

2nd Annual Biomarker Conference



Driving precision medicine: CDx, Immuno-Oncology, NGS

6 - 7 February 2017, San Diego, USA



Event Overview

After an overwhelming response on our Annual Biomarker Conference, MarketsandMarkets is pleased to announce **The 2nd Annual Biomarker Conference** which will take place on the **6th and 7th of February 2017, in San Diego, USA.**

The recent success of companion diagnostics along with the increasing regulatory pressure for better identification of the target population has created an extraordinary spur for drug discovery companies to invest in novel strategies for biomarker discovery. Also, the confluence of immunology and oncology tributaries has triggered a biomarker turbulence that is novel to the cancer community.

The pursuit to drive precision medicine and the quest to refine a biomarker model for immuno-oncology drug development, **The 2nd Annual Biomarker Conference** aims to gather experts from pharma, bio-pharma companies and research institutes to discuss current challenges and opportunities in biomarker discovery, CDx, NGS, regulatory and reimbursement issues and novel technologies.

Key Highlights

- ✓ Companion Diagnostics
- ✓ Immuno-Oncology
- ✓ NGS & Novel Technologies in Biomarker Discovery
- ✓ Circulating Biomarkers
- ✓ Translational Biomarkers

Interactive Panel Discussions

- Complementary diagnostics v/s Companion Diagnostics; How do we ensure success in biomarker efforts?
- Translation from Pre-clinical to clinical; Challenges and Novel Strategies

Advisory Panel



Rajiv Raja
Director R & D
Translational Medicine &
Pharmacogenomics,
MedImmune AstraZeneca,
Maryland



Jianda Yuan
Director Translational
Immuno-Oncology Research,
Early Clinical Oncology,
Merck, New York



Darrell Borger
Director, Biomarker
Laboratory
Mass General Hospital,
Massachusetts



Thomas Schlange
Senior Biomarker Scientist,
Global Biomarker
Research, Bayer
Healthcare, UK



Dave Hoon
Director,
Molecular Oncology,
John Wayne
Cancer Institute,
California

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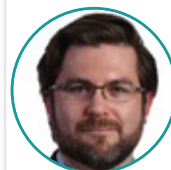
Speaker Panel



Gary Kelloff
Special Advisor
NIH/NCI, Washington D.C



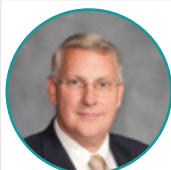
Mark Curran
VP Systems Pharmacology
and Biomarkers, Immunology
Therapeutic Area, **Janssen
Research & Development,
LLC, New York**



Zach Boyd
Companion Diagnostic
Program Leader - Tecentriq
(Atezolizumab),
Genentech, California



Abdel Halim
VP Translational Medicine,
Biomarkers & Diagnostics
**Celldex Therapeutics, New
York**



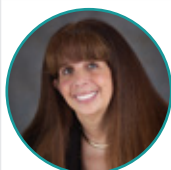
Carl Barrett
VP Translational Science
**Astrazeneca,
Massachusetts**



Sriram Sathyanarayanan
Director Translational
Sciences
**Jounce Therapeutics, Inc.,
Massachusetts**



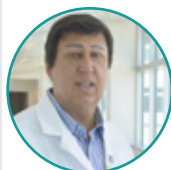
Aung Naing
Asso. Prof. Department
of Investigational Cancer
Therapeutics, **The University
of Texas MD Anderson
Cancer Center, Texas**



Razelle Kurzrock
Chief, Division of Hematology
and Oncology
**UCSD Moores Cancer
Center, California**



Jianda Yuan
Director Translational
Immuno-Oncology Research,
Early Clinical Oncology
Merck, New York



Dave Hoon
Director Molecular Oncology
**John Wayne Cancer
Institute, California**



Anneli Andersson
Scientific Project Manager
NEBION AG, Switzerland



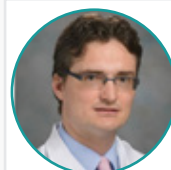
Catherine Tribouley
Senior Director, Correlative
Sciences
Novartis, New York



Ann Kapoun,
VP Translational Medicine,
Onco Med Pharmaceuticals



Jon Armstrong
CSO
**Cofactor Genomics, San
Diego**



Janku Filip
Associate Professor
**MD Anderson Cancer
Center, Texas**



Deepak Khatri
Science Associate Director,
Statistical Sciences
**MedImmune, Washington
D.C**



Saurabh Gupta
Associate Director
Translational Medicine Group
**Takeda Oncology,
Massachusetts**



Sandip P. Patel
Medical Oncologist, Assistant
Professor of Medicine, **UC
San Diego Health, San
Diego**



Janusz Dutkowski
CEO
Data4Cure, Inc., California



Kamala K Maddali,
VP, Biopharm Market
Development, Collaborations
and Companion Diagnostics
**Cancer Genetics, Inc.,
New Jersey**



