGY (CONT.)

10:10 Chairperson's Remarks

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

10:15 RNA, DNA or Protein? Or All Three? Development of Multiple Diagnostics Predicting Response to Pembrolizumab

Matt Marton, Ph.D., Director, Genomics and Companion Diagnostics, Translational Biomarkers, Merck

An effective diagnostic strategy for anti-PD1 therapy may require multiple predictive biomarkers that assess the complexity of both tumor biology and the immune system. In addition to PD-L1 protein expression, multiple biomarkers, including gene expression and mutation burden, have been proposed as predictors of response to anti-PD1 therapy. We will discuss analytical performance characteristics of potential diagnostic devices under development, including an RNA-based gene expression device being studied in multiple indications.

10:40 Precision Medicine and IO Biomarkers

Jean-Marie Bruey, Ph.D., Companion Diagnostics Group Leader, Genentech

The past decade has witnessed a revolution in our understanding of the immune system and our ability to develop safer and more effective immunotherapies. Classification of diseases according to their biological underpinnings will guide more precise targeting of new therapies, and molecular/biomarker characterization of therapeutic responses will provide direction for therapy improvement. The PD-1/PD-L1 checkpoint inhibitors are important contributions in finding more effective treatments against cancer, and it is likewise important that we have companion diagnostics available that will guide treatment.



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11:05 Enabling Immuno-Oncology Based Development through Image-Based Cell Sorting to Recover Pure Cell Populations from Complex Patient Tumor Tissue Specimens

Farideh Bischoff, Ph.D., Chief Clinical Development Officer, Menarini Silicon Biosystems

Ana Paula Da Silva, Ph.D., Senior Scientist, Menarini Silicon Biosystems

Tumor infiltrating lymphocytes (TILs) are biomarkers that play a critical role in cancer, including differential diagnosis, determination of prognosis, treatment response, and disease progression. However, analysis of gene expression in fresh tissue may not accurately depict the gene profile as it can change aggressively during lymphocyte isolation and RNA extraction. In this presentation, we demonstrate the use of the DEPArray™ platform to isolate pure populations of lymphocytes from fixed mouse tissue for downstream RNA analysis.



11:35 Enabling Companion Diagnostic Development for Challenging Biomarkers with RNAscope: A Quantitative In Situ RNA Biomarker Platform

Robert Monroe, M.D., Ph.D., CMO, Advanced Cell Diagnostics, Inc.

Recent advances have made RNA ISH an attractive platform for companion diagnostics. RNA ISH now has the ability to detect RNA expression in automated, chromogenic assays at the single cell level in histological sections, allowing for biomarker assessment by diagnosticians at the light microscope. This presentation will review how RNA ISH addresses various issues with IHC and other CDx platforms and how it is being used in CDx development for a variety of challenging biomarkers.



12:05 Session Break

12:15 pm Luncheon Presentation: Simoa for the Ultra-Sensitive Measurement of Proteins as Biomarkers of Immuno-Oncology Therapeutics

Mark Roskey, Ph.D., Vice President and General Manager, Quanterix

We will describe the use of single molecule arrays (Simoa) to measure proteins that are emerging as important biomarkers for the effectiveness of immuno-oncology therapies. Immune-targeted therapies, e.g., checkpoint inhibitors, have emerged as the next generation approaches to treating cancer.



CLINICAL UTILITY OF LIQUID BIOPSY

1:30 Chairperson's Remarks

Stefan Scherer, M.D., Ph.D., Vice President, Global Head, Correlative Science, Novartis

1:35 Liquid Biopsy – Next-Generation Medical Innovation

Stefan Scherer, M.D., Ph.D., Vice President, Global Head, Correlative Science, Novartis

Predictive biomarkers that can guide treatment decisions have been sought after for a long time to help identify patient sub-populations that are most likely to respond to specific cancer therapies. Cell free DNAs (cfDNAs) are short fragments of DNA present outside of cells, in the circulatory system. Specific non-invasive “liquid biopsy” can provide personalized and complementary information to help with the diagnosis, prognosis, and management of treatment in patients with cancer. In addition, it provides a dynamic management of cancer and has the potential to enable a paradigm shift in the treatment regimen and drug development.

2:00 Application of Liquid Biopsy in Characterization of Patients with Advanced Small Cell Lung Carcinoma

Sunita Badola, MS, Director, Functional Genomics, Takeda

2:25 Antibody Independent Isolation of Rare Cells: Analytical Aspects

Craig Miller, Clinical Studies Director, ANGLE plc

The requirements and challenges for analytical validation of an antibody independent rare cell isolation system will be presented.



2:40 High Definition Multiplexing for Biomarker Discovery

Louis Levy, Director, Corporate and Business Development, Ultivue

Biomarker discovery in immuno-oncology requires the analysis of multiple protein markers (n>4) with their spatial relationships at an amenable throughput. The scrutiny of the tumor micro-environment demands whole-slide multiplexed images featuring immune and tumor cells. Ultivue's InSituPlex platform fulfills this need with the data reproducibility relevant to CDx.



2:55 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Liquid Biopsies in Personalized Medicine in Cancer

Filip Janku, M.D., Ph.D., Assistant Professor, Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center

Assessment of genomic aberrations, which is required for precision medicine, has been challenging because of the difficulties in capturing intratumoral heterogeneity and in real-time assessment of tumors. Recent advances in technology have enabled detection and analysis of cell-free DNA in cancer patients, which provides real-time assessment of tumor evolution. The recent advances in our understanding of the clinical utility of cell-free DNA and the future directions for its use in cancer management will be discussed.



Clinical and Translational Biomarkers

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4:10 Quantification of Somatic Chromosomal Rearrangements in Circulating Cell-Free DNA from Ovarian Cancers

George Vasmatzis, Ph.D., Assistant Professor, Laboratory Medicine and Pathology; Co-Director, Biomarker Discovery Program, Mayo Clinic

Our team has developed MPseq, an accurate and inexpensive whole genome sequencing platform that has been used to detect structural variants. MPseq is a combination of a protocol and algorithms that can deliver a detailed description of all DNA rearrangements at almost nucleotide resolution, thus providing the sequence of a patient's tumor-specific junctions. Such junctions can be subsequently detected in the plasma of these patients using quantitative PCR (qPCR).

4:35 Counterintuitive Observations Made While cfDNA-Watching

Seth Crosby, M.D., Director, Partnerships & Alliances, Washington University School of Medicine

This presentation will cover: 1) enrichment by baits rather than amplification, 2) sometimes less (uniqueness) is actually more, 3) informatics challenges.

5:00 Welcome Reception in the Exhibit Hall with Poster Viewing

5:30 Short Course and ThinkTank Registration

6:00-9:00 pm Dinner Short Course*

SC4: Next-Generation Sequencing as a Clinical Test

6:00-9:00 pm Dinner ThinkTank*

SC5: PD-L1 Assays for Biomarkers and Companion Diagnostics

*Separate registration required

WEDNESDAY, MAY 3

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

TRANSLATIONAL BIOMARKERS IN DRUG DEVELOPMENT

7:55 Chairperson's Remarks

Michael E. (Ted) Burczynski, Ph.D., PPM Expert, Director, Personalized & Predictive Medicine, Analytics & Big Data, Teva Pharmaceuticals

8:00 Translational Medicine to Increase the Probability of Success of Clinical Trials

Maria Jure-Kunkel, D.V.M., Ph.D., Director, Immuno-Oncology Translational Medicine, MedImmune

To increase the probability of success of early clinical trials, we employ a translational medicine approach to first understand disease heterogeneity at the molecular level and develop hypotheses about which patients will benefit the most from therapeutics in clinical development. I will present examples from

ongoing clinical development programs to illustrate how we apply this translational medicine approach to MedImmune's pipeline.

8:25 Use of Ultra-Sensitive Multiplex Protein Arrays in Immuno-Oncology Biomarker Development

Andrew Nixon, Ph.D., MBA, Associate Professor of Medicine and Director of the Duke Phase I Biomarker Laboratory, Molecular Reference Laboratory, Duke University

This study helps us to understand the application of ultra-sensitive protein multiplex array in biomarker development, describe the levels of several key immunologic cytokines across a variety of trials and patients and benchmark to more traditional methodologies, and understand the use of these data to develop novel pharmacodynamics, prognostic and predictive biomarkers.

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8:55 From Preclinical Model Mechanisms to Clinical Hypotheses Testing in Huntington's Disease

Michael E. (Ted) Burczynski, Ph.D., PPM Expert, Director, Personalized & Predictive Medicine, Analytics & Big Data, Teva Pharmaceuticals

The present talk will discuss recent laboratory investigations into, and subsequent modeling of, disease mechanisms in an animal model of Huntington's disease. The talk will highlight insights gained into the mechanism of action of therapeutic candidate(s), as well as potential patient stratification approaches to be tested in future clinical studies which were informed by a systems-level analysis of the animal disease model and subsequent pathway and informatics approaches to identify relevant human markers to evaluate.

9:20 Improved Monitoring of Tumor Growth with a Novel Serum Proliferation Biomarker

Martin Shaw, Business Development Manager, AroCell AB

The AroCell TK210 ELISA is a novel, sensitive and specific assay for serum Thymidine Kinase 1, a well-known proliferation biomarker. It is the first CE-marked TK1 ELISA. Data will be presented on the value of the AroCell TK210 ELISA in the study of a range of hematological and solid tumors.

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9:35 The Gut Microbiome as a Biomarker of Disease and Treatment Response

Take Ogawa, Director, Second Genome, Inc.

Microbiomes are complex communities of microbes that interact with each other and their surrounding environment (e.g. tumors, gut or skin). Understanding which microbes alleviate or exacerbate health outcomes is leading to novel insights for deepening our understanding of disease, uncovering new therapeutic approaches and uncovering predictive biomarkers.

