19th International

Molecular Med TRI-CON 2012

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February 19-23

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Drug Discovery & Development Channel

Core **Programs** February 21-23

Mastering Medicinal Chemistry Summit
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Strategies & Technologies for Targets & Molecules

Oncology Clinical Trials
Advancing Cancer Drug Development by Improving Trial Methodology

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Reasons to Attend

1. **HEAR** the latest developments in therapeutic programs for Oncology, CNS, Pain, Allergy, Obesity and Infectious Diseases
2. **LEARN** the advantages of multiparameter physicochemical properties analyses for candidate optimization
3. **LEARN** more about clinical development of personalized cancer therapy and understand the main features of biomarker driven clinical trials
4. **ENJOY** the detailed case studies of clinical trials for recently approved cancer therapies including Xalcori and Zelboraf

Keynote **Presenters**

J. Carl Barrett, Ph.D., Vice President, Translational Medicine, ***AstraZeneca***

Nicholas A. Meanwell, Ph.D., Executive Director, Medicinal Chemistry, ***Bristol-Myers Squibb Research & Development***

Hal Barron, M.D., Executive Vice President, CMO, Global Product Development, ***Roche Holding AG***

Steven Piantadosi, M.D., Ph.D., Chair & Director, Phase One Foundation, Samuel ***Oschin Comprehensive Cancer Institute***

Mark Bunnage, Ph.D., Head, Medicinal Chemistry, Sandwich Laboratories, ***Pfizer***

David C. Stump, M.D., Executive Vice President, Research & Development, ***Human Genome Sciences, Inc.***

Z. Alex Cao, Ph.D., Associate Director, Oncology Translational Research, ***Novartis Oncology Translational Medicine***

Margaret A. Tempero, M.D., Doris and Donald Fisher Distinguished Professorship, Clinical Cancer Research; Professor, Medicine, Division of Hematology and Oncology; Director, Research Programs; Deputy Director, ***UCSF Helen Diller Family Comprehensive Cancer Centerr***

P. Jeffrey Conn, Ph.D., Lee E. Limbird Professor of Pharmacology; Director, Vanderbilt Center for Neuroscience Drug Discovery, ***Vanderbilt University Medical Center***

Malcolm Young, Ph.D., CEO, ***e-Therapeutics***

Stuart Lutzker, M.D., Ph.D., Vice President, BioOncology Exploratory Clinical Development, ***Genentech***

David E. Watson, Ph.D., Research Advisor, ***Eli Lilly & Co.***

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Present your solution for 15 or 30 minutes in the session room during lunch or as part of the main conference program. You will be able to target your audience by selecting a specific program for your talk.

Plenary Keynote Presentation

Receive optimum visibility by participating in a panel discussion during the Wednesday afternoon Plenary Keynote Session at MMTC. You will have the opportunity to join the discussion and present for up to ten minutes before an audience of over 1,000 delegates.

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Exclusive Cocktail Receptions

(Program-specific)
CHI will invite all delegates from a specific conference program, of your choice, to your private reception at the host hotel. Cocktails and hors d'oeuvres will be served in a setting conducive to networking. These receptions are available on a first-come, first-served basis.

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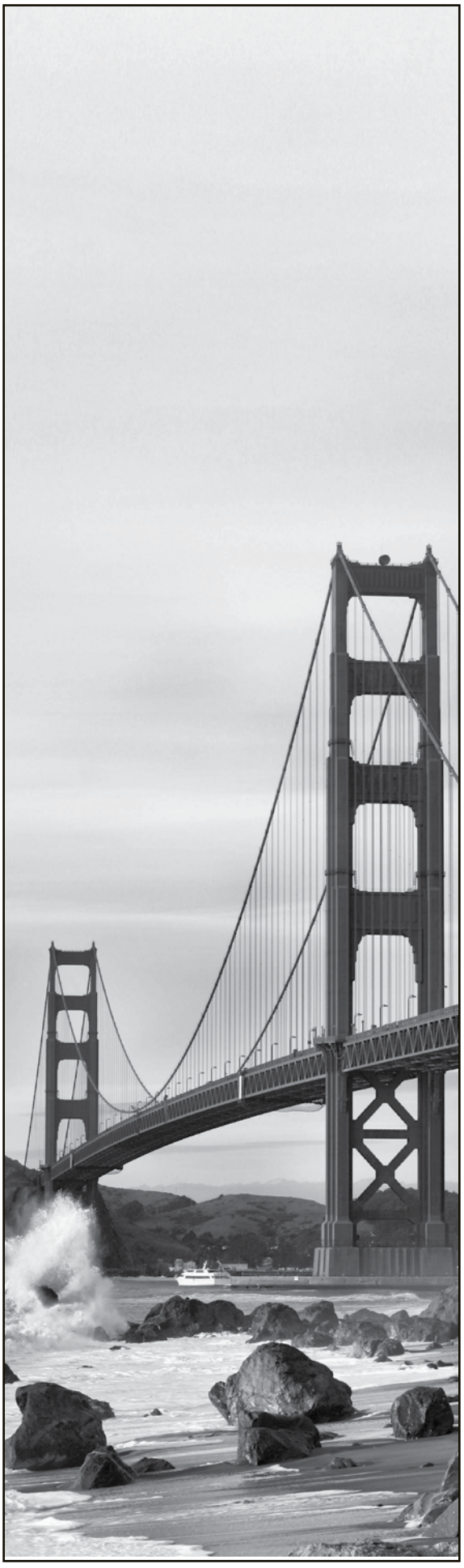

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February 19-20

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Targeting Cancer Stem Cells in Oncology
Cloud Computing
Phage and Yeast Display of Difficult Targets
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Next-Generation Pathology

Pharma-Bio Partnering Forums

InterContinental San Francisco Hotel

Emerging Targeted Oncology
Early Stage Molecular Diagnostics

February 20

Event Short Courses

The Moscone North Convention Center

February 21-23

Core Programs

The Moscone North Convention Center

Diagnostics Channel

Molecular Diagnostics
Personalized Diagnostics
Cancer Molecular Markers
Circulating Tumor Cells
NEW - Genomic Screening and Diagnosis

Drug Discovery & Development Channel

Mastering Medicinal Chemistry Summit
Translational Science
NEW - De-Risking Drug Discovery
Oncology Clinical Trials

Informatics Channel

Integrated R&D Informatics for Knowledge Management
NEW - Bioinformatics & Cancerinformatics

Cancer Channel

Cancer Molecular Markers
Circulating Tumor Cells
Oncology Clinical Trials
NEW - Bioinformatics & Cancerinformatics
Cancer Biologics

Plenary Keynotes

Tuesday, February 21

8:00-9:40am
Positive Exposure: Celebrating the Beauty of Genetic Diversity
Rick Guidotti, Director, Positive Exposure

Rick, an award-winning fashion photographer, is the founder and director of Positive Exposure, an innovative arts, education and advocacy organization working with individuals living with a genetic difference. Positive Exposure utilizes the visual arts to significantly impact the fields of genetics, mental health and human rights. Rick's photo and video presentation explores the social and psychological experiences of people living with genetic, physical and behavioral conditions of all ages and ethno-cultural heritages. His presentation provides new opportunities to see individuals living with a genetic difference first and foremost as a human being with his/her own challenges rather than as a specific diagnosis/disease entity.

Wednesday, February 22

10:10-11:00am
Overcoming Adversity When Life Throws Curve Balls
Dave Dravecky, former Pitcher, San Francisco Giants and Cancer Survivor

Dave Dravecky was an outstanding major league baseball pitcher for the San Francisco Giants when life threw him a curve ball. At the height of his pitching career, he was diagnosed with cancer, a desmoid tumor, in the deltoid muscle of his pitching arm. In 1989, Dave recovered and briefly returned to Major League ball. Soon after, cancer claimed his pitching arm and shoulder. Both were amputated. His presentation shares the struggles he and his wife Jan experienced as they dealt with cancer, years of surgery and radiation, and how the power of cancer reshaped their lives.

2:30-3:50pm
Plenary Keynote Panel: Emerging Technologies & Industry Perspectives
As a change-up to our usual keynote program, we're offering a session that will feature a series of presentations on emerging and hot technologies in diagnostics, drug discovery & development, informatics, and oncology. Interactive Q&A discussion with the audience will be included.

Harry Glorikian, Founder & Managing Partner, Scientia Advisors LLC
Jeremy Bridge-Cook, Senior Vice President, Assay Research and Development, Luminex Corporation
Gary Kennedy, Chairman & CEO, Remedy Informatics
Richard Lawn, Ph.D., Executive Director of Translational Medicine, SomaLogic
Jeffrey T. Yap, Ph.D., Assistant Professor of Radiology, Harvard Medical School, Senior Diagnostic Physicist, Dana-Farber Cancer Institute

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Get the best 5-day value!