Jianyu Rao
Professor, Pathology and
Epidemiology, Director,
Cytopathology/International
Telepathology, **University of
California, California**



Jeffrey Miner
Executive Director
**AstraZeneca (Ardea
Biosciences), California**

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Day 1, Monday, 6th February 2017

08:00 Registration

08:55 MarketsandMarkets' Welcome Address

09:00 Opening remarks from the chairman

09:10 **Keynote Presentation - progress in development of circulating biomarkers, the promise of liquid biopsies**

- Different methods in development for liquid biopsies provide complementary information.
- Minimal Residual Disease (MRD) has great promise in Heme cancer drug development and patient care.
- Intended use for biomarkers dictates the developmental pathway required

Gary Kelloff, Special Advisor, **NIH/NCI, Washington D.C**

Trends in Immuno-Oncology and CDx

09:35 **Immunotherapy of solid tumors: state of the art in biomarker science**

- Predictive biomarkers for immunotherapeutic response in cancer, with a focus on novel biomarker assays.
- Nuances in the development of PD-L1 IHC with a focus on alternative predictive biomarkers that may better determine patient response to immune checkpoint modulation.
- Next generation of cancer immunotherapeutics currently under development including cell-based approaches.

Sandip P. Patel, Medical Oncologist, Assistant Professor of Medicine, **UC San Diego Healthm, California**

10:00 **Marrying genomics and immunotherapy: the perfect match**

- Immunotherapy enables the immune system to recognize tumors
- The immune system often recognizes tumors based on the genomic mutations--mutanome
- Choosing the best patients for immunotherapy can be done with the use of genomics

Razelle Kurzrock, Chief, Division of Hematology and Oncology, **UCSD Moores Cancer Center, California**

10:25 **Finding highly specific disease markers by co-analysis of thousands of public RNA-seq and microarray studies**

Anneli Andersson, Scientific Project Manager, **NEBION AG, Switzerland**

10:40 *Morning Refreshments | Poster Presentations | One-to-One Networking*

11:25 **Presentation by Cancer Genetics Inc.**

11:55 **Companion Diagnostics; are we delivering on the promise?**

- Promise and attraction
- Challenges- Undermined by overexcitement
- Lesson learned- Real life examples
- Future consideration

Abdel Halim, VP Translational Medicine, Biomarkers & Diagnostics, **Celldex Therapeutics, New York**

12:20 **Challenges of drug and diagnostic co-development: examples in auto-immune disorders**

- Precision Medicine in auto-immune disorders
- Progress toward Prognosis and Prediction in RA and IBD
- Digital Health Application in Rheumatoid Arthritis

Mark Curran, VP Immunology Biomarkers, **Janssen, Pharmaceutical Companies of Johnson and Johnson, New York**

12:45 **Presentation by Data4Cure Inc.**

13:15 *Lunch Poster Presentations | One-to-One Networking*

14:15 **Panel Discussion: Complementary diagnostics v/s Companion Diagnostics**

How do we ensure success in biomarker efforts?

- Different aspects of biomarker development to be considered
- Regulatory hurdles
- Ensuring success in biomarker efforts

Panelists:

Abdel Halim, VP Translational Medicine, Biomarkers & Diagnostics, **Celldex Therapeutics, New York**

Zach Boyd, Sr. CDx Project Leader, **Genentech, California**

Mark Curran, VP Immunology Biomarkers, **Janssen, Pharmaceutical Companies of Johnson and Johnson, New York**

Kamala K Maddali, VP, Biopharm Market Development, Collaborations and Companion Diagnostics, **Cancer Genetics, Inc., California**

NEBION

CANCER GENETICS INCORPORATED
Engineering Personalized Cancer Treatment

Data4Cure
Biomedical Intelligence

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14:45 Presentation by Oxford Biodynamics Ltd.

15:15 **Need for non-invasive Biomarkers for Nonalcoholic Steatohepatitis**

- Challenges in diagnosis and monitoring of NASH
- Challenges in drug development in NASH
- Opportunities for developing circulating markers for NASH

Saurabh Gupta, Associate Director Translational Medicine Group, **Takeda, Massachusetts**

15:40 **Development and regulatory considerations for development of a companion or complementary diagnostic**

- Regulatory requirements for companion diagnostic development
- Adaptive development of a companion diagnostic for TECENTRIQ
- Approval of a complementary diagnostic for TECENTRIQ

Zach Boyd, Companion Diagnostic Program Leader - Tecentriq (Atezolizumab), **Genentech**

16:05 Presentation by Asterand Biosciences

16:20 *Afternoon Refreshments and Poster Presentation | One-to-One Networking Meetings*

Novel technologies

17:00 **Diagnosing and monitoring cancer using liquid biopsy technologies**

- Understanding the basic science
- Clinical findings of using saliva for liquid biopsy

Speaker TBA

17:25 **Molecular profiling of circulating sources of tumor DNA and applications for cancer therapy**

- Novel, minimally invasive methods that represents the prevailing molecular profile of cancer
- Multiple clinically useful applications
- Determination of cancer prognosis and diagnosis of cancer recurrence or progression.