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 SECOND GENOME SOLUTIONS

9:50 Coffee Break in the Exhibit Hall with Poster Viewing



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10:45 Can We Predict Nephrotoxicity before It Occurs: The Promise of Metabolomic Biomarkers

Lawrence J. Lesko, Ph.D., Clinical Professor, Center for Pharmacometrics and Systems Pharmacology, University of Florida, Lake Nona

Safety, not efficacy, is the single most important reason for project closure in new drug development. Over 50% of failures in early phase development and 30% in mid- to late-phase development are due to unacceptable adverse drug events. Unanticipated renal toxicity accounts for 10% of these adverse events. Metabolomic biomarkers can be used as early reporters of drug-induced acute kidney injury thereby improving upon the use of traditional markers of renal function.

11:10 Identification and Translation of Pharmacodynamic Biomarkers from Bench to Bedside

Tammie Yeh, Ph.D., Associate Director, iMED Oncology Translational Sciences, AstraZeneca

Providing evidence in the clinic that the compound being tested is modulating its target and having the expected effects can be extremely informative during drug development. This information can help with building confidence in the compound, determining optimal dosing/scheduling, or understanding negative efficacy data; ultimately, these data can be useful when programs need to be prioritized. Two examples of pharmacodynamic (PD) biomarkers will be presented. The first is on the identification and validation of a robust PD biomarker for BET/BRD4 inhibitors using preclinical studies. The second is on the generation and interpretation of PD data from paired tumor biopsies from a Phase I "anti PD-L1 + kinase inhibitor" combination trial.

11:35 Enabling Clinical Development of Therapeutics with Greater Confidence: The Use of Pharmacodynamic Biomarkers in Early Stage Clinical Studies to Demonstrate Target Engagement

Mark Matijevic, Associate Director and Head, Translational Biomedicine Lab, Eisai AiM Institute

12:00 pm Advanced and Agile Visual Analytics for Biomarker Discovery

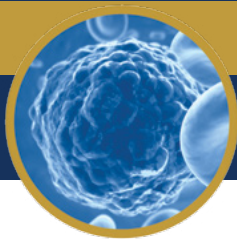
Eduardo Gonzalez, Ph.D., Product Manager, PerkinElmer Informatics

- Using the cloud for translational data storage and advanced analytics
- Signals for Translational: a platform for Translational medicine
- Extending Spotfire visual analytics with flexible Apps

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12:30 Close of Conference



Immuno-Oncology Biomarkers

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MONDAY, MAY 1

12:00 - 5:00 pm Short Course Registration and Conference Pre-Registration

1:00 - 4:00 Short Course*

SC1: Fit-for-Purpose Biomarker Assay Development and Validation

5:00 - 8:00 Dinner Workshop*

SC2: Liquid Biopsy for Immuno-Oncology and Precision Medicine

5:00 - 8:00 Dinner Short Course*

SC3: Preparing for Companion Diagnostic Device Studies and Submissions to FDA

**Separate registration required*

TUESDAY, MAY 2

7:00 am Conference Registration and Morning Coffee

COMPANION DIAGNOSTIC DEVELOPMENT IN IMMUNO-ONCOLOGY

8:00 Chairperson's Opening Remarks

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

8:10 Immuno-Oncology Companion Diagnostics Development: A Complex Systems Approach

Lourdes Barrera, Ph.D., Global Capability Director, Diagnostics, AstraZeneca
 Development of companion diagnostics for emerging immunotherapies is more complicated because they are not dependent on driver mutations in the drug target. Consequently, we need to develop new biomarker strategies for the development of immunotherapies. During this review, we will give some examples of how complex systems approach is supporting the development of new biomarkers and potentially companion and complementary diagnostic tests.

8:35 The Evolution of Oncology Companion Diagnostics from Signal Transduction to Immuno-Oncology

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

Companion diagnostic (CDx) tests for signal transduction inhibitors measure the activation status of the drug target. CDx tests for immune modulating drugs will be much more complicated and need to measure the immune status of tumors and differentiate those with a suppressed immune response from those with no prior immune response. These new CDx tests will drive the choice of therapeutic intervention with checkpoint inhibitors or alternative approaches to prime a new immune response.

9:00 An Industry Perspective on Clinical Biomarkers and Companion Diagnostics for Checkpoint Inhibitor Therapies

Arnold B. Gelb, M.D., MS, FASCP, FCAP, Senior Director, Global Clinical Biomarkers and Companion Diagnostics, EMD Serono

Ongoing trends in clinical oncology support the value proposition of using a precision medicine approach for patient selection and enrichment strategies when developing immuno-oncology therapeutics. This presentation will review aspects pertinent to checkpoint inhibitor therapies of exploratory analyses of clinical biomarkers to identify predictive/prognostic clinical biomarkers that may lead to co-development of a companion diagnostic or a complementary diagnostic. Examples will be drawn from the current status of approved PD-L1 assays, citing the limitations thereof, and other clinical biomarkers and candidate companion or complementary diagnostics, including characterizations of the tumor microenvironment, immune cell phenotyping, T cell repertoires, IFN-gamma gene signature, neoantigen burden/mutational load, microsatellite instability status, and potentially other "hot topics" such as liquid biopsies.

9:25 Coffee Break in the Exhibit Hall with Poster Viewing

COMPANION DIAGNOSTIC DEVELOPMENT IN IMMUNO-ONCOLOGY (CONT.)

10:10 Chairperson's Remarks

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

10:15 RNA, DNA or Protein? Or All Three? Development of Multiple Diagnostics Predicting Response to Pembrolizumab

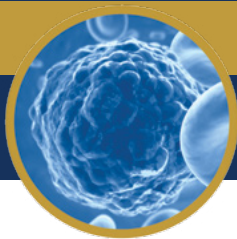
Matt Marton, Ph.D., Director, Genomics and Companion Diagnostics, Translational Biomarkers, Merck

An effective diagnostic strategy for anti-PD1 therapy may require multiple predictive biomarkers that assess the complexity of both tumor biology and the immune system. In addition to PD-L1 protein expression, multiple biomarkers, including gene expression and mutation burden, have been proposed as predictors of response to anti-PD1 therapy. We will discuss analytical performance characteristics of potential diagnostic devices under development, including an RNA-based gene expression device being studied in multiple indications.

10:40 Precision Medicine and IO Biomarkers

Jean-Marie Bruey, Ph.D., Companion Diagnostics Group Leader, Genentech

The past decade has witnessed a revolution in our understanding of the immune system and our ability to develop safer and more effective immunotherapies. Classification of diseases according to their biological underpinnings will guide more precise targeting of new therapies, and molecular/biomarker characterization of therapeutic responses will provide direction for therapy improvement. The PD-1/PD-L1 checkpoint inhibitors are important contributions in finding more effective treatments against cancer, and it is likewise important that we have companion diagnostics available that will guide treatment.



Immuno-Oncology Biomarkers

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11:05 Enabling Immuno-Oncology Based Development through Image-Based Cell Sorting to Recover Pure Cell Populations from Complex Patient Tumor Tissue Specimens

Farideh Bischoff, Ph.D., Chief Clinical Development Officer, Menarini Silicon Biosystems

Ana Paula Da Silva, Ph.D., Senior Scientist, Menarini Silicon Biosystems



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Robert Monroe, M.D., Ph.D., CMO, Advanced Cell Diagnostics, Inc.

Recent advances have made RNA ISH an attractive platform for companion diagnostics. RNA ISH now has the ability to detect RNA expression in automated, chromogenic assays at the single cell level in histological sections, allowing for biomarker assessment by diagnosticians at the light microscope. This presentation will review how RNA ISH addresses various issues with IHC and other CDx platforms and how it is being used in CDx development for a variety of challenging biomarkers.



12:05 Session Break

12:15 pm Luncheon Presentation: Simoa for the Ultra-Sensitive Measurement of Proteins as Biomarkers of Immuno-Oncology Therapeutics

Mark Roskey, Ph.D., Vice President and General Manager, Quanterix

We will describe the use of single molecule arrays (Simoa) to measure proteins that are emerging as important biomarkers for the effectiveness of immuno-oncology therapies. Immune-targeted therapies, e.g., checkpoint inhibitors, have emerged as the next generation approaches to treating cancer.



BIOMARKERS TO PREDICT RESPONSE TO IMMUNOTHERAPY

1:30 Chairperson's Remarks

Ann Kapoun, Ph.D., Vice President, Translational Medicine, OncoMed Pharmaceuticals

1:35 The New Precision Medicine: The Role of Dynamic Tumor and Immune Sampling in Immunotherapy

Morganna Freeman, D.O., Medical Oncologist, Immunotherapeutics, The Angeles Clinic and Research Institute

Immunotherapy has revolutionized the oncology treatment landscape, and as therapies evolve, there is a recognized need for biomarkers to inform the likelihood and duration of response. Radiologic assessments, i.e. RECIST, may be supplanted by biologically relevant markers in order to develop timely, cost-effective, and potentially personalized therapy. This presentation will review dynamic tumor and immune sampling as early markers of clinical response and their emerging role in clinical decision making.

2:00 Developing Biomarker Strategies for Immuno-Oncology

Ann Kapoun, Ph.D., Vice President, Translational Medicine, OncoMed Pharmaceuticals

This presentation will cover: precision medicine in IO, challenges to developing biomarkers preclinically in the IO space, and examples of clinical applications.

2:25 An RNA-Based Immunophenotyping Assay; Robust Tumor Microenvironment Characterization from a Single RNA Isolation

Jarret Glasscock, Ph.D., CEO, Cofactor Genomics, Inc.

Immune recognition, activation, and infiltration are all required for effective clearance of a tumor by the immune system. Impairment of tumor avoidance mechanisms each requires a different therapeutic strategy. We have developed Paragon to provide a comprehensive profile of a tumor's microenvironment, including measurement of the expression levels of immune checkpoint genes, quantification of the total mutational burden of the tumor, and levels of infiltration of multiple immune cell subtypes; from a single RNA sample.