Our All Access Package is a convenient, cost-effective way to attend each aspect of Molecular Med TRI-CON 2012. Package includes access to 1 Symposium OR Partnering Forum, 2 Short Courses, 1 Core Program, Plenary Keynotes, and the Exhibit Hall.

Example of a Suggested ALL ACCESS Package:

Symposium	Event Short Course	Event Dinner Short Course	Core Program
Next Generation Pathology	Pharmacology and Drug Discovery in the Allosteric World	Regulatory Approval of a Therapeutic & Companion Diagnostic	Translational Science

The Symposia and Partnering Forums are taking place at the InterContinental San Francisco Hotel

Ninth Annual

Mastering Medicinal Chemistry Summit

Success Stories in Applied Medicinal Chemistry

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations *(See Page 2 for Details)*

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

11:00 Chair's Opening Remarks

Matt Wessel, Senior Principal Scientist, Seurat Applications Support, Schrodinger

KEYNOTE PRESENTATION

11:10 Getting Pharma R&D Back on Target – Open Innovation in Epigenetics

Mark Bunnage, Ph.D., Head, Medicinal Chemistry, Sandwich Laboratories, Pfizer

IMPROVING DRUG CANDIDATES BY USING PHYSICOCHEMICAL PROPERTY ANALYSIS

11:40 Integration of SBDD & Physicochemical Properties-Based Analysis and Design Approaches to Drive Multiparameter Optimization to Deliver Improved Drug Candidates

Martin P. Edwards, Vice President, Discovery Chemistry, Pfizer San Diego

Analyzing multiple lead series physicochemical properties - data relationships yields knowledge critical for designing for improved potency, selectivity and ADMET. Strategies using this knowledge, strengthened with key insights from protein-ligand structures, have delivered high quality clinical candidates.

12:10 pm Next-Generation Glucokinase Activators: Property-Based Design of AZD1656

Darren McKerrecher, Associate Director, Medicinal Chemistry & Project Leader, Cardiovascular & Gastrointestinal Innovative Medicines Unit, AstraZeneca

We identified and overcame a testicular toxicological liability in a series of acidic glucokinase activators and used property-based design to yield a series of neutral compounds with good solubility, permeability and hERG selectivity, culminating in the identification of PhII clinical candidate AZD1656.

12:40 LUNCHEON PRESENTATION: Case Studies of Successful Drug Design

Sponsored by SARmont

Randy Weiss, President and CEO, SARmont

We will present case studies of successful drug design that were conceived by Dr. John Talley, co-inventor of Celebrex. Dr. Talley leads SARmont's drug design team. We will also provide examples of ongoing drug design projects with clients that optimize the likelihood of identifying a high quality IND drug candidate.

12:55 Enjoy Lunch on Your Own

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

Walter Huber, Ph.D., Distinguished Scientist & Group Leader, Discovery Technologies, F.Hoffmann - La Roche Ltd.

2:20 Mapping Your Drug Discovery Efforts in Chemico-Biological Space: AtlasCBS

Celerino Abad-Zapatero, Ph.D., Professor, Center for Pharmaceutical Biotechnology, Department of Medicinal Chemistry and Pharmacognosy, University of Illinois, Chicago

Ligand Efficiency Indices (LEIs) are becoming more accepted in medicinal chemistry to relate the potency of compounds to their physico-chemical properties. The concept and application of LEIs to map, guide and optimize drug-discovery efforts will be illustrated with examples.

FRAGMENT-INSPIRED MEDICINAL CHEMISTRY

2:50 Knowledge Generated by Fragment Screening to Inspire Chemistry

Walter Huber, Ph.D., Distinguished Scientist & Group Leader, Discovery Technologies, F.Hoffmann - La Roche Ltd.

Fragment screening methods have evolved for generation of ligand binding information. The impact ranges from a drugability assessment of binding sites and targets to the use of a fragment moiety from screening to market as exemplified with Zelboraf, the first fragment derived FDA-approved drug molecule.

3:20 Efficiency Driven Drug Discovery: Application of Fragment and Structure-Based Methods

Siegfried H. Reich, Ph.D., Fragment-Based Drug Discovery, Translational Sciences and Technologies (TST), Lilly Biotech Center

An approach focused on ligand efficiency combined with enabling supporting technologies (SBDD, NMR, SPR) can help identify optimal starting points for design, that can start and remain in good physicochemical space, resulting in candidate molecules which have a greater likelihood of clinical success.

3:50 Fragment-to-Lead Using Fragment Molecular Orbital QM Calculations

Sponsored by evotec

Richard Law, Group Leader, Computational Chemistry, Evotec (UK) Ltd.

FMO is one of multiple computational chemistry techniques that play a vital role in devising routes for structure-guided medicinal chemistry. FMO can help prioritize fragment hits for expansion, perform virtual fragment expansion and guide subsequent rounds of fragment-to-lead drug design.

4:20 Reception in the Exhibit Hall *(Sponsorship Available)*

5:20 Breakout Discussions in the Exhibit Hall *(see website for details)*

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks

Nicholas A. Meanwell, Ph.D., Executive Director, Medicinal Chemistry, Bristol-Myers Squibb Research & Development

KEYNOTE PRESENTATION

8:00 Hepatitis C Virus NS5A Replication Complex Inhibitors

Nicholas A. Meanwell, Ph.D., Executive Director, Medicinal Chemistry, Bristol-Myers Squibb Research & Development

This presentation will provide an overview of the discovery and development of the hepatitis C virus (HCV) NS5A replication complex inhibitor BMS-790052, a first-in-class therapeutic for the treatment of HCV.

NOVEL STRATEGIES & APPLICATIONS IN MEDICINAL CHEMISTRY

8:30 Antibody-Drug-Conjugates (ADCs) for the Treatment of Cancer

John A. Flygare, Ph.D., Senior Scientist, Discovery Chemistry, Genentech, Inc.

Successful Antibody-Drug-Conjugates (ADCs) require assembling the correct combination of antibody, linker , and cytotoxic drug. This presentation will review successful applications of this technology and discuss future directions of the linkers and cytotoxic drugs used in this approach.

9:00 Accessing New Chemical Space through Flow-Enabled "Forbidden" Chemistries

Neal Sach, Ph.D., Senior Principal Scientist, Oncology Medicinal Chemistry, Pfizer

A flow technology is presented with the capability to run and analyze 100-300 reactions per day. The application of this technology in accessing new chemical space in drug discovery is presented, with examples of chemistries, traditionally considered 'forbidden' in batch, exemplified.

9:30 Drug Design and Development by Molecular Interaction Fields

Sponsored by Intelligent Pharma

Jascha Blobel, Ph.D., Product Manager, Intelligent Pharma

Molecular interaction fields are the key property of a molecule in binding to different receptors in the cell. Thanks to the constantly growing information about molecules and their associated functions in biological systems, Intelligent Pharma will present the use of comparing molecules on basis of their interaction fields to predict the functions of new and unknown molecules.

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

10:10 Plenary Keynote Presentation *(See Page 2 for Details)*

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

12:00 pm Using Chemical Biology to Increase Biochemical Understanding that Enables Therapeutic Intervention

Lyn H. Jones, Ph.D., FRSC, Senior Director & Head, Chemical Biology and Orphan & Genetics Diseases, WorldWide Medicinal Chemistry, Pfizer

The pharmaceutical industry is plagued by a low return on its investment in research and development. Successful applications of chemical biology in the drug discovery setting will be presented to illustrate a new paradigm for medicinal chemistry design at the interface with biology.

12:30 Chemical Proteomics: Applications to Compound Profiling and Target Discovery
Robert W. Johnson, Ph.D., Senior Group Leader, Structural Chemistry - Advanced Technology, Abbott Laboratories

1:00 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE PANEL

2:30 Plenary Keynote Panel *(See Page 2 for Details)*

3:50 Refreshment Break & Poster Awards in the Exhibit Hall

HOT TARGETS TO WATCH: ALLOSTERIC MODULATORS

4:25 Chairperson's Remarks
Sylvain Célanire, Group Leader, Medicinal Chemistry Section, Addex Pharmaceuticals

KEYNOTE PRESENTATION

4:30 Optimization of Allosteric Modulators of GPCRs for Treatment of CNS Disorders
P. Jeffrey Conn, Ph.D., Lee E. Limbird Professor of Pharmacology; Director, Vanderbilt Center for Neuroscience Drug Discovery, Vanderbilt University Medical Center
Allosteric modulators of GPCRs exhibit multiple modes of efficacy that dramatically impact *in vivo* effects. This new understanding provides important insights to guide medicinal chemistry efforts aimed at developing allosteric modulators that are suitable as drug candidates.

