ONCOLOGY BIOLOGICS
PARADIGM SHIFT IN CANCER TREATMENT
EXAMINING THE NEXT GENERATION OF ONCOLOGY BIOLOGICS, CANCER TREATMENT, PERSONALIZED HEALTHCARE & GENOMICS

JANUARY 28–29, 2014 | HYATT BOSTON HARBOR | BOSTON, MA
CO-LOCATED WITH 3RD DRUG FORMULATION & BIOAVAILABILITY

FEATURED SPEAKERS

JOHN LAMBERT, PhD
IMMUNOGEN

HANS-PETER GERBER, PhD
PFIZER, INC.

CHARLES DRAKE, MD, PhD
THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

ROBERT J. KREITMAN, MD
NATIONAL INSTITUTES OF HEALTH

RAKESH DIXIT, PhD
MEDIMMUNE

F. STEPHEN HODI, MD
DANA-FARBER CANCER INSTITUTE

ADDITIONAL KEY SPEAKERS INCLUDE:

Neil H. Bander, MD, Bernard & Josephine Chaus Professor, WEILL CORNELL MEDICAL COLLEGE, MEMORIAL SLOAN-KETTERING CANCER CENTER

David F. McDermott, MD, Associate Professor, Department of Medicine, HARVARD MEDICAL SCHOOL

Ramy Ibrahim, MD, Senior Director, MEDIMMUNE (ASTRAZENECA BIOLOGICS)

Ravi A. Madan, MD, Assistant Clinical Investigator, Laboratory of Tumor Immunology and Biology & Medical Oncology Branch, NATIONAL CANCER INSTITUTE

Ahmad A. Tarhini, MD, PhD, Associate Professor, Dept of Medicine, Hematology-Oncology, Clinical and Translational Science Institute, UNIVERSITY OF PITTSBURGH SCHOOL OF MEDICINE

Robert A. Beckman, MD, Executive Director, Clinical Development Oncology, DAIICHI-SANKYO, INC.

Stanley Frankel, MD, Executive Director, AMGEN, Adjunct Associate Professor of Medicine, COLUMBIA UNIVERSITY MEDICAL CENTER

Michelle Krogsgaard, PhD, Assistant Professor, Department of Pathology and NYU Cancer Institute, NYU SCHOOL OF MEDICINE

Neil H. Bander, MD, Bernard & Josephine Chaus Professor, Weill Cornell Medical College, MEMORIAL SLOAN-KETTERING CANCER CENTER

Erin Macrae Olson, MD, Assistant Professor of Internal Medicine, Breast Medical Oncology, THE OHIO STATE UNIVERSITY

Lawrence Fong, MD, Associate Professor in Residence, Division of Hematology/Oncology, Department of Medicine, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

KEY PROGRAM SESSIONS INCLUDE:

- Immunotherapy and Cancer Vaccines
- Antibody-drug conjugates
- Immunoconjugates
- Anti-angiogenesis biologics
- Stem cell targeting biologics
- Novel biologics beyond antibodies
- Bispecific antibodies
- Oncology biologics enabling diagnostics technologies
- Personalized cancer treatment
DEAR COLLEAGUE,

Biological therapies including new generation of monoclonal antibodies, immunotherapy and biological response modifier therapy treatments have revolutionized the treatment of cancers in recent years. Many types of cancers are now considered a chronic disease that can be managed through a combination of new generation of biologics, radiation and small molecule oncology drugs.

This inaugural innovative event is unique in that it will bring the most current progress in cancer biologics, as well as focus on current innovations in biologics, future drug development and novel treatment options.

Key strategic insights shared at this event include:

- Distinguished speakers from leading US academic/medical, government and biopharmaceutical R&D
- Miracles of Immunotherapy and cancer vaccines in treating previously untreatable cancers
- New armed antibodies in cancer: advances in antibody-drug conjugates and Immunotoxins
- Novel biologics beyond antibodies, bispecific antibodies
- Personalized cancer treatment

Benefits of Attending:

- Network with leading clinical oncology experts
- Learn unprecedented progress made in the development of novel oncology biologics to date from both industry and academic experts
- Uncover next generation of biologics, including immune mediated targeted biologics, antibody drug conjugates, bispecific antibodies, personalized approaches
- Examine which new targets and biologics formats are being explored, and why
- Develop knowledge of the utility of personalized genomics, biomarkers and targets in development of cancer biologics
- Understand how new generation of biologics are helping patients to fight previously untreatable cancers, including melanoma and lung cancers

This event will provide you with a comprehensive understanding of the next generation of oncology biologics for cancer treatment from industry and academia’s leading experts. We look forward to seeing you in Boston for this timely 2014 event!

