

Register by December 19th and Save up to \$200!



Cambridge Healthtech Institute's Inaugural...

TRANSLATIONAL CANCER MEDICINE

"Top Ten" Opportunities in Oncology Drug and Diagnostic Development

January 26-28, 2009 | The Westin San Diego | San Diego, California

FEATURED SPEAKERS:

J. Carl Barrett
Global Head, Oncology Biomarker and
Imaging, **Novartis**

Jon M. Wigginton
Director, Clinical Oncology, **Merck**

Anne-Marie Martin
Director, Oncology, **GlaxoSmithKline**

Scott D. Patterson
Executive Director, Medical Sciences,
Amgen

James Christensen
Director, Translational Pharmacology,
Pfizer

Bahija Jallal
Head, Oncology, **MedImmune**

Herbert A. Fritsche
Chief, Clinical Chemistry, **Anderson
Cancer Center**

Martin Fleisher
Chair, Clinical Laboratories, **Memorial
Sloan-Kettering Cancer Center**

J. Milburn Jessup
Chief, Diagnostics Evaluation, **NCI**

Glenn Merlino
Chief, Cancer Biology and Genetics, **NCI**

Francis Kalush
Network Leader, Diagnostics,
CDRH, FDA

Top 10 Opportunities in Translational Cancer Medicine:

1. Combination Therapies
2. New Targets
3. Molecular Diagnostics
4. Companion Diagnostics
5. Better *in vitro* Models
6. Better *in vivo* Models
7. Biomarkers to Predict Drug Response
8. Cancer Biologics
9. Phase 0 Clinical Trials
10. Translational Imaging

ADDITIONAL COVERAGE:

- Case Studies in Oncology Drug Development
- Cancer Biomarkers
- Translation from In-House Development to Clinical Laboratory
- Circulating Tumor Cell Assays

PRE-CONFERENCE SHORT COURSES:

- Novel Cancer Biomarkers
- Fit-for-Purpose Biomarker Assay Development and Validation

Co-located with the **Biomarker Assay Development** meeting www.biomarkerassaydevelopment.com
Register for Translational Cancer Medicine meeting and receive complimentary access to Biomarker Assay Development.



Cambridge Healthtech Institute
250 First Avenue, Suite 300, Needham, MA 02494
Telephone: 781-972-5400 or
Toll-free in the U.S. 888-999-6288
Fax: 781-972-5425 • www.healthtech.com



Hotel & Travel Information

Conference Venue and Hotel:

The Westin San Diego
400 West Broadway
San Diego, CA 92101
T: 619-239-4500
F: 619-239-3274

Discounted Room Rate: \$220/s, \$230/d

Discounted Room Rate Cut-off Date: December 29, 2008

Please call the hotel directly to reserve your sleeping accommodations. Identify yourself as a Cambridge Healthtech Institute conference attendee to receive the discounted room rate. **Reservations made after the cut-off date or after the group room block has been filled (whichever comes first) will be accepted on a space-and-rate-availability basis. Rooms are limited, so please book early.**

Flight Discounts:

To receive a 5% discount on American Airlines, American Eagle and American Connections call and make your flight reservations at 1-800-433-1790 or go online at www.aa.com. Please refer to the authorization number AN# A2418SS via phone or enter it in the promotion discount box online.

Car Rental Discounts:

Special discount rentals have been established with AVIS for this conference. Please call AVIS directly at 800-331-1600 and reference our Avis Worldwide Discount (AWD) Number J868190 or go to www.avis.com.

Present A Poster:

Cambridge Healthtech Institute encourages attendees to gain further exposure by presenting their work in the poster sessions. To secure a poster board and inclusion in the conference proceedings, your abstract must be submitted, accepted and registration paid in full by January 5, 2009. [Register online to use the Poster Abstract Submission form](#). If you register by phone, fax, or mail, you will receive Poster Abstract Submission guidelines via email.

Sponsorships & Exhibits:

Brand your company as a thought leader in the global biomarker community by participating as an active sponsor. Showcasing your technologies, services and solutions to our highly targeted audience can significantly impact their buying decisions and help you achieve your sales and business development objectives.

Sponsorship Opportunities Include:

- **Technology Showcase:** Includes a presentation within main scientific agenda
- **Breakfast Technology Workshop:** Includes 20-minute presentation and 10-minute Q&A
- **VIP Dinner:** Invitation-only event for 15+ select delegates
- **Exhibit Hall Reception:** Use this lively social occasion to launch a new product or solution; drive delegates to your exhibit!

Sponsorship packages can be customized to best suit your company's strategic sales and business development goals.

Exhibiting:

Exhibiting allows your company to differentiate your technologies, services or solutions from competitors and demonstrate its commitment to this science. Exhibitors will enjoy facilitated networking opportunities with 150+ qualified delegates, making it a perfect platform to launch a new product, collect feedback and generate new leads.

Promotional programs:

Reinforce your branding messages, or enhance your booth presence with promotional opportunities such as tote bags, tote bag inserts, session room literature drops and more.