5:00 Allosteric Modulator for a Pain Indication
Michael R. Schrimpf, Ph.D., Senior Chemistry Group Leader, Neurological Urological, Abbott Labs

5:30 A Drug Discovery Journey across Allosteric Modulators of Metabotropic Glutamate Receptors: from Hit to Candidate
Sylvain Célanire, Group Leader, Medicinal Chemistry Section, Addex Pharmaceuticals
Individual members of mGluR family have been difficult to target selectively using conventional approaches. Allosteric modulators offer a strategy for developing highly selective oral small molecule therapeutics that can readily cross blood-brain barrier against these historically undruggable targets. Discovery and characterization of novel allosteric modulators of Class C GPCRs mGluR2, mGluR4 and mGluR5 will be presented, including extensive structure-activity and structure-property relationship studies.

HOT TARGETS IN CANCER: KINASES

6:00 Linsitinib (OSI-906), a Potent and Highly Selective Dual Inhibitor of IGF-1R and IR Currently Undergoing Clinical Testing in a Phase III Clinical Trial in ACC Patients
Mark J. Mulvihill, Ph.D., Director of Chemistry, Oncology, OSI Pharmaceuticals LLC, a subsidiary of Astellas US
Our drug discovery efforts, including structure-based design and empirical medicinal chemistry efforts have resulted in the discovery of OSI-906, a potent, selective and orally available inhibitor of both IGF-1R and IR. In addition to its activity in preclinical models, OSI-906 has recently shown preliminary activity in Adrenocortical carcinoma (ACC) patients and is currently in a Phase III clinical trial in ACC.

6:30 Close of Day

THURSDAY, FEBRUARY 23

HOT TARGETS IN CANCER: KINASES & Hsp90

8:30 am Chairperson's Remarks
Mark Ashwell, Ph.D., Vice President, Medicinal Chemistry, ArQule, Inc.

8:35 Discovery of PI3K Inhibitors Based on the 5,6-dihydrobenzo[f] imidazo[1,2-d][1,4]oxazepine Scaffold with Improved *in vivo* Anti-Tumor Activity Due to Increased Unbound Drug Exposure
Chudi O. Ndubaku, Ph.D., Scientist, Discovery Chemistry, Genentech, Inc.
We recently discovered novel inhibitors of PI3K based on the benzoxepin chemical structure that are potent, highly selective and have favorable *in vivo* pharmacokinetic profiles. We reveal our structure-guided and physicochemical property-based approach to optimize unbound drug exposure.

9:05 Identification of NVP-BKM120 as a Potent, Selective, Orally Bioavailable Pan Class I PI3K Inhibitor for the Treatment of Cancer
Sabina Pecchi, Ph.D., Senior Investigator I, Global Discovery Chemistry, Oncology & Exploratory Chemistry, Novartis Institutes for Biomedical Research
The PI3K pathway is frequently de-regulated in tumors. This presentation describes the structure guided optimization of a series of 2-morpholino pyrimidines PI3K inhibitors culminating in the discovery of NVP-BKM120, currently undergoing Phase II clinical trials for the treatment of cancer.

9:35 The RAS-MAPK and PI3K-AKT Cascades: Novel Assays for Detection and Quantitation of Key Phospho Proteins- Part II
Sponsored by BIOSCALE
W. Matthew Dickerson, Ph.D., Senior Scientist, BioScale, Inc.
The RAS-MAPK and PI3K-AKT pathways are involved in signaling cascades that control numerous physiological and pathological processes. This study elucidates the selectivity and sensitivity of a novel assay platformfor analysis of phosphoproteins including pAKT, pALK, pERK, pJNK, pp38, pMEK.

10:05 Activation-State Dependent Conformational Differences in Protein Kinases and the role of Hydrophobic Motifs in Inactive Kinases: Lessons Learned in Drug Discovery and Optimization
Mark Ashwell, Ph.D., Vice President, Medicinal Chemistry, ArQule, Inc.
The presentation will describe the utilization of a new understanding of the role of hydrophobic residues within the ATP-binding cleft of inactive protein kinases in order to discover novel inhibitors. Through the application of this knowledge ArQule has established a new paradigm for kinase inhibitor discovery and will present results on its impact in increasing efficiency and effectiveness in discovery and development.

10:20 Coffee Break

11:00 Discovery of NVP-HSP990, A Potent Oral Inhibitor of Hsp90 in Phase I Clinical Trials
Tim Machajewski, Ph.D., Global Discovery Chemistry, Novartis Institutes for BioMedical Research
Hsp90 is a molecular chaperone whose function is essential for activity of tumorigenic signaling molecules. A structure guided optimization of aminodihydroquinazolinone Hsp90 inhibitors culminated in the discovery of NVP-HSP990, undergoing Phase I trials for treatment of cancer.

11:30 Understanding Structure Intricacies of Protein Kinases: The Road to Invention of c-Met/ALK Dual Inhibitor Crizotinib
Jean Cui, Ph.D., Associate Research Fellow, Oncology Medicinal Chemistry, Pfizer Global R&D
A 2-Amino-5-aryl-3-benzyloxypyridine scaffold was created based on the autoinhibitory conformation of c-Met, and optimized to generate Xalkori (Crizotinib, PF-02341066) as a potent and highly selective c-Met/ALK dual inhibitor with good pharmaceutical properties.

HOT TARGETS IN ALLERGY & OBESITY

12:00 pm The Discovery and Development of ARRY-502: A Potent, Selective CRTh2 Antagonist for Allergic Diseases
Larry Burgess, Ph.D., Senior Director, Medicinal Chemistry, Array BioPharma
Drug discovery efforts focused on substituted phenyl acetic acids lead to the identification of ARRY-502, a potent, selective CRTh2 antagonist. Phase I clinical studies have demonstrated it is well tolerated and possesses excellent pharmacokinetics and prolonged pharmacodynamic activity.

12:30 Rapid Drug Discovery at Nimbus and the Role of Seurat
Sponsored by SCHRÖDINGER.
Matt Wessel, Senior Principal Scientist, Seurat Applications Support, Schrodinger

12:45 Enjoy Lunch on Your Own

1:45 Chairperson's Remarks
Larry Burgess, Ph.D., Senior Director, Medicinal Chemistry, Array BioPharma

1:50 The Discovery of MK-7725, a Potent and Selective Bombesin Receptor Subtype-3 (BRS-3) Agonist for the Treatment of Obesity
Harry Chobanian, Ph.D., Research Fellow, Discovery Chemistry, Merck Research Labs
The BRS-3 receptor is an orphan GPCR expressed primarily in the hypothalamus region of the brain and has been implicated to regulate food intake and metabolic rate. This presentation outlines the effort that led to the discovery of MK-7725 for the treatment of obesity.

HOT TARGETS IN CNS

2:20 Selective JNK Inhibitors for the Prevention of Neurodegeneration
Simeon Bowers, Ph.D., Staff Scientist, Medicinal Chemistry, Elan Pharmaceuticals
The development of a series of selective JNK inhibitors is described. Optimization of the HTS hit led to single digit nanomolar compounds with improved pharmacokinetic properties and greater CNS exposures.

2:50 Inhibiting Caspases in New and Unexpected Ways
Brian Hearn, Ph.D., Medicinal Chemistry, Small Molecule Discovery Center, University of California, San Francisco
Caspase-6 plays a key role in the neurodegeneration associated with Huntington's disease. Our efforts to identify new caspase-6 inhibitors led to the discovery of non-covalent and non-ionic compounds that demonstrate substrate-dependent inhibition. This presentation will focus on lead optimization and mechanism of action studies.

3:20 Close of Conference

Eighth Annual

Translational Science

Translating Pre-Clinical & Clinical Knowledge to Success

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations *(See Page 3 for Details)*

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC

TRANSLATIONAL IMAGING

11:00 Chairperson's Opening Remarks
Theresa LaVallee, Ph.D., Director, Research & Development, MedImmune

11:10 Impact and Translational Opportunities of Pre-Clinical Imaging in Biomarker Discovery and Drug Development
Paul McCracken, Ph.D., Director, Imaging, Eisai Research Institute
Review of pre-clinical imaging modalities - applications of SPECT, PET, MRI, and CT, including integration with and utilization of molecular biomarkers to drive imaging development, selected neuroscience and oncology discovery imaging examples, and translational opportunities.