Sincerely,
Dr. Rakesh Dixit,
Vice President, R & D
MedImmune (AstraZeneca Biologics)

WHO SHOULD ATTEND

This conference is specifically designed for Biopharmaceutical, Medical Device, and Diagnostic professionals specializing in:

- Oncology Clinical Research/Development/Pharmacology/Pathology
- Biomarker Discovery/Validation/Qualification
- Experimental Medicine
- Translational Medicine
- Molecular & Cell Biology
- Legal Affairs
- Preclinical/R&D
- Regulatory Affairs/Safety Assessment
- Pharmacokinetics/Pharmacodynamics
- Drug Safety Assessment
- Imaging
- Toxicology
- Drug Metabolism
- Epigenetics

VENUE

Hyatt Boston Harbor
101 Harborside Drive|Boston, MA 02128
1–888–421–1442

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DAY ONE | TUESDAY | JANUARY 28, 2014

8:00 REGISTRATION & CONTINENTAL BREAKFAST

8:30 CHAIR’S DAY ONE WELCOME AND OPENING REMARKS
Rakesh Dixit, PhD, Vice President, R&D, MEDIMMUNE
(AstraZeneca Biologics)

8:40 HARNESSING THE POWER OF T-CELL CHECKPOINT ANTAGONISTS IN TREATING CANCERS

- Understand rationale behind checkpoint blockade
- Current clinical activity of checkpoint blockade
- Future development and hurdles

Frank Stephen Hodi (Jr.), MD, Melanoma Disease Center Leader; Associate Professor of Medicine, DANA-FARBER CANCER INSTITUTE, HARVARD MEDICAL SCHOOL

9:20 NEW INNOVATIVE TARGETS OF IMMUNE ACTIVATION: Next Generation of Immunotheapeutics and Innovative Combinations

- Overview of clinical combination data over the past decade
- Future directions
- Combination between biologics and targeted agents
- Novel: combinations

Ramy Ibrahim, MD, Senior Medical Director, Oncology Clinical Development, MEDIMMUNE (AstraZeneca Biologics)

10:00 IMMUNE CHECKPOINT BLOCKADE IN CANCER TREATMENT: From Single Agents to Combinations

- Single agent blockade of both CTLA-4 and PD-1 shows clear clinical activity in several cancer types
- Combined checkpoint blockade is promising, both in preclinical studies as well as in early clinical studies
- Immune checkpoint blockade can also be combined with other approaches, including cancer vaccines

Charles Drake, MD, PhD, Associate Professor, Department of Oncology, THE JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE

10:40 NETWORKING AND REFRESHMENT BREAK

11:10 COMPARATIVE EFFICACY AND SAFETY OF IMMUNE CHECKPOINT INHIBITORY ANTIBODIES

- Summarize emerging clinical data and potential of PD-1 pathway–targeted antibodies in development
- Blocking the PD-1/PD-L1 pathway will prove valuable additions to the growing armamentarium of targeted immunotherapeutic agents

David F. McDermott, MD, Associate Professor, Department of Medicine, HARVARD MEDICAL SCHOOL

11:50 T-CELL RECEPTOR AFFINITY AND AVIDITY DEFINES ANTITUMOR RESPONSE AND AUTOIMMUNITY IN T-CELL IMMUNOTHERAPY

- Challenges in immunizing against cancer
- Adoptive cell transfer (ACT) with genetically modified T-cells
- Types of recombinant receptors for use in adoptive T-cell therapy
- Can higher affinity TCRs render ACT more effective?
- Is there an optimal affinity range that balances effective anti-tumor activity and minimal autoimmunity?