For more information, or to contract your sponsorship or exhibit space today, please contact:

Ilana Schwartz
Manager, Business Development
781-972-5457
ischwartz@healthtech.com

PRE-CONFERENCE EVENTS:

MONDAY, JANUARY 26

8:30-12:00 Registration for Pre-Conference Events*

11:00-3:00 Pre-Conference Short Course*

Fit-for-Purpose Biomarker Assay Development and Validation

Instructors:

- *Jean Lee, Ph.D., Scientific Director, PKDM, Amgen*
- *Viswanath Devanarayan, Ph.D., Director, Statistics, Biomarker Research, Abbott Laboratories*
- *John Allinson, FIBMS, Laboratory Director, Veeda Clinical Research*

This tutorial will provide recommendations on the "fit-for-purpose" best practices in the development and validation of biomarker assays for the intended exploratory or advanced biomarker applications. Strategies for different applications at various phases of biomarker development will be described. Key elements in the method development and validation will be illustrated with examples, including reference to standard material, sample stability and collection integrity, validation and QC samples, validity of reference standards, calibration curve fitting methods, method optimization and method feasibility studies. The special challenges in protein biomarker assays will be discussed, including strategies for moving from biomarker panels in the exploratory phase to the few markers chosen to support clinical trials.

Outline:

1. Introduction - Nomenclature, types of biomarker methods/assays, biomarker method development & validation road map, fundamental validity, similarity and differences from PK assays & diagnostic application.
2. Pre-analytical and bioanalytical elements: Target range, standards, validation & QC samples, stability, matrix effect, specificity, and relative selectivity.
3. Calibration curve model selection, evaluation, and weighting.
4. Method feasibility and optimization with precision profiles.
5. Evaluation of some pre-study validation characteristics such as precision, bias, sensitivity and quantification limits.
6. Use of Sample Controls for in-study performance monitoring and conformance testing among laboratories.

(*Separate registration required)

9:00-3:00 Pre-Conference Short Course*

Novel Cancer Biomarkers

9:00-9:05 Chairperson's Opening Remarks

9:05-9:30 *in vivo* Discovery and Validation of Biomarkers of Human Drug Response and Resistance

Joerg Heyer, Ph.D., Principal Scientist, Group Leader, Genetic Models, AVEO Pharmaceuticals, Inc.

With the emerging elucidation and understanding of the human genome, the complexities of genetic changes in cancer have become apparent. Traditional models of preclinical research and development have generally not recapitulated the dynamics of the genome found in cancer. New approaches to genetically engineered models, i.e. exploiting the natural diversity of signaling pathways in genetically engineered cancer models, or generating spontaneous human tumors in tissue transplantation models, have shown great promise to faithfully capture the complexity of genomic changes seen in cancer. We have generated a Human Response Prediction approach, based on naturally occurring variation in our genetically defined models of cancer, which allows us to identify genetic biomarkers of therapeutic response.

9:30-9:55 Preclinical Biomarker Discovery and Validation for a Small Molecule Inhibitor of MEK Kinase

Mark R. Lackner, Ph.D., Scientist, Developmental Oncology Diagnostics, Genentech, Inc.

Abstract unavailable at the time of printing.

Please visit www.translationalcancermedicine.com for updates.

(*Separate registration required)

Lead Sponsoring Publications:



9:55-10:20 Development of Clinically Relevant Gene Expression Profiles for Prognosis of Early Stage Breast Cancer

Richard Bender, M.D., FACP, Chief Medical Officer, Agendia, Inc.

Gene Expression Profiling is rapidly becoming the new frontier for the development of biomarkers for the diagnosis of disease, for the assessment of prognosis and for the prediction of the likelihood of responding to a particular drug or class of drugs. The ability to analyze patient groups with multi-gene profiles using either RT-PCR or microarray oftentimes belies the complexity of the clinical question and is subject to over-fitting the data, as many genes are used to discriminate between 2 groups of patients, oftentimes simply responders or non-responders, "low" risk or "high" risk or disease present or absent groups. As such, meticulous attention to all experimental details from extraction of genomic material from patient specimens to interpretation of gene expression, must be rigidly controlled. As interpretation of the multi-gene readout is not "intuitive" to the ordering physician (unlike a single analyte assay, such as CA 27-29) requiring a "black box" mathematical algorithm to generate or risk profile or result, the FDA has issued IVDMA Guidance for the Industry suggesting how these assays need to be regulated. The presentation will discuss the process of assay development for breast cancer prognosis as a way of illustrating the key steps in this process and will review the latest developments in governmental oversight.

10:20-10:40 Networking Coffee Break

10:40-11:05 Circulating HER-2/neu, A Biomarker for HER-2 Positive Breast Cancer, from Discovery to Patient Management

Walter Carney, Ph.D., Head, Oncogene Science, Siemens Healthcare Diagnostics, Inc.

Pharmaceutical companies are developing a large number of targeted oncology therapies that will require specific biomarker tests or targeted diagnostics to guide the use of these agents. This presentation will provide an overview and update on the serum HER-2/neu test, which is a specific biomarker for HER-2 positive breast cancer. The serum HER-2/neu test measures the extracellular domain (ECD) of the HER-2/neu oncoprotein in the blood of breast cancer patients. The test is used clinically to measure the rise and fall of the ECD which parallels clinical course of disease. Since the test specifically measures the circulating ECD, it is used to monitor the response or lack of response of the HER-2 positive tumor exposed to a variety of therapies, including hormone therapy, chemotherapy, and Herceptin/chemotherapy or Tykerb monotherapy.