2:55 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Biomarker Considerations in Early Phase Immunotherapy Clinical Trials

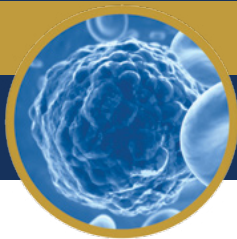
Lucy Xu, Ph.D., Associate Director, Biomarker Development Support & Global Health, hhc Data Creation Center, Eisai

The recent successes in immuno-oncology have been attained with immune checkpoint blockade, targeting T-lymphoid cell-based immunosuppressive mechanisms. Despite success with checkpoint inhibitor monotherapies, some patients develop resistance. Successful integration of the large body of new data from the translational science disciplines, including biomarkers, is critical. As a case study, a novel first-in-class immunotherapy drug targeting myeloid immunosuppressive mechanisms and clinical biomarker approaches used will be discussed.

4:10 Rational Biomarker Development for Checkpoint Inhibition in Colon Cancer

Robert Anders, M.D., Ph.D., Associate Professor, Pathology, Johns Hopkins University

Cancer samples can be used to predict response to treatment. For example, patients whose breast cancer samples express HER2/neu may be treated with and respond to HER2 blockade. Recently PD-L1 expression has been touted as a predictive biomarker for immune therapy. While PD-L1 does have some predictive power, it is not a perfect biomarker. A better approach for developing predictive biomarkers is to integrate genomic, protein and immunologic markers. When this strategy is applied to patients with colorectal cancer, it is possible to select over 90% of patients that are likely to show a biologic response to anti-PD-1/L1 therapy. This lecture will cover ideas of integrating multiple platforms to predict who will respond to therapy.



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4:35 Identifying Immune Biomarkers for Treatment Prognosis and Response in Genitourinary Malignancies

Susan F. Slovin, M.D., Ph.D., Attending Physician, Member, Genitourinary Oncology Service, Sidney Kimmel Center for Prostate and Urology Cancers, Memorial Sloan Kettering Cancer Center; Professor, Medicine, Weill Cornell Medical College

The identification of novel immune-based biomarkers that can portend treatment response or change in a cancer's biology remains a major imperative for clinical trials with immunologic agents. Controversy exists from clinical trial to clinical trial for a specific malignancy with regard to the up- or down-regulation of checkpoint markers such as PD-1 and PD-L1, and their association with clinical benefit, thereby making it difficult to assess their role as biomarkers. The potentials and pitfalls of using immune biomarkers will be discussed with relevance to current successful Phase II and Phase III trials for genitourinary cancers.

5:00 Welcome Reception in the Exhibit Hall with Poster Viewing

5:30 Short Course and ThinkTank Registration

6:00 - 9:00 pm Dinner Short Course*

SC4: Next-Generation Sequencing as a Clinical Test

6:00 - 9:00 pm Dinner ThinkTank*

SC5: PD-L1 Assays for Biomarkers and Companion Diagnostics

*Separate registration required

WEDNESDAY, MAY 3

7:30 am Morning Coffee

IMMUNE MONITORING: BIOMARKERS OF RESPONSE TO IMMUNOTHERAPY

7:55 Chairperson's Remarks

Michael J. Overman, M.D., Associate Professor, Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center

8:00 Immune-Profiling Platform for Biomarker Discovery in Immune-Oncology

Ignacio I. Wistuba, M.D., Professor & Chair, Translational Molecular Pathology, The University of Texas MD Anderson Cancer Center

The discovery of new molecules and pathways with pivotal functions regulating the immune system facilitated the emergence of new cancer treatments and the investigation of novel biomarkers to predict response. The development of these biomarkers requires the participation of immunology, pathology and genomics. We developed a translational molecular pathology immune-profiling platform to discover and validate biomarkers in tissue and fluids for immune-oncology in clinical samples from patients in clinical trials.

8:25 NGS Solutions Across IO Drug Development: From Biomarker Discovery to IVD

John Simmons, Ph.D., Director, Translational Science and Diagnostics, Personal Genome Diagnostics

Personal Genome Diagnostics is a next-generation sequencing (NGS) company that collaborates with Bio-Pharma to support biomarker discovery and diagnostic development with assays using both tissue (FFPE) and plasma (ctDNA) inputs. Here we will discuss applications of our core technologies, including whole exome sequencing (WES), neoantigen prediction, RNA-Seq, targeted ctDNA panels, tumor mutational burden (TMB), and microsatellite instability (MSI) assays relevant to the IO space.

8:55 Immune Monitoring of Cancer Vaccines and Immunotherapy: What Have We Learned and Where to Go Next?

Sacha Gnjjatic, Ph.D., Associate Professor, Tisch Cancer Institute, Hematology/Oncology, Immunology, Icahn School of Medicine at Mount Sinai

With clinical success of cancer immunotherapy, it is essential to understand the mechanisms of novel drugs by measuring their effect on immune cells, in the periphery and at the tumor site. Novel approaches and technologies are needed to address the complex task of identifying biomarkers of clinical activity and to improve the design of future therapies.

9:20 Biomarker Strategies for Cancer Vaccine Trials

Stephanie Traub, Ph.D., Biomarker Specialist, Centre for Drug Development, Cancer Research UK

Recent developments in the PD-1 field have shown promising progress in combination of checkpoint inhibitors and cancer vaccines. However, one critical point that hasn't been answered yet, which is probably the initial pitfall of cancer vaccines, is the question of how an effective immune response should look and how this immune response can be monitored.

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

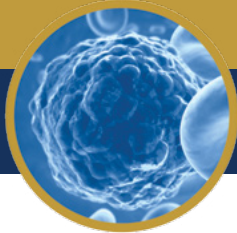
GENOMIC BIOMARKERS FOR IMMUNOTHERAPY PATIENT SELECTION

10:45 The Evolving Role of Immune Checkpoint Therapy in Colorectal Cancer with and without Deficient Mismatch Repair

Michael J. Overman, M.D., Associate Professor, Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center

Immune checkpoint therapy targeting PD-1/PD-L1 has shown robust activity in colorectal cancer with mismatch deficiency or microsatellite instability (MSI-high) but not microsatellite stable (MSS) colorectal cancer. It is now clear that MSI-high cancers represent a unique molecular tumor subset that should be approached with immune-based therapy. This talk will discuss the current combinatorial efforts within MSI-high colorectal cancer and also the emerging combinations that are being explored in MSS colorectal cancer.

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11:10 Somatic Alterations in HLA Genes as an Immune Escape Mechanism in Cancer

Sachet A. Shukla, Ph.D., Senior Scientist, Dana-Farber Cancer Institute

Mutations in HLA genes, which are located in the most polymorphic region of the genome, are difficult to characterize and may profoundly affect the efficacy of many immunomodulatory therapies. Computational analyses strongly suggest acquisition of HLA mutations to be an adaptive response to immunological pressure in many different tumor types. Lack of somatic alterations in HLA genes may therefore be a useful patient selection criterion in immunotherapeutic clinical trials.

11:35 Combinatorial Therapeutic Strategies for Ovarian Cancer

Yvonne Lin, Ph.D., Associate Medical Director, Product Development, Oncology, Genentech-Roche

Ovarian cancer remains the leading cause of death among all gynecologic cancers. Recent advances in understanding molecular profiles of ovarian cancer have led to incorporating targeted therapies into the treatment plan. Characterization of an immunoreactive subtype of ovarian cancer supports pairing immune checkpoint inhibitors with ovarian cancer therapies to deliver highly effective therapy for patients.

12:00 pm Immunohistological and Genomic Correlations and Differences Between Various Anti-PD-L1 Clones

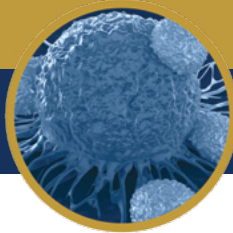
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Maher Albitar, M.D., Senior Vice President, CMO and Director, Research and Development, NeoGenomics Laboratories

Expression of PD-L1 protein as detected by immunohistochemistry is commonly used for selecting patients for immunotherapy. Multiple assays using different antibody clones are currently used. Current research is focused on exploring if genomic abnormalities can be used for better selection of patients for immunotherapy. Furthermore, as combination therapy is being planned, there is a need to correlate immunotherapy biomarkers with targeted therapy biomarkers. This presentation will discuss the correlation between genomic abnormalities and the various PD-L1 immunohistochemistry assays.

12:30 Close of Conference



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MONDAY, MAY 1

12:00 - 5:00 pm Short Course Registration and Conference Pre-Registration

1:00 - 4:00 Short Course*

SC1: Fit-for-Purpose Biomarker Assay Development and Validation

5:00 - 8:00 Dinner Workshop*

SC2: Liquid Biopsy for Immuno-Oncology and Precision Medicine

5:00 - 8:00 Dinner Short Course*

SC3: Preparing for Companion Diagnostic Device Studies and Submissions

**Separate registration required*

TUESDAY, MAY 2

7:00 am Conference Registration and Morning Coffee

COMPANION DIAGNOSTIC DEVELOPMENT IN IMMUNO-ONCOLOGY

8:00 Chairperson's Opening Remarks

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

8:10 Immuno-Oncology Companion Diagnostics Development: A Complex Systems Approach

Lourdes Barrera, Ph.D., Global Capability Director, Diagnostics, AstraZeneca

Development of companion diagnostics for emerging immunotherapies is more complicated because they are not dependent on driver mutations in the drug target. Consequently, we need to develop new biomarker strategies for the development of immunotherapies. During this review, we will give some examples of how complex systems approach is supporting the development of new biomarkers and potentially companion and complementary diagnostic tests.