11:40 Integrating Imaging in Early Drug Development: Lessons Learned from the VEGFR TKI Experience
Glenn Liu, M.D., Associate Professor, Medicine, Carbone Cancer Center, Wisconsin Institute for Medical Research, University of Wisconsin
Anatomic imaging is commonly used to assess treatment efficacy in late-phase cancer clinical trials; however, this assumes that the therapy will result in anatomic tumor shrinkage (cytotoxic) and predict survival. Advanced quantitative 12:10 pm Translational Imaging for De-risking Pharmaceutical Pipelines
Anthony M Giamis, Ph.D., Head, Radiochemistry/Radiopharmaceutical Sciences, Translational Sciences-Advanced Technology, Abbott
functional imaging methods can be used to assess early treatment response.

12:40 Luncheon Presentation

Use and Validation of Image Based Biomarkers of Drug Response: a CRO Perspective

Sponsored by Molecular Imaging

Patrick McConville, Ph.D., Chief Scientific Officer/COO, Molecular Imaging, Inc.
An overview of the use of multiple preclinical imaging modalities for image-based biomarker assessment of disease progression and drug response will be provided. Special attention will be given to biomarker validation, and examples using probe facilitated imaging will be discussed.

12:55 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

KEYNOTE PRESENTATION

2:20 PET Imaging as a Quantitative Biomarker in CNS Drug Development: Illustration by Examples
Yiyun Henry Huang, Ph.D., Associate Professor, Co-Director, PET Center, Department of Diagnostic Radiology, Yale University
Results from these PET imaging studies for novel CNS therapeutic agents have been shown to be critically important to inform the go/no-go decision in drug development.

2:50 Use of Biomarkers and Translational Science to Improve and Accelerate Oncology Drug Development
J. Carl Barrett, Ph.D., Vice President, Translational Medicine, AstraZeneca

3:50 The JAX Cancer Consortium: Changing the Course of Clinical Advancement

Sponsored by The Jackson Laboratory

Brandy Wilkinson, Ph.D., in vivo Study Director, The Jackson Laboratory-West
The JAX Cancer Consortium has established a publically available patient derived xenograft (PDX) resource. This presentation will highlight the diverse library of solid and liquid PDX models available to further drug discovery programs.

4:20 Reception in the Exhibit Hall *(Sponsorship Available)*

5:20 Breakout Discussions in the Exhibit Hall *(see website for details)*

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

7:55 am Chairperson's Remarks

8:00 PANEL DISCUSSION: How Have Biomarkers Been Applied in Clinical Development?
Moderator: Prakash Purohit, Ph.D., Associate Director, Scientific Affairs, IPSEN Biomeasure, Inc.
Panelists:
Dominic G. Spinella, Ph.D., Head, Translational and Molecular Medicine, Pfizer
James Watters, Ph.D., Head, Applied Genomics, Sanofi Oncology
Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology Research & Development, a unit of J&J PRD, LLC
Panelists will discuss how to much more efficiently turn biomarker assays into diagnostics. What challenges are there? What strategies are best for future use of biomarkers for clinical development? Case examples will be used.

9:30 From Bench to Clinic: Quantitatively Assessing Cancer Targets and Biomarkers for Targeted Therapies

Sponsored by Theranostics Health

Corinne Ramos, Ph.D., Executive Director, Clinical Research, Theranostics Health
Theranostics Health utilizes Laser Capture Microdissection and highly sensitive, quantitative protein microarrays to accurately measure the presence and phosphoactivation status of the target and its downstream signaling pathway elements in tumor or diseased cells at the site of drug action.

9:45 Sponsored Presentation *(Opportunity Available)*

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

10:10 Plenary Keynote Presentation *(See Page 3 for Details)*

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC

TRANSLATIONAL BIOMARKERS

Chairperson: Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology Research & Development, a unit of J&J PRD, LLC

12:00 pm Biomarkers: How to Find them and Apply Them in Clinical Trials
Suso Platero, Ph.D., Director, Oncology Biomarkers, Centocor, Ortho Biotech Oncology Research & Development, a unit of J&J PRD, LLC

12:30 Back to Biomarker Basics for Drug Development
Terry Walker, Ph.D., Director, Translational Immunology, Immunology & Autoimmunity Research Unit, Pfizer
The presentation will provide case study illustrations of simple biomarker challenges: Right drug target for the disease? Does the drug hit the target? Does the drug modify disease activity?

1:00 Luncheon Presentation I

Sponsored by DEFINIENS Understanding Images

Image Miner for Biomarker Development & Data Quality Control
Thomas Haberichter, Definiens
There is a growing need for automated and integrated software solutions that can enable scientists to make more informed decisions on scientific programs. Definiens offers a comprehensive end to end solution for Biomarker Development and Data Quality Control. Definiens is the first to market to offer a wholly integrated solution that combines state of the art Image Analysis software "Tissue Studio" with new innovation "Image Miner" an integrated Imaging miner software package. Image Miner enables scientists to extract meaningful image base classifiers, correlate them to patient and sample outcome data, and identify which characteristics are best suited for comparing cohorts in a given study.

1:30 Luncheon Presentation II

Sponsored by DEFINIENS Understanding Images

Sponsored by SomaLogic

SOMAmers Enable High Throughput Screening for Protein Biomarkers and Diagnostics
Stephen A. Williams, M.D,. Ph.D., CMO, SomaLogic
A synergistic combination of attributes: >1000 proteins measured simultaneously

with ELISA-like performance, sample volumes of a few microliters, increasingly high throughput (currently >30,000 samples/yr.), and the same reagents useable for discovery and commercialization. This has enabled an unprecedented productivity breakthrough in mechanistic, diagnostic and prognostic biomarkers.

2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE PANEL

2:30 Plenary Keynote Panel *(See Page 3 for Details)*

3:50 Refreshment Break & Poster Awards in the Exhibit Hall

4:25 Chairperson's Remarks

4:30 Molecular Profiling of Breast Cancer Trial Sets to Unravel Driving Oncogenic Hubs and Parallel Pathways
Brian Leyland-Jones, M.D., Ph.D., Director, Winship Cancer Institute, Emory University
We are applying complementary molecular profiling methods to tumor bank specimens from several international clinical trials that include all of the major breast cancer subtypes and established a large panel of *in vitro* cell lines and several xenograft models.

5:00 Talk Title to be Announced
Speaker to be Announced

5:30 Biomarker Discovery and Validation: What is Missing
Joerg Heyer, Ph.D., Director, Genetic Models, Translational Research, AVEO Pharmaceuticals
Efforts to establish biomarker discovery in the pre-clinical stage have been limited by insufficient pre-clinical models. Approaches utilizing novel pre-clinical models that enable early pre-clinical biomarker identification and validation.

KEYNOTE PRESENTATION

6:00 Cancer Pharmacology in Translational Medicine
Z. Alex Cao, Ph.D., Associate Director, Oncology Translational Research, Novartis Oncology Translational Medicine
Oncology Translational Research at Novartis has extensive activities in cancer cell biology, genomics, pharmacology, pathology and informatics. Translational Pharmacology is uniquely positioned to bridge such efforts and drive the clinical development of novel anti-cancer agents.

6:30 Close of Day

THURSDAY, FEBRUARY 23

CENTERS OF EXCELLENCE: ACADEMICS IN TRANSLATIONAL RESEARCH

8:30 am Chairperson's Remarks

8:35 Translational Research at Scripps Florida
Patrick Griffin, Ph.D., Director, Translational Research, The Scripps Research Institute
Discussion focused on the Scripps National Screening Center, as well as the successful collaborations in translational research with pharmaceutical partners; examples from Eli Lilly and Pfizer.

9:05 Translating Innovation into Personalized Medicine: A Centralized Approach for Fostering Research and Engaging Physicians in a Large National Community Hospital Network
Jeffrey M. Otto, Ph.D., M.B.A., National Director, Catholic Health Initiative's Center for Translational Research
Research partnerships leverage the CTR's CLIA MDx laboratory, biospecimen procurement / repository, healthcare data analytics, and research capabilities to develop improved tools for physicians in the community hospital setting.

9:35 Driving Innovation with Forward and Reverse Translation in the Academic Setting
Virginia Burns, Ph.D., Associate Director, Technology Resources, Duke Translational Medicine Institute, Duke University

Sponsored by MYRIAD RBM

10:05 Plasma-Based Biomarkers in the Preclinical and Clinical Development of Novel Human Immunomodulators
Robert Hershberg, MD, Ph.D., President and Chief Medical Officer, VentiRx Pharmaceuticals
Certain immunomodulators target molecules that show marked differences between species. The HumanMAP v1.6 panel of biomarkers (Myriad RBM) provided a link between non-human primates and human clinical development of VTX-2337—a novel small molecule targeting Toll-like receptor 8 (TLR8).