11:05-11:30 Discovery of miRNA-Based Biomarkers for Cancer

Søren Møller, Ph.D., Vice President, Research and Development, Exiqon A/S

Abnormal expression of microRNAs (miRNAs) in cancer implies that these small ~22-nucleotide molecules play a role in oncogenesis. Therefore miRNAs may comprise a novel class of diagnostic and prognostic signatures. This talk will focus on examples of using microRNA for cancer classification, prognosis and treatment selection.

11:30-12:30 Lunch on your own

12:30-12:55 Cancer Biomarker Discovery in the Context of Personalized Medicine

Josip Blonder, M.D., Senior Research Scientist, Laboratory of Proteomics and Analytical Technologies, SAIC-Frederick Inc., NCI-Frederick

The major goal of oncoproteomics is the discovery of clinically relevant molecular biomarkers. So far, the translation of proteomic assays to applicable diagnostic and/or prognostic tests in clinical oncology and personalized medicine has been disappointing. We developed an innovative proteomic platform for cancer biomarker discovery that is amenable to personalized medicine since all specimens were obtained from a single patient, diagnosed with renal cell carcinoma. This approach relies on concurrent profiling of peripheral serum/plasma specimens obtained prior to surgery coupled with subtractive analysis of non-tumorous and tumorous tissue samples procured after the surgical intervention. Multidimensional shotgun proteomic analysis, rigorous bioinformatic data processing coupled with orthogonal validation was employed to narrow the selection/panel of potential renal cancer biomarker proteins.

12:55-1:20 Industrialized Proteomics for the Discovery and Validation of Oncology Biomarkers

Daniel Chelsky, Ph.D., Chief Science Officer, Caprion Proteomics

The success of many investigational drugs is dependent on matching treatments with the appropriate target populations. Variability in response to therapy, both with regards to efficacy and to adverse events, is leading the pharmaceutical industry down the path of personalized medicine. Further pushing the process along are government and private insurance payors who are faced with very expensive treatments that can help some but provide little benefit and possible harm to others. One promising solution to the problem is to identify predictive biomarkers of drug efficacy; circulating proteins that stratify patients into populations of likely responders and non-responders to a proposed therapy. Finding such biomarkers has been challenging due to the complexity of human plasma, the sample of choice, and to the available technologies for detection and quantification of thousands of proteins. Based on the experience of over two dozen preclinical and clinical proteomic studies with pharmaceutical partners, an "industrialized" and very productive approach to biomarker discovery and validation has been developed. Results from multiple oncology biomarker discovery studies will be presented that make the case for accelerating the move to personalized medicine.

1:20-1:45 Metabolite Biomarkers of Prostate Cancer Aggressivity

Jeffrey Shuster, Ph.D., Director, Diagnostics Development, Metabolon, Inc.

Even with all the diagnostics methods in use today, it is difficult to determine with surety which prostate cancers are indolent, and which are aggressive and have the potential to metastasize. Diagnostic tests that distinguish indolent from aggressive tumors have the potential to reduce the number of unnecessary biopsies and prostatectomies. Prostate cancer aggressivity was investigated at the biochemical level using metabolomics with urine from men at-risk for prostate cancer, and from post-surgical prostate tissue. The results identified sets of mechanism-based biomarkers correlated with prostate cancer aggressivity. In this talk, we will briefly describe the metabolomics platform and its utility for developing cancer diagnostics.

1:45-2:10 Networking Refreshment Break

2:10-2:35 From Discovery to the Clinic: The Novel DNA Methylation Biomarker, Septin 9, for the Detection of Colorectal Cancer in Blood

Shannon Payne, Ph.D., Senior Scientist, Epigenomics, Inc.

Detection of colorectal cancer (CRC) at early stages has been shown to greatly decrease mortality from the disease. Availability of a blood-based test for CRC is expected to improve screening compliance in the general population. Through DNA methylation-sensitive, restriction enzyme-based biomarker discovery we identified a region of the Septin 9 gene that is methylated in over 90% of colorectal cancer tissues with little or no methylation in normal colon tissue and other controls. Using a systematic method of biomarker development, we demonstrated specific detection of CRC DNA using the Septin 9 methylation biomarker in multiple studies of plasma from CRC patients and controls. A prospective clinical trial is now underway to determine the clinical performance of the Septin 9 biomarker in the CRC screening-eligible population.

2:35-3:00 Multiplexed Analysis of Glycan Variation on Serum Proteins Using An Antibody Array for Biomarker Profiling

Bryce P. Nelson, Ph.D., Vice President, Research and Development, Gentel Biosciences

Protein glycosylation is a critical determinant of protein function, but there is a lack of tools for discovery and validation of the glycosylation of specific proteins for use as biomarkers. We have developed a 46-plex antibody array in a 96-well format to measure changes in both the glycosylation and concentration of specific cancer biomarker proteins in patient serum samples. To do this, an array of antibodies captures specific proteins from serum and the glycosylation of captured proteins is measured using one of eight unique biotinylated lectins. Chemical derivatization of the glycans on the spotted antibodies prevents lectin binding to those glycans. Relative abundance of serum proteins is measured on a separate antibody array after labeling with a universal conjugate. By profiling both protein and glycan variation in multiple serum samples using parallel protein abundance and glycan-detection assays, new disease-associated glycan alterations can be identified and validated for use as biomarkers.