8:35 The Evolution of Oncology Companion Diagnostics from Signal Transduction to Immuno-Oncology

Nicholas C. Dracopoli, Ph.D., Vice President, Oncology Diagnostics, Janssen Research & Development

Companion diagnostic (CDx) tests for signal transduction inhibitors measure the activation status of the drug target. CDx tests for immune modulating drugs will be much more complicated and need to measure the immune status of tumors and differentiate those with a suppressed immune response from those with no prior immune response. These new CDx tests will drive the choice of therapeutic intervention with checkpoint inhibitors or alternative approaches to prime a new immune response.

9:00 An Industry Perspective on Clinical Biomarkers and Companion Diagnostics for Checkpoint Inhibitor Therapies

Arnold B. Gelb, M.D., MS, FASCP, FCAP, Senior Director, Global Clinical Biomarkers and Companion Diagnostics, EMD Serono

Ongoing trends in clinical oncology support the value proposition of using a precision medicine approach for patient selection and enrichment strategies when developing immuno-oncology therapeutics. This presentation will review aspects pertinent to checkpoint inhibitor therapies of exploratory analyses of clinical biomarkers to identify predictive/prognostic clinical biomarkers that may lead to co-development of a companion diagnostic or a complementary diagnostic. Examples will be drawn from the current status of approved PD-L1 assays, citing the limitations thereof, and other clinical biomarkers and candidate companion or complementary diagnostics, including characterizations of the tumor microenvironment, immune cell phenotyping, T cell repertoires, IFN-gamma gene signature, neoantigen burden/mutational load, microsatellite instability status, and potentially other "hot topics" such as liquid biopsies.

9:25 Coffee Break in the Exhibit Hall with Poster Viewing

NEOANTIGEN-TARGETED THERAPIES

10:10 Chairperson's Opening Remarks

Philip M. Arlen, M.D., President & CEO, Precision Biologics

10:15 Monoclonal Antibodies Targeting Novel Immunogenic Neo-Epitopes for the Treatment of Solid Tumors

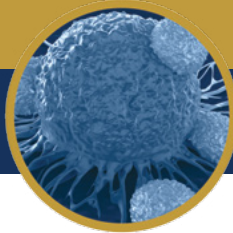
Philip M. Arlen, M.D., President & CEO, Precision Biologics

Immunogenic neoantigens were derived from a membrane preparation of pooled allogeneic colorectal cancer and screened for immunogenicity. The immunogenic fraction was used as a vaccine for chemotherapy refractory disease and a positive correlation was observed in patients who developed antibody responses to therapy. Using this vaccine as a platform, monoclonal antibodies were developed and characterized that were sensitive and specific to cancer, not normal cells, and demonstrated antitumor activity.

10:40 Turning Tumor Mutations into Personalized Cancer Therapies

Roman Yelensky, Ph.D., Executive Vice President, Sequencing and Bioinformatics, Gritstone Oncology

Tumor-specific neo-antigens (TSNAs) can be targeted by the immune system. Gritstone Oncology is exploiting this tumor vulnerability in a therapeutic immunization strategy. The approach includes NGS to identify candidate TSNAs, proteomics and machine learning to predict which TSNAs can activate T cells, the manufacture of a personalized TSNA-based vaccine, and delivery in a combination regimen.



Personalized Immunotherapy

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11:05 *In silico* Discovery of Gene Fusion Neoantigens for Personalized Cancer Immunotherapy

Christopher Maher, Ph.D., Assistant Professor, Department of Medicine, Division of Oncology, Washington University

Studies have used NGS to discover tumor specific neoantigens. However, these analyses have relied on somatic missense mutation-based neoantigen discovery workflows, thereby missing gene fusions that may translate into a novel immunogenic peptide. To address this critical gap, we developed INTEGRATE-Neo for gene fusion neoantigen discovery using NGS data and demonstrate its utility for discovering novel personalized cancer immunotherapy targets.

11:30 High-Throughput Generation of Neoantigen-Specific T Cell Receptors for Adoptive T Cell Therapy

Markus Dangl, Ph.D., Senior Vice President, Research & Pre-Clinical Development, Medigene AG

TILs specific for neoantigens and tumors with high mutational loads underlie effective immunotherapies. Questions remain whether neoantigens are good targets only for highly mutated tumors and patients with pre-existing neoantigen-specific T cells. Medigene uses its immunotherapy platform technologies to investigate neoantigens as future targets for vaccine and adoptive T cell therapies.

11:55 Enjoy Lunch on Your Own

PERSONALIZED CANCER VACCINES

1:30 pm Chairperson's Remarks

Joshua Brody, M.D., Director, Lymphoma Immunotherapy Program, Icahn School of Medicine at Mount Sinai

1:35 *In situ* Vaccination: Potential Mechanism(s) of Action and Biomarker Development

Robert Pierce, M.D., Scientific Director, Immunopathology Core, Fred Hutchinson Cancer Research Center

In situ vaccines (ISVs), intratumoral therapies that aim to enhance tumor immunogenicity, offer the potential to generate tumor antigen-specific TIL and augment anti-PD1 blockade. Multiple ISVs are in clinical development, including TLR agonists, STING agonists, oncolytic viruses and proinflammatory cytokines. ISVs offer a potential safety advantage due to relatively low systemic exposure and may be useful in combination with systemic immunotherapies. Mechanism of action-based biomarker development will be discussed.

2:00 *In situ* Vaccination to Potentiate Checkpoint Blockade Therapy

Joshua Brody, M.D., Director, Lymphoma Immunotherapy Program, Icahn School of Medicine at Mount Sinai

We have developed a novel *in situ* vaccine, in an animal model and in patients with low-grade lymphoma, combining: 1) Flt3L to recruit DC, 2) radiotherapy (XRT) to load DC with tumor-associated antigens (TAA), and 3) toll-like receptor agonist (TLRa) to activate TAA-loaded DC for cross-presentation. Strikingly, we observed partial and complete systemic tumor regressions, improving months after therapy, and even elimination of malignant B cells with sparing of healthy B cells, all suggesting a systemic anti-tumor immune response. Pre-clinical studies show similar results and enhancement with PD1 blockade. These data have motivated a new trial of the

combination therapy which should compel future trial designs to consider optimizing cross-presentation to maximize the potential of checkpoint blockade therapy.

2:25 Playing the Numbers Game: Driving High-Titer T Cell Responses to Tumor Neoantigens

Raphael Rousseau, M.D., Ph.D., CMO, Gritstone Oncology

2:55 Refreshment Break in the Exhibit Hall with Poster Viewing

3:45 Immunotherapy for Prostate Cancer: Challenges and Opportunities

Marijo Bilusic, M.D., Ph.D., Associate Research Physician, National Cancer Institute, National Institutes of Health

The efforts are underway to develop better and more targeted therapies for prostate cancer. The first therapeutic cancer vaccine which demonstrated survival advantage in metastatic castration-resistant prostate cancer while maintaining an excellent quality of life was sipuleucel-T, approved in 2010. With several novel agents in clinical development, immunotherapeutics will likely continue to play an important role in the treatment of prostate cancer.

4:10 Development of Commercially Viable Private Neoantigen-Based Vaccines

Agnete Fredriksen, Ph.D., CSO, Vaccibody

Increasing evidence supports the role of neoantigens as promising targets of anti-tumour responses. However, development of commercially viable private neoantigen vaccines faces many challenges. Vaccibody is combining the attractive rapid, robust and cost-effective manufacturing of individual DNA vaccines with a unique mechanism of action of the encoded Vaccibody fusion protein that ensures efficient immune responses through attraction, activation and antigen loading of APC, and will pursue clinical trials in 2017.

4:35 Th1-Selected Epitope-Based Vaccination as the Lynchpin for Cancer Immunotherapy Combinations

William Watt, Ph.D., President & CEO, EpiThany

The proliferation of targets and molecules for immunomodulation of the tumor microenvironment highlights the need for a new vaccine approach to generate reliable anti-tumor immune responses for modulating. Decades of investment in vector and adjuvant technologies have achieved modest progress in the diversity and immunogenicity of self-antigen cancer vaccines. On a new platform, EpiThany is developing a pipeline of Th1-selective MHCII epitope-based vaccines as the lynchpin for emerging immune-oncology combinations.

5:00 Welcome Reception in the Exhibit Hall with Poster Viewing

5:30 Short Course and ThinkTank Registration

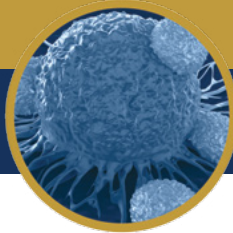
6:00-9:00 Dinner Short Course*

SC4: Next-Generation Sequencing as a Clinical Test

6:00-9:00 Dinner ThinkTank*

SC5: PD-L1 Assays for Biomarkers and Companion Diagnostics

*Separate registration required



Personalized Immunotherapy

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WEDNESDAY, MAY 3

7:30 am Morning Coffee

IMMUNE MONITORING: BIOMARKERS OF RESPONSE TO IMMUNOTHERAPY

7:55 Chairperson's Remarks

Michael J. Overman, M.D., Associate Professor, Gastrointestinal Medical Oncology, The University of Texas MD Anderson Cancer Center

8:00 Immune-Profiling Platform for Biomarker Discovery in Immune-Oncology

Ignacio I. Wistuba, M.D., Professor & Chair, Translational Molecular Pathology, The University of Texas MD Anderson Cancer Center

The discovery of new molecules and pathways with pivotal functions regulating the immune system facilitated the emergence of new cancer treatments and the investigation of novel biomarkers to predict response. The development of these biomarkers requires the participation of immunology, pathology and genomics. We developed a translational molecular pathology immune-profiling platform to discover and validate biomarkers in tissue and fluids for immune-oncology in clinical samples from patients in clinical trials

8:25 NGS Solutions Across IO Drug Development: From Biomarker Discovery to IVD

John Simmons, Ph.D., Director, Translational Science and Diagnostics, Personal Genome Diagnostics

Personal Genome Diagnostics is a next-generation sequencing (NGS) company that collaborates with Bio-Pharma to support biomarker discovery and diagnostic development with assays using both tissue (FFPE) and plasma (ctDNA) inputs. Here we will discuss applications of our core technologies, including whole exome sequencing (WES), neoantigen prediction, RNA-Seq, targeted ctDNA panels, tumor mutational burden (TMB), and microsatellite instability (MSI) assays relevant to the IO space.