10:20 Coffee Break

11:00 T-Cell Immunotherapy at UPenn: An Integrated Academic Translational Model for Success
Michael Kalos, Ph.D., Director, Translational and Correlative Studies Laboratory, University of Pennsylvania School of Medicine
We will discuss infrastructure elements whose implementation has been crucial for the successful establishment of the T-cell Immunotherapy program, and discuss specific examples of the successful translation of novel therapies from the bench to the bedside.

11:30 Collaboration in Translational Science: Leveraging the Best of Both Worlds
Moderator: Patricia McDonald, Ph.D., Associate Scientific Director, Translational Research, The Scripps Research Institute
Open discussion focused on the academic-industry collaboration, identification of niche expertise within an academic organization, cultural differences of pharma and academic and how to work within changing timelines/resources/personnel. Audience participation is encouraged.

12:00 pm Presentation to be Announced

12:30 Luncheon Presentation *(Sponsorship Opportunity Available)* **or Lunch on Your Own**

INFORMATICS FOR TRANSLATIONAL SCIENCE

1:45 Chairperson's Remarks

1:50 Informatics Tools for Translational Science: Bench to Bedside and Back
James Cai, Ph.D., Head, Disease & Translational Informatics, Pharma Research & Early Development (pRED) Informatics, F. Hoffmann-La Roche, Inc.

2:20 Building a Translational Informatics Infrastructure Organically
Shoibal Datta, Ph.D., Associate Director, R&D Information Technology, Therapeutic Areas & Translational Medicine, Biogen Idec, Inc.
Translational data sets by their very nature involve the need to meaningfully integrate data from multiple traditional silos within R&D, each with complex and heterogeneous data representations. Biogen Idec's experience will be shared and a case study will be presented.

2:50 Presentation to be Announced

3:20 Close of Conference

Hotel Information

Primary Conference Venue
The Moscone North Convention Center
747 Howard Street, San Francisco, CA 94103 • www.moscone.com

Symposia, Partnering Forums & Host Hotel
InterContinental San Francisco Hotel
888 Howard Street • San Francisco, CA 94103
Discounted Group Rate: $215 s/d* • Discounted Room Rate Cut Off Date: January 19, 2012
(T) 415-616-6500
** Room Rate includes complimentary internet access in your guestroom.*

Additional Recommended Hotel
Marriott San Francisco Hotel
55 Fourth Street • San Francisco, CA 94103
Discounted Group Rate: $229 s/d • Discounted Room Rate Cut off Date: January 25, 2012
Reservations 888-575-8934 (T) 415-896-1600

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Inaugural

De-Risking Drug Discovery

Strategies & Technologies for Targets & Molecules

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations *(See Page 3 for Details)*

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC

DE-RISKING: SAFETY ASSESSMENT TARGETS

11:00 Chairperson's Opening Remarks
Michael Forstner, M.Sc., Ph.D., Integrated Safety Risk Manager, PDS, Roche

KEYNOTE PRESENTATION

11:10 Detoxifying the Early Portfolio
David E. Watson, Ph.D., Research Advisor, Eli Lilly & Co.

11:40 Reducing Attrition: Combining Predictive *in silico* and *in vitro* Safety Assays to Guide Design Chemistry
Thomas Schroeter, Ph.D., Senior Principal Scientist, Compound Safety Prediction, Pfizer
The greatest challenge facing the pharmaceutical industry today is developing more effective decision making tools and strategies to reduce the attrition rate of novel compounds during candidate selection and clinical development.

12:10 pm Integrated Safety Management Planning as a Tool for Proactive Risk Minimization
Michael Forstner, M.Sc., Ph.D., Integrated Safety Risk Manager, PDS, Roche
Safety risk management of new drugs should commence before entry into humans and be maintained in a comprehensive way throughout development. By a combination of risk analysis and RM methods with an integrated approach to the detection/evaluation of safety issues, it is possible to identify important risks.

12:40 Overcoming 'Rubbish In: Rubbish Out': Effectively Supporting Target Identification & Validation Using Target Insights, a New Product from Elsevier
Sponsored by ELSEVIER
Jabe Wilson, MBA, Ph.D., Senior Product Development Manager, Elsevier (Pharma & Biotech Group)
In target identification/validation the fundamental questions are how is a target identified, and the hypothesis developed using the scientific literature? Reducing time & money investments in literature searching to get to a go-no go decision is crucial. Target Insights from Elsevier is a new online decision support tool for biologists dealing with these issues.

1:45 Dessert in the Exhibit Hall with Poster Viewing

2:15 Chairperson's Remarks

2:20 Safety as a Component of Target Selection
Anne Ryan, D.V.M., Ph.D., Diplomate ACVP, Executive Director, Drug Safety Research and Development, Pfizer, Inc.
Understanding the biology and safety of a proposed target; Understanding Target Expression and Tissue Distribution; Developing a Risk Management strategy early target de-risking studies.

2:50 Early *in vitro* Safety Screening: Impact in Drug Discovery
Mike Rolf, Ph.D., Associate Principal Scientist, Global Safety Assessment, AstraZeneca
Pre-clinical toxicity and clinical safety are one of the major contributors to attrition. To address this, AstraZeneca has created a Safety Screening Centre to identify and mitigate safety hazards early in discovery using automated *in vitro* safety screens. The benefits and challenges will be presented.

3:20 Pearls (and Perils) of Staged Empirical Pre-Clinical Cardiovascular De-Risking Strategies
Gary Gintant, Ph.D., Research Fellow, Integrative Pharmacology, Chair, Abbott QT/Proarrhythmia Working Group, Abbott Laboratories
Detection of compounds early and later during drug discovery can reduce later stage compound attrition. This talk will focus on strategies and examples of "frontloading" safety pharmacology studies for cardiovascular liabilities, a prominent source of continuing concern in drug development.

3:50 Using Mechanism of Action to Predict Safety Signals and Understand Sub-Populations
Sponsored by Biovista
Aris Persidis, Ph.D., President, Biovista
Mechanism of action (MoA) can be used to predict potential system-driven safety signals. it can also guide the selection of the right sub-populations in clinical trial design. Examples of inclusion/exclusion criteria will be given.

4:20 Reception in the Exhibit Hall *(Sponsorship Available)*

5:20 Breakout Discussions in the Exhibit Hall *(see website for details)*

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

NETWORK PHARMACOLOGY

7:55 am Chairperson's Remarks
Jake Chen, Ph.D., Associate Professor, Informatics, Indiana University

8:00 Network Polypharmacology in Systems Lead Finding
Jeremy Jenkins, Ph.D., Senior Investigator I, DMP, Quantitative Biology, Chemical Biology Informatics, Novartis Institutes for BioMedical Research
Protein interactomics data provides the basis for network maps that can represent theoretical targets in phenotypic assays. Protein interaction networks as an organizing principle for discovering chemical leads - both alone and in combination - will be presented.

8:30 Translating Systems Biology to Systems Pharmacology: Integrating *in vitro* Systems Biology and Disease-PKPD Modeling to Advance the Discovery of Antibody Therapeutics
John Burke, Ph.D., Senior Principal Scientist, Head, Systems Biology and Pre-Clinical PKPD Modeling, Translational Research, Boehringer Ingelheim Pharmaceuticals
First principals Systems Biology modeling and analysis elucidated seemingly contradictory *in vitro* data via model prediction. The model was then translated into the mechanistic disease-PKPD Systems Pharmacology paradigm to predict optimal therapeutic parameters. As a result, the lead was identified.

9:00 Computational Approaches in Studying Network Pharmacology
Philip E. Bourne PhD, Professor, Pharmacology, University of California, San Diego; Associate Director, RCSB Protein Data Bank; Co-Founder & Editor-in-Chief, PLoS Computational Biology
Recent success in using computational network pharmacology to explain unusual outcomes, both positive and negative, that are seen experimentally and/or clinically. Examples will be given, including Nelfinavir. Our approach combines cheminformatics, structural bioinformatics and systems biology.

KEYNOTE PRESENTATION

9:30 De-Risking Drug Discovery Using Network Pharmacology
Sponsored by e-Therapeutics Llc
Malcolm Young, Ph.D., CEO, e-Therapeutics
Statistical analysis of current attrition rates shows that pre-clinical and early clinical stage data do not predict efficacy, safety and deliverability in human patients nearly well enough. Further, and more accurate, ways to de-risk candidates before expensive clinical trials are urgently required.