3:00 Close of Workshop

Web Partners:



MAIN CONFERENCE:

MONDAY, JANUARY 26

3:00-4:00 Conference Registration

4:00-4:10 Welcoming Remarks from Conference Director

Julia Boguslavsky, Executive Director, Conferences, Cambridge Healthtech Institute

OPENING PLENARY SESSION:

BIOMARKERS IN TRANSLATIONAL MEDICINE

(Shared session with Biomarker Assay Development meeting)

4:10-4:15 Chairperson's Opening Remarks

4:15-4:45 Use of Biomarkers and Translational Science to Accelerate and Improve Oncology Drug Development: Opportunities and Roadblocks

J. Carl Barrett, Ph.D., Global Head, Oncology Biomarker and Imaging, Novartis Institutes for BioMedical Research, Inc.

The steps in oncology drug development in patients include: optimizing dose-schedule, predicting patients that will respond, detecting tumor responses rapidly for proof of concept trials, using surrogate endpoints for disease monitoring, assuring safety of drug therapy, and developing rational-based combination therapies. Biomarkers are pivotal in meeting each of these challenges. A general strategy for using biomarkers in oncology drug development will be presented and includes: having a systematic biomarker plan for each new agent that is consistent, science-based and focused using common standards for assays and data; building a biomarker tool kit with analytical and clinical validated biomarker assays; building on clinical experience (positive and negative) and execution excellence involving a team effort (physicians, clinical staff, biomarker experts and data management) and building a strong partnership between Novartis and its clinical investigators.

4:45-5:15 To be Announced

Please visit www.TranslationalCancerMedicine.com for updated info.

5:15-6:30 Reception with Exhibit and Poster Viewing

Sponsorship available. Contact Ilana Schwartz, Manager, Business Development, at 781-972-5457 or ischwartz@healthtech.com.

TUESDAY, JANUARY 27

7:30-8:15 Sponsored Presentation (Opportunity Available) or Morning Coffee

Contact Ilana Schwartz, Manager, Business Development, at 781-972-5457 or ischwartz@healthtech.com.

TOP 10 OPPORTUNITIES IN TRANSLATIONAL CANCER MEDICINE

1. Combination Therapies

8:30-9:00 Combination Approaches for the Treatment of Solid Tumors: Opportunities and Obstacles in the Era of Targeted Therapy

Jon M. Wigginton, Ph.D., Director, Clinical Oncology, Merck & Co., Inc.

Abstract unavailable at the time of printing. Please visit www.TranslationalCancerMedicine.com for updated info.

2. New Targets

9:00-9:30 To be Announced

Please visit www.TranslationalCancerMedicine.com for updated info.

9:30-10:00 Sponsored Presentations (Opportunities Available)

Contact Ilana Schwartz, Manager, Business Development, at 781-972-5457 or ischwartz@healthtech.com.

10:00-11:00 Coffee Break with Exhibit and Poster Viewing

3. Molecular Diagnostics

11:00-11:30 To be Announced

Please visit www.TranslationalCancerMedicine.com for updated info.

4. Companion Diagnostics

11:30-12:00 The Potential Impact of Recently Approved and Emerging Molecular Diagnostics in Drug-Diagnostics Co-Development

Francis Kalush, Ph.D., Network Leader, Diagnostics, Office of the Center Director, Center for Devices and Radiological Health, Food and Drug Administration

The FDA under its Critical Path Initiative is leading several efforts to streamline regulatory pathways in Personalized Medicine. An overview of the strategies and impact of recently and emerging molecular diagnostic biomarkers in companion drug-diagnostics will be discussed.

5. Better *in vitro* Models

12:00-12:30 Employing Brain Tumor Stem-Like Cells for Drug Testing and Drug Development

Gregory J. Riggins, M.D., Ph.D., Irving J. Sherman M.D. Professor of Neurosurgery Research, Professor of Neurosurgery & Oncology, Department of Neurosurgery, Johns Hopkins University

Traditional cell lines do not always maintain the same genomic or *in vivo* characteristics when compared to the primary tumor. We have developed oncosphere cultures grown in stem cell media that maintain better the original genomic profile. These cells produce intracranial tumors that grow invasively, similar to the primary tumor. Small molecule screens and drug testing based on these oncospheres cultures have been developed. Evidence suggests that cultures and tumors grown from stem-like cells produce a model more faithful to tumor biology and drug response.