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8:55 Immune Monitoring of Cancer Vaccines and Immunotherapy: What Have We Learned and Where to Go Next?

Sacha Gnajatic, Ph.D., Associate Professor, Tisch Cancer Institute, Hematology/Oncology, Immunology, Icahn School of Medicine at Mount Sinai

With clinical success of cancer immunotherapy, it is essential to understand the mechanisms of novel drugs by measuring their effect on immune cells, in the periphery and at the tumor site. Novel approaches and technologies are needed to address the complex task of identifying biomarkers of clinical activity and to improve the design of future therapies.

9:20 Biomarker Strategies for Cancer Vaccine Trials

Stephanie Traub, Ph.D., Biomarker Specialist, Centre for Drug Development, Cancer Research UK

Recent development in the PD-1 field have shown promising progress in combination of checkpoint inhibitors and cancer vaccines. However, one critical point hasn't been answered yet, what is probably the initial pitfall of cancer vaccines, is the question how an effective immune response should look like and how this immune response can be monitored.

9:45 Coffee Break in the Exhibit Hall with Poster Viewing

NEW DIRECTIONS IN PERSONALIZED CELL THERAPY AND COMBINATIONS

10:45 CAR T Cells for Hematologic Malignancies

David L. Porter, M.D., Director, Blood and Marrow Transplantation; Jodi Fisher Horowitz Professor, Leukemia Care Excellence, University of Pennsylvania

Chimeric antigen receptors (CARs) combine an antigen recognition domain of an antibody with intracellular T cell signaling domains. Gene transfer techniques introduce the CAR into normal T cells redirecting them to target new antigens. CAR T cells targeting CD19 have unprecedented activity in relapsed and refractory B cell neoplasms including ALL, CLL and NHL. Newer approaches are being developed to enhance the activity, application, and safety of CAR T cells.

11:10 Tumor Microenvironment Modulation by Focal Adhesion Kinase Inhibitors

David Weaver, Ph.D., Vice President, Translational Medicine, Verastem

An immunosuppressive tumor microenvironment develops in many cancers. Immunotherapies can be more effective by combining with agents that modulate the tumor microenvironment. FAK inhibitors in Phase I and Phase II clinical trials and the preclinical rationale supporting these agents and their use in combination therapies will be introduced. The essential role of biomarkers of response and patient stratification will be discussed.

12:00 pm Close of Conference



Biomarkers for Patient Selection

WEDNESDAY, MAY 3

12:00 pm Conference Registration

12:40 Luncheon Presentation (*Sponsorship Opportunity Available*) or Enjoy Lunch on Your Own

1:30 Dessert Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTES

2:00 Chairperson's Opening Remarks

Robert Iannone, M.D., Senior Vice President & Head, Immuno-Oncology, Global Medicines Development, AstraZeneca

2:05 Immunophenotyping to Differentiate Responder and Non-Responder Patients in Cancer Immunotherapy

George Poste, D.V.M., Ph.D., Chief Scientist, Complex Adaptive Systems, Arizona State University

The clinical benefits of immune checkpoint inhibitors in a variety of malignancies are unprecedented. Unfortunately, the level of positive therapeutic response is not consistent across different tumor classes and even in responsive tumor lineages non-responders still dominate. The need for comprehensive immunophenotyping to identify the mechanisms underlying these differential responses and better predict responder patients is an urgent clinical and economic imperative.

2:30 Rational Combinations with PD-L1 Antagonists

Robert Iannone, M.D., Senior Vice President & Head, Immuno-Oncology, Global Medicines Development, AstraZeneca

2:55 Non-Clinical Approaches to Predict Single Agent vs. Combination Value and Clinical Development Strategies for Emerging Cancer Immunotherapies

James Smothers, Ph.D., Senior Director & Head, Discovery, Immuno-Oncology & Combinations DPU, GlaxoSmithKline

A rapidly growing number of immunotherapy treatments for cancer have entered clinical trials and are being evaluated for both single agent and combination therapeutic value. Currently approved or mature Phase III evaluations of immunology treatments are largely limited to strategies that employ either autologous T-cell treatments or use of monoclonal antibodies (mAbs) to block T-cell checkpoints of either activation or exhaustion. Other modalities being explored in late phase preclinical and early clinical development include agonistic mAbs that modulate healthy immune cell populations, small molecule chemistries to inhibit or drive enzymatic function, and other emerging or reconsidered approaches to experimental medicine design. Non-clinical research studies historically support preclinical development and regulatory submission satisfaction and provide critical support of early clinical development hypotheses and clinical trial design including managing expectations of single agent efficacy or setting strategic vision for combination value through biology synergies. Moreover, following early clinical

development milestones, an experimental medicine requires ongoing translational review of the clinical readouts beyond efficacy which in turn requires additional non-clinical analyses and experimental execution to drive results-based decision making and data-informed design of late stage clinical trials in anticipation and hope of drug approvals. Examples of non-clinical studies to support all of these activities will be reviewed including choice of experimental models and design.

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

COMPANION DIAGNOSTICS ASSAYS: BIOMARKER TRANSLATION FROM ASSAY TO CLINIC

4:10 Chairperson's Opening Remarks

Jeff Fill, MBA, MT (ASCP), Director, Diagnostic & Experimental Pathology, Eli Lilly and Company

4:15 From Research to CAP/CLIA to GCP – How to Make It Work!

Jeff Fill, MBA, MT (ASCP), Director, Diagnostic & Experimental Pathology, Eli Lilly and Company

It is a challenge to maintain a quality system to span from research grade assays to providing data for diagnostic submission. The Clinical Diagnostic Laboratory is utilizing a unique quality system which allows for flexibility in early biomarker discovery all the way to being a clinical trial site for diagnostic registration and all under one laboratory system.

4:40 The Application of NGS Panels for Patient Selection

Sponsored by

Cheryl McFarlane, Ph.D., Assay Development and Validation Manager, illumina Almac Diagnostics

NGS panels are a powerful tool for parallel assessment of genomic integrity and expression across multiple targets. This facilitates biomarker discovery in early phase clinical trials and also subsequent development of a suitable core assay for multiple drug targets. We will summarise the main considerations of development and analytical validation of such panels for patient selection and describe Almac Diagnostics' experience identifying important technical and regulatory challenges.

5:10 Developing Robust Patient Selection Assays for Early Clinical Oncology Trials

Steven Pirie-Shepherd, Ph.D., Director, Oncology Translational Research, WRD, Pfizer

Targeted therapies are directed towards specific protein target in tumors. Tumors with the highest expression of drug targets are hypothesized to be the most likely to respond to therapy. We describe the development and analytical validation of assays intended to be used as clinical companion diagnostics to guide patient selection and stratification strategies in early stage clinical trials.

5:35 Cell-Free DNA Analysis Enabling Drug Development

Rajiv Raja, Ph.D., Director, Translational Medicine and Pharmacogenomics, MedImmune

Oncogenic mutations play an important role in patient responses to cancer therapy. Analyzing cell-free DNA (cfDNA) derived from patients can provide a robust, non-invasive method for identifying such mutations and monitoring their levels as a

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measure of tumor burden. Results from the evaluation of changes in variant allele frequencies in response to therapy will be presented.

5:45 Short Course and ThinkTank Registration

6:15-9:15 Dinner Executive ThinkTank*
SC6: Complementary Diagnostics

6:15-9:15 Dinner Short Course*
SC7: Immune Monitoring in Cancer

**Separate registration required*

THURSDAY, MAY 4

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

IMPLEMENTING PRECISION MEDICINE: PATIENT STRATIFICATION STRATEGIES

9:00 Chairperson's Remarks

Johan Luthman, D.D.S., Ph.D., Vice President, Neuroscience Clinical Development, Eisai Pharmaceuticals

9:05 Precision Medicine: Why the Time Is Now!

Daniel Edelman, Ph.D., Core Manager, Clinical Molecular Profiling Core, National Cancer Institute, NIH

Once called personalized medicine, the term precision medicine has become the norm after President Obama's support of the Precision Medicine Initiative® (PMI) in the FY 2016 budget. This new expanded research effort has the promise to create a health care system with greater efficiency of treatment and improved outcomes. In this talk we will explore multiple facets of PMI on its impact from the individual to greater health policy.

9:30 Biomarker-Supported Patient Identification Strategies for Alzheimer's and Parkinson's Disease

Johan Luthman, D.D.S., Ph.D., Vice President, Neuroscience Clinical Development, Eisai Pharmaceuticals

9:55 Attend Concurrent Session

10:20 Networking Coffee Break

GENOMIC BIOMARKERS FOR PERSONALIZED THERAPY

10:45 Genomics and Precision Medicine: Applications in Oncology

Juliann Chmielecki, Ph.D., Associate Director, Translational Sciences, AstraZeneca

The incorporation of genomic analyses into the design of clinical trials has helped to accelerate precision medicine in oncology. Analysis of both tumor tissue and ctDNA with corresponding clinical data can help to identify mechanisms of both drug sensitivity and resistance. Examples from recent trials will be discussed. This data can then be used to identify prospective patients likely to derive maximum therapeutic benefit from targeted agents.