Michelle Krogsgaard, PhD, Assistant Professor, Department of Pathology and NYU Cancer Institute, NYU SCHOOL OF MEDICINE

12:30 LUNCHEON

1:30 | CASE STUDY | IMMUNE-MEDIATED ADVERSE EVENTS ASSOCIATED WITH CTLA-4, PD1 AND PDL1 BLOCKADE THERAPY, THE UNDERLYING MECHANISMS AND CLINICAL MANAGEMENT

- Efficacy of Ipilimumab immunotherapy in Advanced Melanoma (brief summary)
- Efficacy of Anti-PD1, Anti-PDL1 mAb immunotherapy in Advanced Melanoma (brief summary)
- Adverse Event Profile of Ipilimumab, Nivolumab and MPD3280A
- Timing, Resolution and Management of irAEs
- Apparent/Known Underlying Mechanisms of Action of Immune Related/Mediated AE

Ahmad A. Tarhini, MD, PhD, Associate Professor; Dept. of Medicine, Hematology-Oncology, Clinical and Translational Science Institute; University of Pittsburgh School of Medicine, Melanoma and Skin Cancer Program, UNIVERSITY OF PITTSBURGH CANCER INSTITUTE

2:10 ADVANCES IN PROSTATE CANCER IMMUNOTHERAPY

- Sipuleucel-T mechanisms of action
- Immune checkpoint blockade
- Combination therapies

Lawrence Fong, MD, Associate Professor in Residence, Division of Hematology/Oncology, Department of Medicine, UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

2:50 NETWORKING AND REFRESHMENT BREAK

3:20 EMERGING DATA SUPPORTING IMMUNOTHERAPY COMBINATIONS IN PROSTATE CANCER

- Immunotherapy may be able to generate sustained anti-tumor activity in patients with prostate cancer and have its greatest impact in earlier stages
- Debubling tumor followed by immunotherapy may be a way to enhance clinical outcomes
- Combinations of immunotherapy with radiation/anti-androgen therapy may synergize to produce improved clinical outcomes

Ravi Madan, MD, Clinical Investigator, Laboratory of Tumor Immunology and Biology & Medical Oncology Branch, NATIONAL CANCER INSTITUTE (NIH)

4:00 NEXT GENERATION PERSONALIZED CANCER MEDICINE STRATEGIES MAY LEAD TO IMPROVED PATIENT OUTCOMES

- Tumors are genetically unstable because this is the most efficient way for cancer to evolve
- Genetic instability leads to the development of minor subclones and to continuous evolution of the tumor
- Novel personalized medicine strategies, and evolutionary dynamics can greatly improve patient outcomes

Robert A. Beckman, MD, Executive Director; Clinical Development Oncology, DAIICHI-SANKYO, INC.
DAY ONE CONTINUED

4:40 IMMUNE PROFILING AND PATIENT ENRICHMENT IN IMMUNOTHERAPY DRUG DEVELOPMENT: Challenges and Opportunities
- Therapeutic modulation of immune function in diverse patient populations and disease settings has been achieved with multiple approaches however, the determinants of response have yet to be elucidated. Greater understanding of the immune status and capacity of patients before, during and after treatment may help guide the development and use of immunotherapies.
  - Given the complexity of the immune system, tumor biology and diverse MOA of potential therapies
  - What makes sense to measure?

DAY TWO | WEDNESDAY | JANUARY 29, 2014

8:00 CONTINENTAL BREAKFAST

8:50 CHAIR’S DAY TWO WELCOME AND OPENING REMARKS
Rakesh Dixit, PhD, Vice President, R&D, MEDIMMUNE (AstraZeneca Biologics)

9:00 CURRENT STATUS AND NEXT GENERATION OF ANTIBODY-DRUG CONJUGATES
The recent approvals of brentuximab vedotin and ado-trastuzumab emtansine have demonstrated that antibody-drug conjugate (ADC) technologies utilizing potent tubulin-acting agents are able to generate highly active, well-tolerated, anticancer agents that fulfill the long-awaited promise of ADCs.
- Several ADCs have shown encouraging efficacy in clinical trials in both solid tumors and hematologic malignancies
- These developments have reinvigorated interest in the field of developing next-generation anticancer agents utilizing highly potent cytotoxic agents
- In creating effective, well-tolerated, ADCs, each element in its design, from target selection, selection of the antibody, the cytotoxic “payload,” and the linker, is important