12:30-2:00 Lunch on your own

6. Better *in vivo* Models

2:00-2:30 Mouse Cancer Models in Translation: Past, Present and Future

Glenn Merlino, Ph.D., Chief, Laboratory of Cancer Biology and Genetics; Head, Cancer Modeling Section, National Cancer Institute

Standard preclinical approaches currently employed to evaluate potential anti-cancer agents (e.g., xenograft mouse models) have been mostly ineffective in predicting future clinical benefits. The advent of genetically engineered mouse models that more faithfully recapitulate the development of human cancers with respect to histopathology, molecular genetics and biology have provided novel insights into cancer mechanisms, and a fresh approach to preclinical modeling. It is anticipated that these new mouse models will facilitate target validation, biomarker discovery and tumor response assessment, and significantly improve cancer drug development.

7. Biomarkers to Predict Drug Response

2:30-3:00 Matching Oncology Drugs with Patient Benefit: Preclinical and Clinical Discovery of Predictive Markers of Therapeutic Response

Garret Hampton, Senior Director, Biochemistry & Biomarker Development, Celgene Research

The incremental benefit of oncologic therapeutic intervention over the past 30 years, and the high attrition rate of new oncology therapeutics during development, have focused the industry on how to better evaluate new compounds in the context of disease. This presentation will focus on both prospective and retrospective approaches used to predict likely patient response, in essence matching drugs with causal tumor biology. The output these efforts at Celgene, and in the industry as a whole, is expected to be a significant increase in patient benefit, definable and justifiable cost / benefit propositions and a shift in cancer care from acute, life-threatening illnesses to manageable chronic diseases.

3:00-3:30 Sponsored Presentations (Opportunities Available)

Contact Ilana Schwartz, Manager, Business Development, at 781-972-5457 or ischwartz@healthtech.com.

3:30-4:30 Refreshment Break with Exhibit and Poster Viewing

8. Cancer Biologics

4:30-5:00 Title to be Announced

Bahija Jallal, Ph.D., Vice President, Translational Science; Head, Oncology, MedImmune

Abstract unavailable at the time of printing. Please visit www.Translational-CancerMedicine.com for updated info.

9. Phase 0 Clinical Trials

5:00-5:30 Risk-Based Compliance for Production of Agents for Phase 0 Studies

John A. Gilly, Ph.D., Deputy Director, Biopharmaceutical Development Program, SAIC-Frederick/NCI-Frederick

Exploratory IND studies (Phase 0) describe studies in patients in very early Phase I. ExpIND studies provide for an understanding between the relationship of the drug candidate and the mechanism of the disease. It also provides options to explore the biodistribution of the NME in micro-dosing studies. Many companies and academic laboratories are considering Phase 0 studies as part of their program. Important risk-based compliance decisions must be made in the development of these agents. Examples of drugs under development at the NCI will be discussed.

10. Translational Imaging

5:30-6:00 Translational Molecular Imaging: Oncology

Syed Mahmood, M.D., Associate Medical Director, Clinical Imaging Physician, Oncology Clinical Imaging, Novartis Pharmaceuticals Corporation

This talk is intended to provide an approach to Translational Molecular Imaging in oncology – from an introduction perspective to clinical translation. Specifically, we will address the major areas in which molecular imaging strategies to target the “cancer cell biology” have started to make some progress. We will cover what molecular imaging is, and how it is different from the imaging that is routinely performed in radiology departments. We will briefly discuss how the most commonly employed molecular imaging modalities work and how they can be utilized in current and emerging applications of molecular imaging.

6:00 Close of Day



WEDNESDAY, JANUARY 28

7:30-8:15 Sponsored Presentation (Opportunity Available) or Morning Coffee

Contact Ilana Schwartz, Manager, Business Development, at 781-972-5457 or ischwartz@healthtech.com.

CASE STUDIES IN ONCOLOGY DRUG DEVELOPMENT

Vectibix

8:30-9:00 The KRAS Signaling Pathway Biomarker in Oncology: From Prognostic to Predictive

Scott D. Patterson, Executive Director, Medical Sciences, Amgen, Inc.

There are a number of biomarkers that are considered to be prognostic, although the difficulty in proving this with the array of treatment options available makes confirmation difficult. In some cases these same biomarkers may be predictive of response to specific therapies. Demonstration of this requires analysis of samples from clinical studies with control arms – often not employed until phase 3. Our experience in the elucidation of KRAS as a patient stratification biomarker will be presented.

Vandetanib

9:00-9:30 Pretreatment Circulating VEGF Levels as A Predictive Biomarker of Efficacy in NSCLC Patients Treated with Vandetanib

Anderson Ryan, Ph.D., Principle Translational Scientist, Cancer BioScience, AstraZeneca

Vandetanib has demonstrated improvements in progression-free survival (PFS) in advanced NSCLC in three randomized phase II studies: vandetanib versus gefitinib; docetaxel ± vandetanib; carboplatin and paclitaxel (CP) ± vandetanib. We performed an exploratory analysis of the relationship between baseline circulating VEGF concentrations and PFS and OS. These analyses suggest that low baseline circulating VEGF may be predictive of PFS and OS advantage in patients with advanced NSCLC receiving vandetanib versus gefitinib, or vandetanib + docetaxel versus docetaxel. Notably, patients with low VEGF levels had similar outcome with either vandetanib monotherapy or CP doublet chemotherapy raising the possibility that this test could be used to select patients for treatment with a targeted therapy instead of treatment with a standard cytotoxic chemotherapy regimen.

