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Biomarkers & Immuno-Oncology

World Congress 2017

The Leading Annual Meeting Where
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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 & Head, Translational Research, Oncology,
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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Conference Venue & Hotel: Philadelphia Marriott Downtown
1201 Market Street
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Phone: 215-625-2900

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

RESERVATIONS AND ADDITIONAL TRAVEL INFORMATION: Go to the travel page of BiomarkerWorldCongress.com
**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

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

**Dinner Short Course**

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

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

**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

Talk Title to be Announced
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.
assays, citing the limitations thereof, and other clinical biomarkers and candidate diagnostic. Examples will be drawn from the current status of approved PD-L1 drugs to identify predictive/prognostic clinical biomarkers that may lead to co-development of a companion diagnostic or a complementary diagnostic. Ongoing trends in clinical oncology support the value proposition of using a companion or complementary diagnostics, including characterizations of the tumor microenvironment, immune cell phenotyping, T cell repertoires, IFN-gamma gene signature, neoadtigen 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.)

10:00 Chairperson’s Remarks
Nicholas C. Dracopoli, Ph.D., Vice President & Head, Translational Research, Oncology, Janssen Research & Development

10:10 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.

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

11:35 Sponsored Presentation (Opportunity Available)

12:05 Session Break

12:15 pm Luncheon Presentation to be Announced

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 Presentation to be Announced

2:40 Sponsored Presentation (Opportunity Available)

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.

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 ThinkTank* 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

8:25 Chairperson's Remarks
Michael E. (Ted) Burczynski , Ph.D., PPM Expert, Director, Personalized & Predictive Medicine, Analytics & Big Data, Teva Pharmaceuticals

8:30 Translational Medicine to Increase the Probability of Success of Clinical Trials
Koustubh Ranade, Ph.D., Vice President, 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.

8:55 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.

9:35 Sponsored Presentation (Opportunity Available)

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

10:45 Can We Predict Nephrotoxicity before It Occurs: The Promise of Metabolomic Biomarkers
Lawrence J. Lesko, Ph.D., Clinical Professor, Center for Pharmacoconomics 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., Oncology Translational Strategist, 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/BD44 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 A1M Institute

12:00 pm Sponsored Presentation (Opportunity Available)

12:30 Close of Conference
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.
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.

**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.

**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 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.

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.

**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.

**Genomic Biomarkers for Immunotherapy Patient Selection**

**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.

**Genomic Correlates of Clinical Outcomes to CTLA4 Blockade**

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

CTLA4 blockade can induce durable clinical remissions in a minority of patients with metastatic melanoma, but robust molecular signatures of response are lacking. We analyzed transcriptomic and clinical data from multiple independent melanoma cohorts and found expression of a coordinately transcribed cluster of genes to be associated with resistance to anti-CTLA4 therapy. Evaluation of transcriptional activity of these genes may inform therapeutic preference in this disease.

**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.

**IMMUNE MONITORING: BIOMARKERS OF RESPONSE TO IMMUNOTHERAPY**

**Chairperson’s Remarks**

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

**Immunohistological and Genomic Correlations and Difference Between Various Anti-PD-L1 Clones**

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

**Close of Conference**
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.

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

11:30 High-Throughput Generation of Neoantigen-Specific T Cell Receptors for Adoptive T Cell Therapy
*Roman Yelensky, Ph.D., Executive Vice President, Sequencing and Bioinformatics, Gritstone Oncology*

11:55 Luncheon Presentation (Sponsorship Opportunity Available) or 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 (TLRAs) 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  Sponsored Presentation (Opportunity Available)
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

*Separation registration required

WEDNESDAY, MAY 3

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

8:25  Chairperson's Remarks
Christopher R. Heery, M.D., CMO, Bavarian Nordic

8:30  Immune Monitoring of Cancer Vaccines and Immunotherapy: What Have We Learned and Where to Go Next?
Sacha Gnajotic, Ph.D., Associate Professor, Institute for Cancer Immunology, 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.