11:10 Large-Scale Experience with Comprehensive Clinical Genomics of Actionable Alterations in Every Patient with Advanced Cancer

Marc Ladanyi, M.D., William J. Ruane Chair in Molecular Oncology, Molecular Diagnostics Service and Human Oncology & Pathogenesis Program, Memorial Sloan Kettering Cancer Center

Through an institution-wide initiative in clinical cancer genomics initiated in 2014, we have implemented large scale genomic profiling for targetable cancer drivers and other cancer-relevant alterations in all patients with advanced solid cancers. Over 15,000 patients have been profiled using the MSK-IMPACT targeted, capture-based DNAseq assay. Subsets of patients have also been studied for oncogenic fusions by targeted RNAseq or for germline cancer predisposition alleles. An overview of our experience will be presented.

11:35 Implementing Precision Medicine into Clinical Care: Non-Small Cell Lung Cancer

David B. Roth, M.D., Ph.D., Simon Flexner Professor & Chair, Pathology and Laboratory Medicine; Director, Penn Center for Precision Medicine, Perelman School of Medicine, University of Pennsylvania

Rapid developments in targeted therapies, whose selection is driven by specific somatic mutations in a variety of genes, and in immune checkpoint blockade, whose selection is driven by expression of checkpoint receptors on the surface of tumor cells, has radically altered treatment paradigms in metastatic non-small cell lung cancer. Penn's experience in directing appropriate, precision medicine-based therapies in this disease, involving analysis of more than 1,000 patients with routine genomic testing, will be discussed.

12:00 pm Heterogeneity and Its Effects on Patient Selection in Breast Cancer: Progress and Remaining Challenges

Christos Hatzis, Ph.D., Assistant Professor, Internal Medicine, and Director, Bioinformatics, Breast Medical Oncology, Yale University School of Medicine

Tumors expressing specific markers become eligible for treatment with targeted therapies, but only a subset of these patients respond to the treatment and have a long-term survival benefit. Identifying responding patients is complicated by the genetic heterogeneity of the tumors and its interaction with the stromal components. We will review the progress in breast cancer and outline remaining challenges.



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12:25 Enjoy Lunch on Your Own

BIOMARKER-DRIVEN CLINICAL TRIALS

1:40 Chairperson's Opening Remarks

Kenna R. Mills Shaw, Ph.D., Executive Director, Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy, MD Anderson Cancer Center

1:45 Building a Tool for Precision Oncology Decision Support: Getting the Right Drug(s) to the Right Patient(s) at the Right Time(s)

Kenna R. Mills Shaw, Ph.D., Executive Director, Sheikh Khalifa Bin Zayed Al Nahyan Institute for Personalized Cancer Therapy, MD Anderson Cancer Center

Tumor sequencing has become commonplace in cancer care. Studies reveal though that generally <10% of patients are matched to treatments using this information when outside FDA-approved indications. A resource that distills therapeutic opportunities matched to patient-specific alterations can be deployed to improve sequence data utilization. We describe how real-time notification of therapeutic opportunities and detailed functional annotations of molecular data can improve patient assignment to genomically informed clinical trials and outcome.

2:10 Overcoming Challenges in Biomarker-Associated Clinical Trials: Innovative Designs for Precision Medicine

Amir Handzel, Ph.D., Statistical Science Director, AstraZeneca

Precision medicine (PM) has emerged as a core paradigm of medical treatment, initially in oncology, now spreading to other therapeutic areas. Yet developing a predictive biomarker as companion diagnostic (CDx) is complex and requires thorough planning from early stages. PM drug development poses new challenges which have been addressed by innovative multiplexed trial designs that promise higher probability of success and efficiency. Technical aspects of the biomarkers, including threshold selection for continuous biomarkers, are critical, as demonstrated by known late-stage clinical trial failures.

2:35 Hematological Malignancy Precision Healthcare Strategies in the Therapeutic Development of Small Molecule MDM2 Antagonists
William Pierceall, Ph.D., Senior Principal Scientist, Biomarker Experimental Medicine Leader, Roche Innovation Center - New York

MDM2 antagonists block the MDM2-p53 interaction leading to stabilization and activation of p53 and tumor cell cycle arrest and apoptosis – an attractive but challenging strategy for cancer therapy. Following initial validation of this mechanism of action by nutlin-series small molecules, subsequent generation MDM2 antagonist Idasanutlin has shown notable clinical benefit in relapsed/refractory AML patients as well as patients with solid tumors. Precision healthcare strategies may provide diagnostics for identifying patients with higher likelihood of improved clinical benefit to MDM2 antagonist directed therapeutics.

3:00 Close of Conference

SUBMIT A POSTER

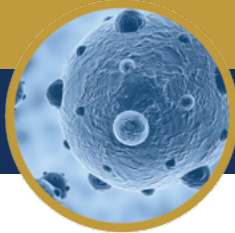
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Immune Profiling in Cancer

WEDNESDAY, MAY 3

12:00 pm Conference Registration

12:40 Luncheon Presentation (Sponsorship Opportunity Available) or Lunch on Your Own

1:30 Dessert Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTES

2:00 Chairperson's Opening Remarks

Robert Iannone, M.D., Senior Vice President & Head, Immuno-Oncology, Global Medicines Development, AstraZeneca

2:05 Immunophenotyping to Differentiate Responder and Non-Responder Patients in Cancer Immunotherapy

George Poste, D.V.M., Ph.D., Chief Scientist, Complex Adaptive Systems, Arizona State University

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2:30 Rational Combinations with PD-L1 Antagonists

Robert Iannone, M.D., Senior Vice President & Head, Immuno-Oncology, Global Medicines Development, AstraZeneca

2:55 Non-Clinical Approaches to Predict Single Agent vs. Combination Value and Clinical Development Strategies for Emerging Cancer Immunotherapies

James Smothers, Ph.D., Senior Director & Head, Discovery, Immuno-Oncology & Combinations DPU, GlaxoSmithKline

A rapidly growing number of immunotherapy treatments for cancer have entered clinical trials and are being evaluated for both single agent and combination therapeutic value. Currently approved or mature Phase III evaluations of immunology treatments are largely limited to strategies that employ either autologous T-cell treatments or use of monoclonal antibodies (mAbs) to block T-cell checkpoints of either activation or exhaustion. Other modalities being explored in late phase preclinical and early clinical development include agonistic mAbs that modulate healthy immune cell populations, small molecule chemistries to inhibit or drive enzymatic function, and other emerging or reconsidered approaches to experimental medicine design. Non-clinical research studies historically support preclinical development and regulatory submission satisfaction and provide critical support of early clinical development hypotheses and clinical trial design including managing expectations of single agent efficacy or setting strategic vision for combination value through biology synergies. Moreover, following early clinical

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3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

IMMUNOPHENOTYPING: BIOMARKER DISCOVERY AND VALIDATION FOR IMMUNO-ONCOLOGY

4:10 Chairperson's Opening Remarks

Christopher R. Heery, M.D., CMO, Bavarian Nordic

4:15 CARTography: Mass Cytometry-Based Approach to Multi-Dimensional Phenotyping of Anti-CD19 CART Cells

Piotr Pierog, Ph.D., Associate Director, Oncology Precision Medicine, Novartis

We have generated highly multiplexed CyTOF data on cellular therapy products. Through data analysis and mining approaches, we have successfully characterized T cell subset frequencies and uncovered their corresponding phenotypes. Deep characterization of immune cells through mass cytometry approach provides a powerful tool for decoding the complexity of immune cell compartments and cellular biomarker discovery. Specific T cell phenotypes, or associated map locations, can then be used to correlate product phenotype with cell manufacturing process, patient outcomes and/or safety profiles.

4:40 SeroTag: Longitudinal Autoantibody Profiling of Clinical Trials in Cancer Vaccination and Checkpoint Inhibition

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Peter Schulz-Knappe, Ph.D., CSO, Protagen AG

We performed Proof-of-Concept studies together with NCI (Bethesda, USA) and NCT (Heidelberg, Germany) in several Immuno-Oncology trials. Are autoantibodies biomarkers which show promise to measure response to immuno-therapy and to monitor immune-related adverse events (irAEs) before and during cancer treatment? Concept, Strategy and PoC results will be presented and discussed.

4:55 Peripheral Immune Correlates of Therapeutic Cancer Vaccine Clinical Trials

Christopher R. Heery, M.D., CMO, Bavarian Nordic

Dr. Heery will discuss the use of a flow-based assay to identify specific immune cell subsets from PBMC in a retrospective analysis of two clinical trials. Immune cell subset populations correlated with clinical impact of immunotherapy in combination with cytotoxic agents, but those same populations did not predict effect of cytotoxic therapy alone. Dr. Heery will discuss how this can be used in future trials for therapeutic development.

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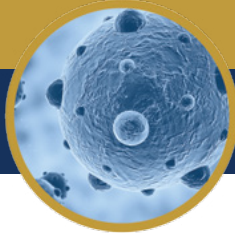
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5:20 Tumor Immunophenotyping of Exhausted T Cells and Response to PD-1 Therapy

Adil Daud, M.D., Professor, Hematology/Oncology, University of California, San Francisco; Director, Melanoma Clinical Research, UCSF Helen Diller Family Comprehensive Cancer Center

5:45 Short Course and ThinkTank Registration

6:15 - 9:15 Dinner Executive ThinkTank*
SC6: Complementary Diagnostics

6:15 - 9:15 Dinner Short Course*
SC7: Immune Monitoring in Cancer

**Separate registration required*

THURSDAY, MAY 4

7:30 am Breakfast Presentation (Sponsorship Opportunity Available) or Morning Coffee

IMMUNOSEQUENCING AND IMMUNE CELL INFILTRATION PROFILING

9:00 Chairperson's Remarks

Lance D. Miller, Ph.D., Associate Professor, Cancer Biology, Wake Forest University

9:05 Deep Sequencing of T Cell Receptor DNA as a Biomarker of Clonally Expanded TILs in Breast Cancer after Immunotherapy

David B. Page, M.D., Medical Oncology, Providence Cancer Center

In early-stage breast cancer (ESBC), the degree of tumor-infiltrating lymphocytes (TIL) predicts response to chemotherapy and overall survival. Immune checkpoint antibody (ipilimumab, anti-CTLA-4) plus tumor cryoablation can induce TILs and improve survival in mice, and was recently evaluated as a pre-operative strategy in ESBC. We will describe how T cell receptor (TCR) DNA sequencing can be used in the context of immunotherapy to quantify TILs and to indirectly assess for antigen-reactive T cell clonal expansions.