Sunitinib

9:30-10:00 Guidance Toward Sunitinib Clinical Development Strategy through Translational Research Approaches

James Christensen, Ph.D., Director, Translational Pharmacology, Pfizer Global Research and Development

Sunitinib malate is an approved agent for treatment of advanced renal carcinoma and/or imatinib refractory gastrointestinal stromal tumors. Efforts are ongoing to develop sunitinib in additional oncology indications including combination studies with a variety of conventional chemotherapeutic agents as well as targeted therapies. Insight towards utility of clinical biomarkers of patient benefit, prospective patient selection strategies, and novel combination approaches are warranted to continue to optimize the clinical development strategies. To this effect, ongoing activities to study sunitinib in both a lab-based and clinical setting to provide insight toward the sunitinib clinical development program will be presented.

10:00-10:30 Sponsored Presentations (Opportunities Available)

Contact Ilana Schwartz, Manager, Business Development, at 781-972-5457 or ischwartz@healthtech.com.

10:30-11:30 Coffee Break with Poster and Exhibit Viewing

Tarceva

11:30-12:00 Incorporation of Biomarkers into Tarceva Clinical Trials

Frank Richardson, Senior Director, Preclinical Safety Assessment and Molecular Markers, OSI Pharmaceuticals, Inc.

Tarceva is an EGFR tyrosine kinase inhibitor approved as monotherapy for the treatment of 2nd-3rd-line advanced non-small cell lung cancer (NSCLC) and in combination with Gemzar for the treatment of 1st-line advanced pancreatic cancer. There is intense interest in finding and validating new biomarkers that predict outcome to Tarceva and thus enhance clinical benefit. The development of biomarkers is a challenging process in which the promise of a specific biomarker can grow or diminish as new information becomes available. This talk will discuss and present preliminary results of two biomarker-selected trials in NSCLC as case examples that highlight ongoing efforts to incorporate and clinically validate emerging biomarkers in an ever-shifting landscape.

12:00-12:30 To be Announced

Please visit www.TranslationalCancerMedicine.com for updated info.

12:30-2:00 Lunch on Your own

TRANSLATION FROM IN-HOUSE DEVELOPMENT TO CLINICAL LABORATORY

(Shared session with Biomarker Assay Development meeting)

2:00-2:30 Development and Integration of Biomarkers into Clinically Useful Diagnostics

Anne-Marie Martin, Ph.D., Director, Oncology, MDC, GlaxoSmithKline

With the advancement of understanding the molecular basis of disease we have increased our ability to identify genomic biomarkers relevant to disease pathogenesis and widened opportunities to develop genomics-based tools to tailor treatment options and assess treatment response. Thus, genomic biomarker research promises to provide more precise predictors of outcome to treatment not previously attainable with traditional biomarkers. However, before genomic biomarker tests become commonplace in clinical practice, several issues need to be addressed in order to generate the essential levels of evidence to demonstrate analytical and clinical validity and utility. Assay validation is required not only in the context of in-house developed assays (i.e. "homebrew" tests) but also prior to the use of commercially available Food and Drug Administration (FDA)-approved diagnostic tests. This presentation will illustrate some the steps required to achieve clinical utility of a diagnostic test.

2:30-3:00 Moving a New Technology into the Routine Lab: Validation and Education Challenges

Lawrence Oliver, Ph.D., Scientific Director, Mayo Clinical Trial Services

When a new technology introduces physiologic measures that have not been used in clinical situations previously, there is an educational barrier to overcome that must be faced simultaneously with the challenges encountered in validating the new technology. For years we have used crude measures of antibody concentration (titers, or the arbitrary "units/L") in clinical evaluation and have had no convenient way to measure the avidity of the antibodies. Using the measurement of insulin antibodies as an example, I will be discussing the planned introduction of surface plasmon resonance technology and the determination of antibody affinity/avidity into the production environment of a CLIA/CAP laboratory. Aspects of analytical validation will be discussed as well as the studies intended to aid in the understanding of the physiology as applied to clinical settings.

3:00-3:30 Molecular Diagnostics Laboratories (MoDEL): A Program to Support Cancer Biomarker Clinical Assay Development

J. Milburn Jessup, M.D., Chief, Diagnostics Evaluation Branch, Cancer Diagnosis Program, DCTD/National Cancer Institute

Although Biomarkers will become increasingly important as targeted and personalized therapies dominate the care of the cancer patient, the development and validation of useful biomarkers is often stopped by inadequate assay development. The Cancer Diagnosis Program (CDP) of NCI issued a Request for Information that defined significant needs for assay development as: specimen acquisition, access to standards and reagents, guidance on assay development for academia to facilitate transfer to industry, and support for improving assay performance, evaluation and validation for clinical use. As a result, CDP will present its plans for developing MoDEL as a suite of services that 1) will assist the utilization of Biomarkers in late phase clinical trials in oncology and 2) will be available to both academia and industry.