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

10:10 Plenary Keynote Presentation *(See Page 3 for Details)*

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC

12:00 pm Modeling Drug Efficacy Using Network Pharmacology
Jake Chen, Ph.D., Associate Professor, Informatics, Indiana University
This will describe how the study of drugs, molecules, and drug-target can benefit predictive modeling of drug effects and evaluations of their efficacy. This opens up new opportunities for future drug development; this new exciting field can revolutionize future drug development.

12:30 EXPERT PANEL: Implementing Network Pharmacology in Current Pharma Strategies: Unveiling & Championing Existing Resources
Moderator:
Jeremy Jenkins, Ph.D., Senior Investigator I, DMP, Quantitative Biology, Chemical Biology Informatics, Novartis Institutes for BioMedical Research
Panelists:
John Burke, Ph.D., Senior Principal Scientist, Head, Systems Biology and Pre-Clinical PKPD Modeling, Translational Research, Boehringer Ingelheim Pharmaceuticals
Jake Chen, Ph.D., Associate Professor, Informatics, Indiana University
Malcolm Young, Ph.D., CEO, e-Therapeutics
Philip E. Bourne Ph.D, Professor, Pharmacology, University of California, San Diego; Associate Director, RCSB Protein Data Bank; Co-Founder & Editor-in-Chief, PLoS Computational Biology

1:00 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE PANEL

2:30 Plenary Keynote Panel *(See Page 3 for Details)*

3:50 Refreshment Break & Poster Awards in the Exhibit Hall

4:25 Chairperson's Remarks

4:30 PANEL DISCUSSION: Creating Safety Endpoints as a Milestone within Pharmaceutical Discovery & Development
Ernie Bush, Ph.D., Vice President, Collaborative Projects, The Drug Safety Executive Council
- Establishing safety assessment endpoints throughout the pipeline
- Why "one fits all" does not work
- Pre-clinical vs. clinical endpoints

KEYNOTE PRESENTATION

5:30 Target Validation of B-Lymphocyte Stimulator and Development of Belimumab—A Case Study
William W. Freimuth, M.D., Ph.D., Vice-President of Clinical Research Immunology, Rheumatology and Infectious Diseases, Human Genome Sciences, Inc.
B-Lymphocyte Stimulator (BLyS) is a member of the TNF ligand super family responsible for the survival of antibody producing B-cells. Its experimental overexpression is associated with an autoimmune phenotype, and its increase in the blood of patients with systemic lupus erythematosus (SLE).

6:30 Close of Day

THURSDAY, FEBRUARY 23

DRUG REPOSITIONING

8:30 am Chairperson's Remarks

8:35 Systematic Drug Repositioning: Maximizing the Value of Drugs for Patients
Mark Hurle, Ph.D., Senior Scientific Investigator, Computational Biology, Molecular Discovery & Development, GlaxoSmithKline
Typically drugs have been repositioned following serendipitous observations. Now, however, there are a number of computational methods that can evaluate and suggest new indications. Dr. Agarwal will discuss some of these that are based on text-mining literature, genetics, expression signatures and pathways.

9:05 Drug Repositioning: IP & Patent Information Every Scientist Needs
Kevin L. McLaren, Ph.D., Esq., Barnes & Thornburg LLP
The requirements for obtaining patent protection, including the new 2011 laws, with an emphasis on the patentability of repositioned drugs; a summary of important court cases where repositioned drug patents have been litigated, discussing both successful challenges and failed attempts.

9:35 Extended Profiling and Identification of Novel Indication Opportunities Using Knowledge Management Analytics
Natalia Novac, M.Sc., Ph.D., Scientist, Research & Development Knowledge Management, Operational Excellence, Merck Serono
In the times of the constantly rising attrition rates in pharma industry, repositioning is a solution for pipeline de-risking via rapid re-loading of the compounds back into the pipeline. Knowledge accumulated in the public and proprietary domains allows early analysis of compounds' indication profile leading to the better compound positioning and ensuring maximum exploration of existing opportunities. My talk will be focused on the knowledge management technologies and methodologies that enable systematic analysis of pipeline compounds and generation of viable hypotheses continuously supporting the pharma value chain.

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

11:15 Selected Poster Presentation
Huijun Wang, Ph.D., Senior Scientist, Pfizer

PRE-CLINICAL DE-RISKING STRATEGIES: TARGETS AND COMPOUNDS

Chairperson: Litao Zhang, Ph.D., Executive Director, Applied Biotechnology, Lead Evaluation

11:30 Driving Right Targets and Right Molecules to Clinic Development by Selectively Integrating Advanced Technology Platforms
Litao Zhang, Ph.D., Executive Director, Applied Biotechnology, Lead Evaluation and Mechanistic Biochemistry, Bristol-Myers Squibb
Several case studies will be discussed to demonstrate how to selectively integrate advanced technology platforms to deliver diverse modalities for target validation and strengthen *in vitro* pharmacology packages for drug candidate selection.

12:00 pm Academia Drives Innovative Target Discovery
Rathnam Chaguturu, Ph.D., Director, High-Throughput Screening Laboratories, University of Kansas; Editor-in-Chief, Combinatorial Chemistry and High-Throughput Screening
The process of target validation from the protein level to the cellular level and eventually in small animal models is at its best in academia, but academia could benefit immensely by adapting pharmaceutical industry's best practices to ensure that the biological targets are therapeutically relevant and chemically tractable.

12:30 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

1:45 Chairperson's Remarks

1:50 Facilitating Early Stage Projects
Lawrence R. McGee, Ph.D., Scientific Director, Medicinal Chemistry, Amgen South San Francisco
Small molecule drug candidates often closely resemble the initial hit. Improved hit characterization may increase the chance for success. A data-driven approach that facilitates entrepreneurial discovery teams through the hit and lead identification process will be discussed.

2:20 Combination Drug Profiling Strategies to De-Risk Drug Development and Improve Clinical Translation
Glenn Short, Ph.D., Director, Discovery Sciences, Zalicus
Performing combination profiling studies early in the drug discovery process, the observance of synergy will lend insight into which drug combinations are most appropriate for a given patient subpopulation and potentially de-risk critical decisions in trial design that improve the odds of clinical success.

2:50 *In vitro* Safety Profiling during Lead Optimization to Reduce Safety Attrition
Murray Brown, Ph.D., Manager, Data Interpretation and Business Process, Screening and Compound Profiling, GlaxoSmithKline
Efforts are underway across the industry to improve the quality of drug candidates by developing molecules with better physiochemical properties (e.g. MWt, clogP) and by assaying molecules in screening assays that are predictive of drug toxicity in animal or human studies. We show GSK's integrated approach.

3:20 Close of Conference

Second Annual

Oncology Clinical Trials

Bringing Targeted & Tailored Cancer Therapy to Patient

February 21-23

TUESDAY, FEBRUARY 21

7:00 am Registration

PLENARY KEYNOTE SESSION

8:00 Plenary Keynote Presentations *(See Page 3 for Details)*

9:40 Grand Opening Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC

CANCER CLINICAL TRIALS IN THE ERA OF PERSONALIZED MEDICINE

11:00 Chairperson's Opening Remarks

11:10 Cancer Clinical Trials in the Era of Personalized Medicine: A Sponsor's Perspective
Hal Barron, M.D., Executive Vice President, CMO, Global Product Development, Roche Holding AG

11:40 Methodologic Issues in Clinical Trials in the Era of Personalized Therapy
Steven Piantadosi, M.D., Ph.D., Chair & Director, Phase One Foundation, Samuel Oschin Comprehensive Cancer Institute
This talk will discuss issues in the design and analysis of trials that test therapies that rely on "personalized" therapy, such as those tailored to specific genetic or other characteristics of the study subjects.

12:10 pm Cancer Clinical Trials in the Era of Personalized Medicine: An Investigator's Perspective
Margaret A. Tempero, M.D., Doris and Donald Fisher Distinguished Professorship, Clinical Cancer Research; Professor, Medicine, Division of Hematology and Oncology; Director, Research Programs; Deputy Director, UCSF Helen Diller Family Comprehensive Cancer Centerr
Recent breakthroughs in clinical science suggest there is more diversity in malignant disease than we previously appreciated. Identifying clinically actionable biomarkers demands a paradigm shift in clinical trial design and a focus on small subsets.