John H. Lambert, PhD, Executive Vice President and Chief Scientific Officer, IMMUNOGEN

9:40 TARGET, DRUG AND LINKER SELECTION STRATEGIES FOR ANTIBODY-DRUG CONJUGATES
- Differences in the mechanism of action between calicheamicin and tubulin inhibitor based ADCs
- Clinical dose fractionation studies conducted with two calicheamicin conjugates (CMC-544/ Inotuzumab Okgaminic and Mylotarg/ Gemtuzumab Ozogamicin)
- Preclinical development of a novel auristatin based ADC targeting the oncofetal antigen ST4, expressed on tumor initiating cells
- Current limitations in ADC development and strategies for next generation ADCs

Hans-Peter Gerber, PhD, Executive Director, BioConjugate Discovery and Development Oncology Research Unit East, PFIZER, INC.

10:20 NETWORKING AND REFRESHERMENT BREAK

10:50 CLINICAL DEVELOPMENT CHALLENGES TO ANTIBODY DRUG CONJUGATES
- Concept vs. reality
- Target selection
- Patient selection
- Pharmacodynamic assessment
- Therapeutic index

Neil H. Bander, MD, Bernard & Josephine Chaus Professor, Weill Cornell Medical College, MEMORIAL SLOAN-KETTERING CANCER CENTER

11:30 RECOMBINANT ANTI-CD22 IMMUNOTOXINS FOR B-CELL LEUKEMIA
- Recombinant immunotoxins can be engineered by replacing the binding domain of Pseudomonas exotoxin with a recombinant binding domain which binds to a cancer antigen
- Anti-CD22 is expressed on several human B-cell leukemias, including chronic lymphocytic leukemia (CLL), acute lymphoblastic leukemia (ALL), and hairy cell leukemia (HCL)
- Several recombinant immunotoxins have achieved major responses in prior clinical trials of hematologic malignancies
- Moxetumomab Pasudotox is an affinity matured mutant of BL22 which achieves major responses including complete remissions in patients with ALL or HCL
- A pivotal phase III trial is underway testing Moxetumomab Pasudotox in patients with relapsed and refractory HCL

Robert J. Kreitman, MD, Chief, Clinical Immunotherapy Section, Laboratory of Molecular Biology, NATIONAL CANCER INSTITUTE

12:10 LUNCHEON

1:30 MAXIMIZING HUMAN EPIDERMAL GROWTH FACTOR RECEPTOR 2 INHIBITION BY T-DM1: A New Oncologic Paradigm in the Era of Targeted Therapy
- Trastuzumab emtansine (T-DM1) is an antibody-drug conjugate consisting of the monoclonal antibody trastuzumab linked to the cytotoxic agent mertansine
- A pivotal phase III clinical trial, the EMILIA study, demonstrated significant clinical efficacy of T-DM1 and was generally better tolerated than the control treatment in patients with pretreated HER2-positive metastatic breast cancer
- Multiple clinical trials are in development testing the efficacy of T-DM1 in patients with different stages of HER2-positive breast and gastric cancer

Erin Macrae Olson, MD, Assistant Professor of Internal Medicine, Breast Medical Oncology, THE OHIO STATE UNIVERSITY

2:15 BITE TECHNOLOGIES AND APPLICATIONS IN ONCOLOGY DRUG DEVELOPMENT: Clinical Results of Bispecific T-Cell Engager (BiTE®) Antibody Studies in Cancer Patients
- Overview of BiTE Technology
- Blinatumomab directed against CD19 has shown clinical activity in B cell malignancies in adults and children and in bulk and minimal residual disease
- Three compounds are under investigation in adult patients with solid tumors

Stanley Frankel, MD, Executive Director, AMGEN, Adjunct Associate Professor of Medicine, COLUMBIA UNIVERSITY MEDICAL CENTER

3:00 END OF CONFERENCE
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