3:30-4:00 Networking Refreshment Break

CLOSING PLENARY SESSION: CIRCULATING TUMOR CELLS

(Shared session with Biomarker Assay Development meeting)

4:00-4:30 Circulating Tumor Cell Assays: A Prognostic and Predictive Factor For Breast, Prostate And Colon Cancer

Herbert A. Fritsche, Ph.D., Professor and Chief, Clinical Chemistry, The University of Texas M. D. Anderson Cancer Center

The current hypothesis of cancer metastasis proposes that tumor cells escape into the blood and circulate until they are either eliminated by host response mechanisms or until they find an environment in which to reside in a dormant condition and to proliferate at a later time. Thus, the detection of circulating tumor cells may represent an early indication of micro-metastasis or of aggressive tumors which are able to shed tumor cells into the blood. The circulating tumor cells can be captured using antibody labeled magnetic beads, either in positive or negative selection schema. After the circulating tumor cells are isolated, they may be characterized by immunohistochemistry and counted. Alternatively, these cells may be characterized by gene expression analysis using RT-PCR. One of the CTC detection methods (Veridex Inc, Cell Search Assay) has been cleared by the US FDA for use as a prognostic test in patients with metastatic cancers of the breast, prostate and colon. In these cases of metastatic cancer, the pre-treatment presence of tumor cells is prognostic of a poor outcome, at any time during the course of the disease. Furthermore, in metastatic breast cancer patients, the presence of tumor cells at the end of the first course of chemotherapy is predictive of treatment failure. Thus, the CTC test may permit the oncologist to make an early decision to discontinue first line therapy for metastatic breast cancer and pursue more aggressive alternative treatments. We have addressed the practical aspects of routine testing for CTC's using the Veridex Cell Search method. We have also evaluated the Adnagen Breast Cancer Cell Select and Detect assay for CTC detection. The method uses multi-antigen cell capture with antibody labeled magnetic beads, followed by RT-PCR characterization of selected genes. This assay may compliment the Cell Search assay for tumor cell detection in blood. Other CTC assays based on new capture technologies are currently in development.

4:30-5:00 Biomarker Assay Development and Validation: An Epiphany for Drug Development and the Management of Patients with Cancer

Martin Fleisher, Ph.D., Chair, Dept. of Clinical Laboratories, Memorial Sloan-Kettering Cancer Center

Biomarkers can be used to predict whether or not a treatment modality is effective in early-stage clinical trials, judge the response to therapy, identify which cancer patients are at high risk of tumor recurrence and predict how effective an investigational drug is against a specific type of cancer. This information is valuable when decisions must be made on stratifying patients based on likely response to the therapy. We have initiated a biomarkers development and validation program that focuses on targeted therapy in patients with prostate and ovarian cancer and mesothelioma. The enumeration of circulating tumor cells (CTC) in patients with metastatic prostate cancer (PC) receiving targeted therapy for androgen receptor over expression has demonstrated impressive clinical sensitivity when compared with PSA response. As new targeted therapies enter the pipeline, predicting the effectiveness of the drug on the target by isolating and characterizing CTC in patients with metastatic cancer is clinically essential. In patients with ovarian cancer, biomarkers validated in our laboratory, such as YKL-40, HE4 and Mesothelin have been shown to be more effective than CA125 in monitoring Stage 1 and 2 ovarian disease and in detecting tumors with mucinous histology. Two biomarkers, Osteopontin and Mesothelin, have been validated and measured in patients with mesothelioma before and after chemotherapy and radiation therapy. Preliminary data suggest that these two biomarkers will be clinically effective in staging patients for future therapy and in monitoring recurrence of disease. Our CLIA certified laboratory has developed a rigorous validation protocol that assesses the pre-analytical, analytical and post-analytical assay performance characteristics of biomarkers under clinical evaluation. This validation protocol optimizes biomarker effectiveness essential for pharmacodynamic and clinical outcome studies.

5:00 Close of Conference

Co-located with the Biomarker Assay Development meeting.

Register for Translational Cancer Medicine meeting and receive complimentary access to Biomarker Assay Development.

Visit www.biomarkerassaydevelopment.com for complete agenda.

TUESDAY, JANUARY 27

Incorporating Assay Development into Overall Biomarker Strategy

8:30-9:00 Opportunities and Challenges of Biomarker Assays in Drug Development

Francois Legay, Ph.D., Head, Marker and Assay Development, Novartis Pharma

9:00-9:30 Moving Beyond Fit-for-Purpose: Use of Lean Practices to Accelerate Biomarker Assay Development

Russell S. Weiner, Ph.D., Group Director, Biomarker and Bioanalytical Sciences, Bristol-Myers Squibb Co.

9:30-10:10 Multiplexed Biomarker Assay Development

Michael Pisano, Ph.D., President and Chief Executive Officer, NextGen Sciences

10:10-11:00 Coffee Break with Exhibit and Poster Viewing

Multiplex Biomarker Assays

11:00-11:30 Application of Intra-Assay Calibration Curves to Quantitate Clinical Biomarker Immunoassays

Paul Rhyne, Ph.D., Associate Director, Bioanalytical Sciences, Research and Development, Bristol-Myers Squibb Co.