Sponsored by Cytel

12:40 Sponsored Presentation
To be Announced

12:40 Keynote Panel Discussion: Clinical Trials as a Way to Improve Abilities to Diagnose, Treat and Prevent Cancer

1:45 Dessert in the Exhibit Hall with Poster Viewing

INDUSTRY-ACADEMIA COLLABORATION

2:15 Chairperson's Remarks
Ionel Mitrica, Ph.D., Director, Clinical Development, Oncology, GlaxoSmithKline

2:20 SWOG, An International NCI-Funded Cancer Cooperative Group Collaboration on Biomarker Development, Cancer Prevention and Cancer Treatment with Industry
Laurence H. Baker, D.O., Professor of Medicine and Pharmacology, University of Michigan Medical School; Group Chair, Southwest Oncology Group (SWOG)
SWOG is engaged in studies designed to improve our abilities to diagnose, treat and prevent cancer. Our clinical trials are performed by 4,000 physicians at over 500 sites. In this presentation we will highlight the methodology of the collaboration as well as describe some obstacles to success.

2:50 Cooperation between Industry and Academic Collaborative Groups in Oncology
Ionel Mitrica, Ph.D., Director, Clinical Development, Oncology, GlaxoSmithKline
This presentation discusses how to effectively approach partnerships between pharma and academic cooperative groups, while meeting both sides' needs as well as regulatory requirements, and ultimately also improving the output of oncology R&D.

NOVEL SURROGATE ENDPOINTS

3:20 Laboratory and Clinical Endpoints in Cancer Immunotherapy
Kim Lyerly, M.D., George Barth Geller Professor of Cancer Research; Professor of Surgery; Associate Professor of Pathology, Duke University School of Medicine
Cancer immunotherapies such as cellular therapies and immune modulators have been recognized to provide clinical benefit, and have received marketing approval in the United States. Nonetheless, well accepted clinical surrogates may not provide effective guidance toward the development of other immunotherapies, or extending the use of the currently approved therapies. The laboratory and clinical endpoints recognized as critical to demonstrating effectiveness will be addressed, along with discussion of their role in informing the development of novel agents.

3:50 CTCs as a Liquid Biopsy
Marielena Mata, Ph.D., Principal Research Scientist, Oncology Biomarkers, Johnson & Johnson
From counting to "seeing" the tumor, CTCs provide access to tumor related information that may significantly impact clinical development decisions. Overview of the use of CTCs in clinical trials as prognostic and predictive markers including practical considerations and logistics.

4:20 Reception in the Exhibit Hall *(Sponsorship Available)*

5:20 Breakout Discussions in the Exhibit Hall *(see website for details)*

6:20 Close of Day

WEDNESDAY, FEBRUARY 22

CASE STUDIES OF LED-TO-APPROVAL CLINICAL TRIALS

Xalkori Case Study

7:55 am Chairperson's Remarks
Keith Wilner, Ph.D., Senior Director, Oncology Clinical Development, Pfizer, Inc.

8:00 Integrating Companion Diagnostics into Clinical Drug Development: Crizotinib Case Study
Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide Research & Development, Clinical Research and Precision Medicine, Pfizer, Inc.
Fully integrating a diagnostic test into crizotinib pivotal trials, leading to a simultaneous submission of a drug-diagnostics combination, presented many challenges as well as opportunities in the development of crizotinib for treatment of NSCLC patients.

8:30 Speed of Drug Development by Incorporation of a Companion Test: Crizotinib Case Study
Keith Wilner, Ph.D., Senior Director, Oncology Clinical Development, Pfizer, Inc.
The use of a diagnostic test to appropriately identify a patient population expected to benefit from crizotinib treatment led to smaller clinical trials in NSCLC to meet the primary statistical endpoints as well as a greater chance of successful trials.

9:00 Simultaneous Approval of a Therapeutic & Companion Diagnostic: Crizotinib Case Study
Erling Thor Donnelly, Ph.D., R.A.C., Director, Worldwide Regulatory Strategy, Pfizer, Inc.
The simultaneous submission and approval of Pfizer's crizotinib and Abbott Molecular's anaplastic lymphoma kinase (ALK) break-apart FISH companion diagnostic presented unique clinical and regulatory challenges, requiring novel approaches as well as close collaboration between Pfizer, Abbott, CDER, and CDRH.

9:30 Transforming Clinical Development with Adaptive Trials Oncology – A Case Study of an Oncology Registration Trial
Cryus Mehta, Ph.D., President and Co-Founder, Cytel Inc.

Why are adaptive approaches on the rise in late phase oncology studies?

Over 50% of confirmatory studies end in failure - a distressing reality for cancer treatment developers and the medical community. In response, adaptive design strategies are helping reverse this discouraging trend. Using examples of ongoing adaptive trials – including the ongoing VALOR trial a pivotal study for the treatment of Acute Myeloid Leukemia, you'll learn:

- the adaptations the FDA and EMA allow in both earlier and confirmatory stages
- harnessing Conditional Power to effectively "de-risk" oncology development
- to make the most of interim analysis with the validated
- "Promising Zone" design strategy
- ethical considerations: what do participating patients gain in an adaptive study?

10:00 Transition to Plenary Keynote

PLENARY KEYNOTE

10:10 Plenary Keynote Presentation *(See Page 3 for Details)*

11:00 Refreshment Break in the Exhibit Hall with Poster Viewing

Sponsored by HOLOGIC MOLECULAR DIAGNOSTICS

Adcetris Case Study

12:00 pm Clinical Development of Brentuximab Vedotin: Five Remarkable Years from First Patient Treated to Accelerated Approval

Eric Sievers, M.D., Vice President, Clinical Affairs, Seattle Genetics

Observation of multiple complete remissions among advanced lymphoma patients treated in a phase one setting led Seattle Genetics to pursue paired, single-arm, registrational trials. We will review the overall strategy that led to marketing registration in 2011.

12:30 Accelerated Approval of a Targeted Antibody-Drug Conjugate (ADC): Brentuximab Vedotin Case Study

Elaine S. Waller, Pharm.D., M.B.A., Senior Vice President, Regulatory Affairs, Seattle Genetics, Inc.

FDA review of the brentuximab vedotin BLAs was complex due to inclusion of two indications, the ADC technology, and an ODAC environment influenced by recent hearings on accelerated approval of oncology drugs.

1:00 Luncheon Presentations *(Sponsorship Opportunities Available)* **or Lunch on Your Own**

2:00 Ice Cream Refreshment Break in the Exhibit Hall with Poster Viewing

PLENARY KEYNOTE PANEL

2:30 Plenary Keynote Panel *(See Page 3 for Details)*

3:50 Refreshment Break & Poster Awards in the Exhibit Hall

Zelboraf Case Study

4:25 Chairperson's Remarks

Elaine S. Waller, Pharm.D., M.B.A., Senior Vice President, Regulatory Affairs, Seattle Genetics, Inc.

4:30 Zelboraf in Metastatic Melanoma: Interim Analysis Considerations in a Phase III Trial

Chris Bowden, M.D., Vice President, Oncology Clinical Development, Genentech, Inc.

BRIM-3, a randomized Phase III trial in patients with V600+ metastatic melanoma, compared Zelboraf to dacarbazine treatment. The rationale for changing the primary endpoint from overall survival to the co-primary endpoints of overall survival and progression-free survival will be discussed.

5:00 Zelboraf/Cobas Lessons Learned: Prospective Co-Development of a Companion Diagnostic in Cancer Medicine

Jeffrey Lawrence, M.D., Director, Oncology, Roche Molecular Systems, Inc.

The cobas 4800 BRAF V600 Mutation Test was the companion diagnostic assay used to screen >2,300 melanoma patients for Phase II and Phase III trials of Zelboraf. Clinical validation of the cobas BRAF test vs. Sanger sequencing will be discussed.

5:30 Zelboraf Regulatory Perspectives: Lessons Learned and Future Implications

Linda Burdette, Ph.D., Director, Drug Regulatory Affairs, F. Hoffmann-La Roche, Inc.

Approval of the BRAF-targeted therapy ZELBORAF with the cobas BRAF diagnostic test exemplifies the process encouraged in FDA's 2011 *In Vitro* Diagnostic Companion Guidance. Lessons learned highlight considerations for navigating co-development approvals and next steps for CDER/CDRH guidance.

6:00 PANEL DISCUSSION: Lessons Learned from Case Studies

Moderator: Hakan Sakul, Ph.D., Executive Director & Head, Diagnostics, Worldwide Research & Development, Clinical Research and Precision Medicine, Pfizer, Inc.