8:55  Peripheral Immune Correlates of Therapeutic Cancer Vaccine Clinical Trials
Christopher R. Heery, M.D., CMO, Bavarian Nordic

Flow-based assay identified specific immune cell subsets from PBMC in retrospective analysis of two clinical trials. Immune cell subset populations correlated with clinical impact of immunotherapy in combination with cytotoxic agents, but those populations did not predict effect of cytotoxic therapy alone.

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  Harnessing Personalized Immunotherapy for the Treatment of Lymphoma
Andrew M. Evans, D.O., MSc, FACP, Professor and Chief, Hematology/Oncology, Tufts University School of Medicine, Director, Tufts Cancer Center, Tufts Medical Center

Promising immunotherapy agents being examined for the treatment of lymphoma include monoclonal antibodies, immunomodulatory agents, PD-1 inhibitors, chimeric antigen receptor (CAR) T-cells, and NK-based therapies. The optimum combinations or sequences of these therapeutics remain to be defined. Additionally, understanding tumor and patient/host heterogeneity is desired in order to fully optimize personalized medicine.

11:10  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.

11:35  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  Sponsored Presentation (Opportunity Available)
12:30  Close of Conference
Targeted therapies are directed towards specific protein targets 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 provide 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.

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.

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

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

Breast 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.

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 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
The discovery of new molecules and pathways with pivotal functions regulating the immune system facilitated the emergence of new cancer treatments. 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. 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 immunophenotyping to differentiate responder and non-responder patients in cancer immunotherapy is evident.

In early-stage breast cancer (ESBC), the degree of tumor-infiltrating lymphocytes (TIL) predicts response to chemotherapy and overall survival. Immune checkpoint antibody (ipi-llumumab, anti-CTLA-4) plus tumor crioablation 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.

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.

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.
9:20 Comprehensive Immune Profiling for Response to Checkpoint Inhibitor Therapy: A Multi-Institutional Retrospective Study

Carl Morrison, M.D., D.V.M., President, CSO and Founder, 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.

9:50 B- and T-Cell Immune Repertoire Characterization by Anchored Multiplex PCR and Next-Generation Sequencing

Laura Griffin, Ph.D., 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.

10:20 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 Sponsored Presentation (Opportunity Available)

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
The immune system’s ability to detect and destroy abnormal cells is the foundation of cancer immunotherapy. Activation of anti-tumor immunity involves multiple features of tumor immunobiology across tumor types, and forming a comprehensive biomarker signature approach – incorporating DNA and RNA-expression in classifying responders to immuno-oncology therapeutics, is 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.

Recent advancement in immuno-oncology has significantly changed oncology practice worldwide. The clinical benefit of immune checkpoint blockers 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.

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.
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.

9:45 Sponsored Presentation (Opportunity Available)

10:15 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.

12:00 pm Novel Approaches for the Combination Immunotherapy of Cancer
Jon Wigginton, M.D., Senior Vice President, Clinical Development & CMO, MacroGenics

12:25 Enjoy Lunch on Your Own

**COMBINING IMMUNOTHERAPY WITH OTHER MODALITIES**

**1:40 Chairperson's Opening Remarks**
Adrian E. Rice, Ph.D., Senior Scientist, Immunology, Etubics Corporation

**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 Multi-Pronged Immune Stimulation in the Implementation of Personalized Immunotherapy**
Adrian E. Rice, Ph.D., Senior Scientist, Immunology, Etubics Corporation

Combination immunotherapy may be necessary to achieve improved anti-cancer responses. We have been exploring various combinations of patient-specific and patient non-specific immune-stimulation; however, to achieve desired anti-cancer effects we believe one must break established tolerance to the tumor. Our programs focus on cancer gene delivery to induce acquired immunity, interleukin-15 as a driver of innate immunity (natural killer cell amplification), and a plethora of checkpoint inhibitors.

3:00 Close of Conference
Pricing and Registration Information

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