11:30-12:00 Automated Platforms for Biomarker Analysis: Multiplexing Assays and Case Histories

John Allinson, FIBMS, Laboratory Director, Veeda Clinical Research

12:00-12:30 Statistical Issues in the Evaluation of Single and Multi-Plex Biomarker Assays

Viswanath Devanarayan, Ph.D., Director, Global Exploratory Statistics, Abbott Laboratories

12:30-2:00 Lunch on your own

Biomarker Assay Development for Diagnostics

2:00-2:30 Pre-Analytical and Analytical Considerations for Assay Development

Gerard J. Davis, Ph.D., Research Scientist and Project Manager, Cancer Diagnostics Research and Development, Abbott Laboratories

2:30-3:00 Biomarker and Companion Diagnostics Assay Development: An IVD Perspective

Thomas Li, Ph.D., Senior Director, Technology Management, Roche, Inc.

3:00-3:30 Sponsored Presentations (Opportunities Available)

Contact *Ilana Schwartz, Manager, Business Development, 781-972-5457 or ischwartz@healthtech.com*

3:30-4:30 Refreshment Break with Exhibit and Poster Viewing

Total vs. Free Analyte Quantification

4:30-5:00 Assessment of Free-and-Total- Drug Concentration in the Development of Biotherapeutic Agents - Analytical and Biological Considerations

Scott Fountain, Ph.D., Senior Director, Translational Research, Department of Pharmacokinetics, Dynamics & Metabolism, Pfizer Global Research and Development

5:00-5:30 Quantification of "Total" and/or "Free" Target Protein Biomarker: Approaches and Applications

Jean Lee, Ph.D., Scientific Director, PKDM, Amgen

5:30-6:00 Target-Related Pharmacodynamic Analysis to Guide Successful Development of Biological Therapies: Novel Biomarker Concepts and Analytical Strategies

Miro Venturi, Ph.D., Head, PK/PD Assay Development Group, Novartis Biologics

6:00-7:00 Roundtable Discussions

7:00 Close of Day

WEDNESDAY, JANUARY 28

7:30-8:15 Sponsored Presentation (Opportunity Available) or Morning Coffee

Contact *Ilana Schwartz, Manager, Business Development, 781-972-5457 or ischwartz@healthtech.com*

Assay Development for 'Omic' Biomarkers

8:30-9:00 Genomics Technologies for Research and Clinical Applications

Don A. Baldwin, Ph.D., Director, Penn Genomics Facility, University of Pennsylvania, School of Medicine

9:00-9:30 Low Abundance Protein Biomarker Quantitation Using Immunoaffinity Enrichment and Nanoflow LC-MS/MS

Hendrik Neubert, Ph.D., Clinical, Quantitative and Innovative Medicine (CQIM), Pfizer Global Research and Development

9:30-10:00 Utilizing a LC/MS/MS (MRM) Quantitative Targeted Biomarker Panel to Elucidate Multiple Biological Changes Simultaneously

Jon Butler, Ph.D., Assistant Senior Biochemist, Integrative Biology, Biomarkers, Eli Lilly and Company

10:00-10:30 Sponsored Presentations (Opportunities Available)

Contact *Ilana Schwartz, Manager, Business Development, 781-972-5457 or ischwartz@healthtech.com*

10:30-11:30 Coffee Break with Poster and Exhibit Viewing

Flow Cytometry and Circulating Cell Assays

11:30-12:00 Validation and Implementation of Flow Cytometric Assay to Evaluate Pharmacodynamic Biomarkers in Clinical Study

Dianna Wu, Ph.D., Principal Scientist, Clinical Biomarker, Bristol-Myers Squibb Co.

12:00-12:30 Validating Cell-Based Biomarker Assays

Iman Jilani, M.S., CLS, MT (ASCP), Biomarker Assay Specialist, Manager, Clinical Assay Group, Pfizer

12:30-2:00 Lunch on your own

Translation from In-House Development to Clinical Laboratory

(Shared session with Translational Cancer Medicine meeting)

2:00-2:30 Development and Integration of Biomarkers into Clinically Useful Diagnostics

Anne-Marie Martin, Ph.D., Director, Oncology, MDC, GlaxoSmithKline

2:30-3:00 Moving a New Technology into the Routine Lab: Validation and Education Challenges

Lawrence Oliver, Ph.D., Scientific Director, Mayo Clinical Trial Services

3:00-3:30 Molecular Diagnostics Laboratories (MoDEL): A Program to Support Cancer Biomarker Clinical Assay Development

J. Milburn Jessup, M.D., Chief, Diagnostics Evaluation Branch, Cancer Diagnosis Program, DCTD/National Cancer Institute

3:30-4:00 Networking Refreshment Break

Closing Plenary Session: Circulating Tumor Cells

(Shared session with Translational Cancer Medicine meeting)

4:00-4:30 Circulating Tumor Cell Assays: A Prognostic and Predictive Factor For Breast, Prostate And Colon Cancer

Herbert A. Fritsche, Ph.D., Professor and Chief, Clinical Chemistry, The University of Texas M. D. Anderson Cancer Center

4:30-5:00 Biomarker Assay Development and Validation: An Epiphany for Drug Development and the Management of Patients with Cancer

Martin Fleisher, Ph.D., Chair, Department of Clinical Laboratories, Memorial Sloan-Kettering Cancer Center

5:00 Close of Conference