9:30 Immunogenomics and Single Cell Omics for Cancer Precision Medicine

Olivier Elemento, Ph.D., Associate Professor & Associate Director, Institute for Computational Biomedicine, Department of Physiology and Biophysics, Weill Cornell Medicine

I will present my group's work on the development and implementation of a clinical grade (CLIA) whole-exome sequencing based genomic test for precision cancer medicine and immunotherapy. A novel analytical pipeline that analyzes genomic profiles to unravel the immune landscape of tumors and integrates multi-omics features using machine learning to predict immunotherapy response will be described. Finally, high-throughput single cell genomics approaches to dissect the tumor microenvironment and unravel immune repertoires at the single cell resolution will be presented.

9:55 Comprehensive Immune Profiling for Response to Checkpoint Inhibitor Therapy: A Multi-Institutional Retrospective Study

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Carl Morrison, M.D., D.V.M., President, Founder and CSO, OmniSeq Precision Medicine

Mutation burden, microsatellite instability, T cell receptor signaling, tumor infiltrating lymphocytes, PD-L1 IHC, and PD-L1/2 copy number have all been identified as candidate biomarkers for response to checkpoint inhibitors (CPI). We have developed a high-throughput CLIA NYS-CLEP approved assay to measure all of these variables in a single assay. A multi-institutional retrospective study of patients with prior CPI therapy and follow-up by RECIST criteria was performed using this approach to predict response.

10:25 Networking Coffee Break

10:45 Genomic Correlates of Immune Infiltration in Colorectal Cancer

Marios Giannakis, M.D., Ph.D., Medical Oncologist & Clinical Investigator, Dana-Farber Gastrointestinal Cancer Treatment Center; Researcher, Broad Institute of MIT and Harvard

Large-scale genomic characterization of tumors with clinicopathologic annotations can yield insights into cancer pathogenesis and immunobiology. We performed whole-exome sequencing of 619 colorectal cancers (CRCs) and integrated the results with tumor immunity, pathology, and survival data. We found that a higher tumor neoantigen load was associated with overall lymphocytic infiltration, tumor-infiltrating lymphocytes (TILs), memory T cells and CRC-specific survival. We also found positive selection of antigen-processing machinery mutations in TIL-rich tumors.

11:10 The Function and Specificity of T Cells in Colorectal Cancer

Arnold Han, M.D., Ph.D., Assistant Professor, Medicine, Digestive and Liver Diseases and Microbiology & Immunology, Columbia University

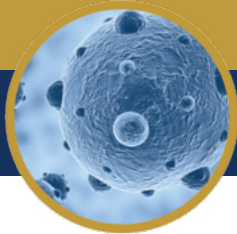
We have begun to systematically study the function and antigen specificity of TILs in colorectal cancer. Through single-cell approaches, we have characterized the TCR repertoire and diverse pro-inflammatory and regulatory phenotypes of colorectal tumor-infiltrating T cells. We are also working to study the TCR specificity of TILs through novel approaches.

11:35 B- and T-Cell Immune Repertoire Characterization by Anchored Multiplex PCR and Next-Generation Sequencing

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Laura Griffin, Ph.D., Scientific Liaison, ArcherDX

The immune repertoire (IR) provides a means to monitor adaptive immune responses to disease, vaccination and therapeutic interventions. NGS-based IR characterization usually requires large primer panels to capture its extensive combinatorial diversity and a complex system of synthetic controls to account for differential amplification efficiency across segment combinations. Here, we discuss how Anchored Multiplex PCR (AMP™) enables NGS-based IR characterization with a minimal set of unidirectional gene-specific primers and molecular barcodes that reduce amplification bias.



Immune Profiling in Cancer

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12:05 pm Genetic Biomarkers of Immune Responsiveness and Breast Cancer Immunogenicity

Lance D. Miller, Ph.D., Associate Professor, Cancer Biology, Wake Forest University

Immunotherapies are advancing in the clinic, but the ability to predict patient benefit remains a major challenge. Central to this problem is a lack of understanding of how tumor-intrinsic factors interact with the host immune system to influence patient outcomes. In this presentation, I will discuss genomic and bioinformatics strategies we've used to uncover cellular and genomic rules that appear to govern the immunogenic potential of breast and other cancers.

12:30 Enjoy Lunch on Your Own

PROFILING THE TUMOR MICROENVIRONMENT

1:40 Chairperson's Opening Remarks

Sam Hanash, M.D., Ph.D., McCombs Institute for Cancer Early Detection and Treatment, MD Anderson Cancer Center

1:45 Density, Distribution and Composition of Immune Infiltrates Correlate with Survival in Merkel Cell Carcinoma

Michael T. Tetzlaff, M.D., Ph.D., Associate Professor, Pathology and Translational and Molecular Pathology, The University of Texas MD Anderson Cancer Center

Merkel cell carcinoma (MCC) is an aggressive cutaneous neuroendocrine carcinoma with frequent metastasis and death. Robust biomarkers predictive of clinical outcome are lacking, and few effective agents exist for MCC therapy. The emergence of immune checkpoint blockade therapies that mobilize antitumoral immunity provides a strong rationale to define the density, distribution, and composition of immune infiltrates in MCC to determine whether any of these impact clinical outcome and thus, could be reasonably leveraged in treatment strategies. We performed immune profiling for CD3, CD8, PD-1, and PD-L1 in a series of MCC with carefully annotated clinical outcomes and used automated image analysis to precisely quantify immune cell density at distinct tumor locations. We confirm a significant association between patient survival and the density of CD3+ and CD8+ T cells specifically at the tumor-stroma interface. Together, our findings provide a robust biomarker to facilitate risk stratification and prognosis in MCC and additional rationale to deploy immune checkpoint inhibitors in MCC treatment.

2:10 Defining Dynamic Changes in the Tumor Microenvironment with Tumor Development and Progression

Sam Hanash, M.D., Ph.D., McCombs Institute for Cancer Early Detection and Treatment, MD Anderson Cancer Center

While genomic alterations are driving forces in tumor development, the tumor microenvironment is critical to tumor development and metastasis. Molecular profiling including proteomics and metabolomics are contributing to defining the constituents of the microenvironment and their source, modifications, interactions and turnover, and how these features relate to tumor development and progression.

2:35 The Impact of STAT3 on Tumor Immunological Environment

Hua Yu, Ph.D., Professor & Co-Chair, Immuno-Oncology, Beckman Research Institute at City of Hope Comprehensive Cancer Center

A crucial role of STAT3 in promoting cancer has been established. STAT3 signaling within tumor cells and tumor-associated immune cells also induces immunosuppression. Our recent studies including metabolic profiling highlight the importance of STAT3 in regulating lipid metabolism in tumor cells and cancer stem cells. Extensive work has also demonstrated the significance of STAT3-regulated metabolism in suppressing tumor T cells. We plan to perform lipid metabolic profiling of tumor-associated T cells.

3:00 Close of Conference



Combination Immunotherapy

WEDNESDAY, MAY 3

12:00 pm Conference Registration

12:40 Luncheon Presentation (*Sponsorship Opportunity Available*) or Lunch on Your Own

1:30 Dessert Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTES

2:00 Chairperson's Opening Remarks

Robert Iannone, M.D., Senior Vice President & Head, Immuno-Oncology, Global Medicines Development, AstraZeneca

2:05 Immunophenotyping to Differentiate Responder and Non-Responder Patients in Cancer Immunotherapy

George Poste, D.V.M., Ph.D., Chief Scientist, Complex Adaptive Systems, Arizona State University

The clinical benefits of immune checkpoint inhibitors in a variety of malignancies are unprecedented. Unfortunately, the level of positive therapeutic response is not consistent across different tumor classes and even in responsive tumor lineages non-responders still dominate. The need for comprehensive immunophenotyping to identify the mechanisms underlying these differential responses and better predict responder patients is an urgent clinical and economic imperative.

2:30 Rational Combinations with PD-L1 Antagonists

Robert Iannone, M.D., Senior Vice President & Head, Immuno-Oncology, Global Medicines Development, AstraZeneca

2:55 Non-Clinical Approaches to Predict Single Agent vs. Combination Value and Clinical Development Strategies for Emerging Cancer Immunotherapies

James Smothers, Ph.D., Senior Director & Head, Discovery, Immuno-Oncology & Combinations DPU, GlaxoSmithKline

A rapidly growing number of immunotherapy treatments for cancer have entered clinical trials and are being evaluated for both single agent and combination therapeutic value. Currently approved or mature Phase III evaluations of immuno-oncology treatments are largely limited to strategies that employ either autologous T-cell treatments or use of monoclonal antibodies (mAbs) to block T-cell checkpoints of either activation or exhaustion. Other modalities being explored in late phase preclinical and early clinical development include agonistic mAbs that modulate healthy immune cell populations, small molecule chemistries to inhibit or drive enzymatic function, and other emerging or reconsidered approaches to experimental medicine design. Non-clinical research studies historically support preclinical development and regulatory submission satisfaction and provide critical support of early clinical development hypotheses and clinical trial design including managing expectations of single agent efficacy or setting strategic vision for combination value through biology synergies. Moreover, following early clinical development milestones, an experimental medicine requires ongoing translational review of the clinical readouts beyond efficacy which in turn requires additional

non-clinical analyses and experimental execution to drive results-based decision making and data-informed design of late stage clinical trials in anticipation and hope of drug approvals. Examples of non-clinical studies to support all of these activities will be reviewed including choice of experimental models and design.