Janku Filip, Associate Professor, **MD Anderson Cancer Center, Texas**

17:50 Closing remarks by the chair

Networking and Drinks Reception

End of Day - 1

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Day 2, Tuesday, 7th February 2017

- 08:15 Registration**
- 08:55 MarketsandMarkets' Welcome Address**
- 09:00 Opening remarks from the chairman**
- 09:10 Keynote Presentation – Development of osimertinib, a third generation EGFR inhibitor**
- EGFR mutant lung cancers
 - Acceleration of drug development
 - Resistance mechanisms with targeted therapies
- Carl Barrett, VP Translational Science, AstraZeneca, Massachusetts**

Translational Biomarkers

- 09:35 Immune Correlates**
- PD-L1 expression
 - Immune Infiltrates
 - Mutational Landscape
- Aung Naing, Associate Professor, Department of Investigational Cancer Therapeutics, The University of Texas MD Anderson Cancer Center, Houston**
- 10:00 Utilization of biomarkers in adaptive clinical trial designs**
- Use of biomarkers, diagnostics, and flexible study designs in optimizing clinical development of precision medicines.
 - Current opportunities and challenges in using biomarkers in adaptive clinical trial designs.
 - Recommendations based on the state-of-the-art knowledge from the scientific literature, latest regulatory thinking, and industry practice
- Deepak Khatry, Science Associate Director, Statistical Sciences, MedImmune, Washington D.C**
- 10:25 Introducing Cofactor Paragon – Multilayer characterization of tumors and their microenvironment from a single RNA sample**
- Reports the gene expression of immune inhibitory molecules.
 - Quantifies the ratios of multiple leukocyte subtypes in the tumor microenvironment.
 - Measures the foreignness of the tumor using RNA mutational burden.
- Jon Armstrong, CSO, Cofactor Genomics, San Diego**



10:55 Morning Refreshments | Poster Presentations | One-to-One Networking

- 11:40 Panel Discussion: Translation from pre-clinical to clinical: challenges and novel strategies**
- Sensitivity, Specificity and Validation algorithms for regulatory approval
 - Need of Regulatory oversight definitions
 - Evaluating clinical validity
- Moderator:**
Gary Kelloff, Special Advisor, NIH/NCI, Washington D.C
- Panelists:**
Dave Hoon, Director Molecular Oncology, John Wayne Cancer Institute, California
Jianda Yuan Director, Translational Immuno-Oncology Research, Early Clinical Oncology, Merck, New York
Catherine Tribouley, Senior Director, Correlative Sciences, Novartis, New York
- 12:10 Next Generation Biomarkers For The Era Of Combination Cancer Immunotherapy**
- First- and second-generation biomarkers that predict response to PD-1-directed monotherapy
 - Biomarker challenges in an era with an enhanced cancer immunotherapy
 - Precision medicine in cancer immunotherapy
- Jianda Yuan, Director, Translational Immuno-Oncology Research, Early Clinical Oncology, Merck, New York**

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12:35 Clinical Change of Paradigm In Liquid Biopsies: Emergence Of cfDNA Assays Over CTC Assays

- Why CTC assays have taken a bad turn and given false belief
- How cfDNA assays have emerged into CLIA and FDA approval
- Is there any hope for CTC assays
- What is the future for liquid biopsy assays

Dave Hoon, Director Molecular Oncology, **John Wayne Cancer Institute**, California

13:00 Presentation by Avacta Lifesciences

13:30 *Lunch and Poster Presentation | One-to-One Networking Meetings*

14:30 Mechanobiological Profiling as a Biomarker for Cancer

- Limitations of current approach for cancer diagnosis/biomarkers development
- Molecular basis for cancer cell mechnolbiology
- Status of mechanobiological profiling studies

Jianyu Rao, Professor, Pathology and Epidemiology, Director, **Cytopathology/International Telepathology**, University of California, California

14:55 Patient selection biomarkers in oncology

- Examples of developing and using patient section biomarkers in the clinic
- Clinical Wnt and Notch programs will be highlighted
- Focus on personalized medicine strategy for early phase studies

Ann Kapoun, VP Translational Medicine, **Onco Med Pharmaceuticals**, California

15:20 Presentation by Cancer Genetics Inc.

15:50 *Afternoon Refreshments and Poster Presentation | One-to-One Networking Meetings*

16:20 Developing an integrated translational science strategy to support clinical development of novel immunotherapies

- Current status of TME biomarkers and response to anti-PD-1 inhibitors in the clinic
- Biomarker-driven indication selection
- Future considerations

Sriram Sathyanarayanan, Director Translational Sciences, **Jounce Therapeutics**, Massachusetts

16:45 Novel biologic therapeutics

Jeffrey Miner, Executive Director, **AstraZeneca (Ardea Biosciences)**, California

17:10 Closing remarks by the chairman

End of Conference

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