3:20 Refreshment Break in the Exhibit Hall with Poster Viewing

BIOMARKERS FOR COMBINATION IMMUNOTHERAPY

4:10 Chairperson's Opening Remarks

David Kaufman, M.D., Ph.D., Executive Director, Translational Immunology & Oncology, Merck Research Laboratories

4:15 Evaluating the Role of Precision Medicine in Immuno-Oncology

David Kaufman, M.D., Ph.D., Executive Director, Translational Immunology & Oncology, Merck Research Laboratories

This presentation will cover: 1) examining the clinical utility of PD-L1 expression in classifying responders to immuno-oncology therapeutics, 2) evaluating novel biomarkers with the potential to describe fundamental features of tumor immunobiology across tumor types, and 3) forming a comprehensive biomarker signature approach – incorporating DNA and RNA-based biomarkers to determine patient treatment approaches in the era of combination cancer immunotherapy.

4:40 Driver-Map™ Targeted RNA Expression Profiling Solution: The Sensitivity of RT-PCR Combined with the Throughput and Range of NGS

Paul Diehl, Ph.D., COO, Cellecta

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5:10 Biomarkers for Combination Immunotherapy

Jeffrey Wallin, Ph.D., Group Leader/Senior Scientist, Oncology Biomarker Development, Genentech

The immune system's ability to detect and destroy abnormal cells is the foundation of cancer immunotherapy. Activation of anti-tumor immunity by immune checkpoint blockade has demonstrated efficacy in a variety of cancers and although durable responses have been observed, combination approaches will be required to extend this benefit beyond a subset of patients. This talk will focus on biomarkers, with specific examples from atezolizumab (anti-PD-L1) clinical combination studies.

5:35 Developing Immunotherapy and Biomarkers in Prostate Cancer: Challenges and Strategies

Ravi Madan, M.D., Clinical Director, Genitourinary Malignancies Branch, National Cancer Institute, National Institutes of Health

There are many studies investigating immunotherapy combinations in prostate cancer, including androgen deprivation therapy, anti-androgen therapy, chemotherapy and radiopharmaceuticals. Emerging data suggests the potential for the development immune biomarker platforms and possibly even imaging biomarkers. These preliminary findings may have relevance in many cancers beyond prostate cancer.

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5:45 Short Course and ThinkTank Registration

6:15 - 9:15 Dinner Executive ThinkTank*
SC6: Complementary Diagnostics

6:15 - 9:15 Dinner Short Course*
SC7: Immune Monitoring in Cancer

**Separate registration required*

THURSDAY, MAY 4

7:30 am **Breakfast Presentation** (*Sponsorship Opportunity Available*) or **Morning Coffee**

STRATEGIES FOR IMMUNOTHERAPY COMBINATIONS

9:00 Chairperson's Remarks

Timothy Yap, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center

9:05 The Art of Immuno-Oncology: Overcome the Barriers to Personalized Cancer Medicine

Zhen Su, M.D., MBA, Vice President & Head of Global Medical Affairs – Oncology, EMD Serono

Recent advancement in immuno-oncology has significantly changed oncology practice worldwide. The clinical benefit of immune checkpoint blockades has been shown in multiple tumor settings especially the “hot tumors” with significant T cell infiltration. However, due to rapid clinical development of these agents, there is a paucity of knowledge of how to integrate this new class of treatment into the treatment algorithm in daily practice. In addition, the complexity and challenges in biomarker development to assist patient selection for the checkpoint blockade also complicated the adaptation of such treatment in the real world setting. A deep dive of recent data and holistic approach in clinical setting is warranted to overcome the barriers to integrate immune-oncology into the personalized cancer medicine era.

9:30 Rational Design of Immunotherapy Combinations

Carol O’Hear, M.D., Ph.D., Associate Medical Director, Cancer Immunotherapy, Genentech

The cancer immunity cycle provides a framework to understand how alterations in the tumor micro-environment can be targeted to enhance clinical response to immunotherapy. In addition, biomarker data obtained through clinical trials has added to our understanding of how to optimize combination immunotherapy. Utilization of this information allows a patient’s immune deficiencies to be targeted rationally to maximize opportunities for clinical success.

9:55 Rational IO Combinations Based on the Presence or Absence of Tumor T Cell Inflammation

Jason Luke, M.D., Assistant Professor, Medicine, Melanoma and Developmental Therapeutics Clinics, University of Chicago

A subset of patients with cancer have a spontaneous anti-tumor immune response and T cell infiltration into tumor sites. The presence of this T cell-inflamed or non-inflamed tumor microenvironment can be most robustly described via gene expression profiling and can be used for IO combination target identification stratified by the presence or absence of T cell inflammation. This model and rationale IO combination therapies will be explored.

10:20 Networking Coffee Break

IMMUNE MODULATORS AND COMBINATIONS

10:45 PD-1 Antibody, a Broad Spectrum Antineoplastic Therapy, is Transforming Management of a Number of Cancers

Roy D. Baynes, M.D., Ph.D., Senior Vice President and Head, Global Clinical Development, CMO, Merck Research Laboratories

In an efficient and biologically targeted screening Phase II program, pembrolizumab has shown activity across more than twenty different cancers. Randomized studies have shown survival benefit for pembrolizumab over standard of care in metastatic malignant melanoma, metastatic non-small cell lung cancer and 2nd line treatment of metastatic bladder cancer. Pembrolizumab is being explored in a number of different combination regimens, many of which are showing promising initial activity that has led to conducting randomized studies.

11:10 Immuno-Oncology Combinations: Raising the Tail of the Survival Curve

Timothy Yap, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center

There have been exponential gains in immuno-oncology in recent times through the development of immune checkpoint inhibitors. Already approved by the FDA for selected cancers, immune checkpoint inhibitors also appear to have significant antitumor activity in multiple other tumor types. Nevertheless, not all patients benefit, and efforts should thus now focus on improving the efficacy of immunotherapy through the use of combination approaches and predictive biomarkers of response and resistance.

11:35 Clinical Activity of PDR001, an Anti-PD-1 Antibody, in Advanced Solid Tumors

Jennifer Mataraza, Ph.D., Senior Investigator II, Exploratory Immune Oncology, Novartis Institutes of Biomedical Research

PDR001 is a humanized anti-PD-1 IgG4 antibody that blocks the binding of PD-L1 and PD-L2 to PD-1. PDR001 binds to PD-1 with high affinity and inhibits the biological activity of PD-1. I will discuss patient case studies from our PDR001 Phase I FIH trial. In addition, I will highlight some of our early biomarker data from our PDR001 trials.



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A Division of Cambridge Innovation Institute

12:00 pm Novel Approaches for the Combination Immunotherapy of Cancer

Jon Wigginton, M.D., Senior Vice President, Clinical Development & CMO, MacroGenics

12:35 Luncheon Presentation: A Novel Phenotypic Platform for Predicting Tumor Response in Drug Development

Mark Paris, Ph.D., Technical Liaison, Mitra Biotech

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COMBINING IMMUNOTHERAPY WITH OTHER MODALITIES

1:40 Chairperson's Opening Remarks

1:45 Opportunities to Combine Targeted and Conventional Cancer Therapy with Immunotherapy

Philip Gotwals, Ph.D., Executive Director, Exploratory Immuno-Oncology, Novartis Institutes for BioMedical Research

Research in cancer therapeutics has largely focused on two distinct, independent lines of inquiry: efforts to understand the underlying cell autonomous, genetic drivers of tumorigenesis, and exploration of the mechanisms of protective tumor immunity. The integration of these potentially complementary research fields provides new opportunities to improve cancer treatments. This presentation will review insights into the effects of targeted therapies on the induction of anti-tumor immunity that may help advance the design of therapeutic combination strategies.

2:10 Combination Immunotherapy with Chemotherapy – Early Results from Clinical Trials

Glen J. Weiss, M.D., MBA, Director, Clinical Research and Phase I & II Clinical Trials, Cancer Treatment Centers of America, Goodyear, AZ

Recently, a number of new immunotherapies are available for clinical use for treating advanced cancer. A small portion of patients treated with single agent monoclonal antibody immunotherapy do experience an impressive durable response. Likely the next wave of approvals will involve combination therapy involving chemotherapy, targeted therapy, or additional immune-modulating agents. This lecture will highlight some of the current data on combination immunotherapy that have been evaluated in advanced cancers.

2:35 Close of Conference

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BEST VALUE (Includes access to entire 3 days of programs, excludes short courses)	Commercial	Academic, Government, Hospital-affiliated
Registrations after March 17, 2017, and on-site	\$2449	\$1199

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May 2 - 3	May 3 - 4
P1: Clinical and Translational Biomarkers in Drug Development	P4: Biomarkers for Patient Selection
P2: Immuno-Oncology Biomarkers	P5: Immune Profiling in Cancer
P3: Personalized Immunotherapy	P6: Combination Immunotherapy

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SC2: Liquid Biopsy for Immuno-Oncology and Precision Medicine (May 1, 5:00-8:00)
SC3: Preparing for Companion Dx Studies and FDA Submissions (May 1, 5:00-8:00)
SC4: Next-Generation Sequencing as a Clinical Test (May 2, 6:00-9:00)
SC5: PD-L1 Assays for Biomarkers and Companion Diagnostics (May 2, 6:00-9:00)
SC6: Executive ThinkTank: Complementary Diagnostics (May 3, 6:15-9:15)
SC7: Immune Monitoring in Cancer (May 3, 6:15-9:15)

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