6:30 Close of Day

THURSDAY, FEBRUARY 23

BIOMARKER-DRIVEN CLINICAL TRIALS

8:30 am Chairperson's Remarks

Hal Mann, Vice President, Clinical Research Services, ResearchDx, LLC

KEYNOTE PRESENTATION

8:35 The Story of MetMAb Discovery and Development

Stuart Lutzker, M.D., Ph.D., Vice President, BioOncology Exploratory Clinical Development, Genentech

9:05 Translational Genomics in a Phase II Clinical Trial for Patients with Previously Treated Advanced Pancreatic Adenocarcinoma

Michael Barrett, Ph.D., Associate Professor, Clinical Translational Research Division, Unit Head, Oncogenomics Laboratory, TGEN

We have developed unbiased methods to molecularly profile tumor genomes in highly admixed and complex clinical biopsies in the setting of a clinical trial. The data for each patient are integrated with prior knowledge of tumor signaling pathways in order to advance improved clinical outcomes.

9:35 Personalized Medicine in a Phase I Clinical Trials Program: The MD Anderson Cancer Center Initiative

Apostolia-Maria Tsimberidou, M.D., Ph.D., Associate Professor, Department of Investigational Cancer Therapeutics, University of Texas, MD Anderson Cancer Center

Tumor molecular profiling for identification of molecular aberrations and use of matched targeted therapy is associated with superior rates of response, time to treatment failure and survival compared to the standard approach in patients with advanced cancer.

10:05 Sponsored Presentation *(Opportunity Available)*

10:20 Coffee Break

11:00 Testing the Predictive Value of a Genomic Assay

William Barlow, Ph.D., Senior Biostatistician, Cancer Research & Biostatistics Research; Professor, Department of Biostatistics, University of Washington

Prediction refers to the ability of a marker to choose the best treatment for a patient. We illustrate how to test a continuous marker in a clinical trial and how to design a trial to test a marker's predictive value.

11:30 Clinical Trial Strategies for Deploying Modern Immunotherapies as Monotherapy or in Combinations

Ravi A. Madan, M.D., Assistant Clinical Investigator, Laboratory of Tumor Immunology and Biology & Medical Oncology Branch, National Cancer Institute

Modern immunotherapies such as therapeutic cancer vaccines are mechanistically different from standard cytotoxic agents, and thus require special considerations for population selection and clinical trial design. Appropriate trial endpoints for monotherapy may be different from studies which employ immune-based combinations.

12:00 pm New Approaches to the Treatment of Breast Cancer: The I-SPY TRIAL

Laura Jean Esserman, M.D., M.B.A., Director, Carol Franc Buck Breast Care Center Professor of Surgery and Radiology, University of California, San Francisco

I-SPY 2 is a precompetitive collaboration that employs an adaptive design, streamlined operational infrastructure, and uses pathologic complete response (pCR) as a "surrogate endpoint" in the neoadjuvant breast cancer setting, to speed the evaluation of new drugs and associated biomarkers.

12:30 Lunch on your Own

1:45 Chairperson's Remarks

1:50 Key Dimensions and Difficulties when Identifying Predictive Signatures in the Survival Analysis Setting

Jared Lunceford, Senior Biometrician, Merck Research Laboratories

In the context of microarray gene expression profiling and the modeling of overall survival or progression free survival, the search for a predictive signature is a delicate task and we will review some of the key statistical issues involved when constructing *de novo* models for survival endpoints.

2:20 Panel Discussion: Biomarkers in Cancer Clinical Trials: a Tool or a Goal?

Laura Jean Esserman, M.D., MBA, Director, Carol Franc Buck Breast Care Center Professor of Surgery and Radiology, University of California, San Francisco

3:20 Close of Conference

Pricing and Registration Information

19th International Molecular Med TRI-CON 2012
February 19-23, 2012
San Francisco, CA
The Moscone North Convention Center & InterContinental San Francisco Hotel

Regular Pricing – A La Carte Options

PARTNERING FORUMS (FEB 19-20)

Emerging Targeted Oncology Partnering Forum	$1395
Early Stage Molecular Diagnostics Partnering Forum	$1395

SYMPOSIA (FEB 19-20)

Targeting Cancer Stem Cells in Oncology	$1395	$995
Cloud Computing	$1395	$995
Phage and Yeast Display of Difficult Targets	$1395	$995
Point-of-Care Diagnostics	$1395	$995
Next-Generation Pathology	$1395	$995

SHORT COURSES (FEB 20)

1 Short Course	$595	$295
2 Short Courses	$895	$495

Afternoon

SC1 Identification, Characterization and Targeting of Cancer Stem Cells
SC2 Roadmap for Accelerating Commercialization of Molecular Diagnostics
SC3 Understanding EMT: Mechanisms and Metastasis to MET
SC4 Network Pharmacology
SC5 Next-Generation Sequencing in the Cloud Era
SC6 Marketing and Sales: Science Training 101
SC7 Latest Advances in Molecular Pathology, Part I (Basic)
SC8 Best Practices in Translational Informatics
SC9 Pharmacology and Drug Discovery in the Allosteric World

Dinner

SC10 Digital PCR Applications and Advances
SC11 CTCs from Bench to Bed: Streamlining from Research to Clinical Practice
SC12 First-in-Human Study and Risk Mitigation Strategy for Biologics
SC13 Scientists: Business Training 101
SC14 Adaptive Oncology Clinical Trials
SC15 Latest Advances in Molecular Pathology, Part II (Advanced)
SC16 Ontologies for the Bio-Science Industry: Development & Use
SC17 Mastering Physicochemical Properties-Based Analysis to Deliver Improved Drug Candidates
SC18 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts

CORE PROGRAMS (FEB 21-23)

Advance Registration until January 20, 2012	$2055	$1155
Registration after January 20, 2012, and on-site	$2195	$1205

Diagnostics Channel
Molecular Diagnostics
Personalized Diagnostics
Cancer Molecular Markers
Circulating Tumor Cells
Genomic Screening and Diagnosis

Drug Discovery & Development Channel
Mastering Medicinal Chemistry
Translational Science
Oncology Clinical Trials
De-Risking Drug Discovery

Informatics Channel
Integrated R&D Informatics
Bioinformatics/ Cancerinformatics

Cancer Channel
Cancer Biologics
Cancer Molecular Markers
Circulating Tumor Cells
Oncology Clinical Trials
Bioinformatics/Cancerinformatics

TRI-CON ALL ACCESS PACKAGE- BEST VALUE! (FEB 19-23)

See bottom left for recommended pairings.

Includes: 1 Symposium OR Partnering Forum, 2 Short Courses, and 1 Conference Program	Commercial	Academic, Government, Hospital-affiliated
Advance Registration until January 20, 2012	$3095	$1835
Registration after January 20, 2012, and on-site	$3215	$1905

ADDITIONAL REGISTRATION DETAILS

Each registration includes all conference sessions, posters and exhibits, food functions, and access to the conference proceedings link.

Handicapped Equal Access: In accordance with the ADA, Cambridge Healthtech Institute is pleased to arrange special accommodations for attendees with special needs. All requests for such assistance must be submitted in writing to CHI at least 30 days prior to the start of the meeting.

To view our Substitutions/Cancellations Policy, go to www.healthtech.com/regdetails

Video and or audio recording of any kind is prohibited onsite at all CHI events.

CONFERENCE DISCOUNTS

Poster Discount ($50 Off)
Alumni Discount (20% Off)
BayBio Discount (20% Off)

*Alumni and BayBio Discount cannot be combined. Discounts not applicable on Event Short Courses

Alumni Discount SAVE 20%:
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Reserve your hotel and save $100 OFF your conference registration *you must book your reservation under the Tri-Conference room block for a minimum of 4 nights
**1 discount per hotel room

Poster Submission-Poster abstracts are due by **January 13, 2012.** Once your registration has been fully processed, we will send an email containing a unique and session-specific link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com.
Dedicated poster sessions for Symposia and Core Programs. Present your poster at both!**
* CHI reserves the right to publish your poster title and abstract in various marketing materials and products.
**One poster discount per registration.

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TRI-CON ALL ACCESS PACKAGE - Recommended Pairings

Symposia
Next Generation Pathology
AND
Short Courses
SC9 Pharmacology and Drug Discovery in the Allosteric World
SC12 First-in-Human Study and Risk Mitigation Strategy for Biologics
SC14 Adaptive Oncology Clinical Trials
SC 17 Mastering Physicochemical Properties-Based Analysis to Deliver Improved Drug Candidates
SC18 Regulatory Approval of a Therapeutic & Companion Diagnostic: Nuts & Bolts

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Reserve Your Space by Jan. 13th!

Dedicated poster sessions for Symposia and Core Programs!

- Your research will be seen by leaders from top pharmaceutical, biotech, academic and government institutes
- Your poster abstract will be published in the conference materials
- $50 off your registration fee**

** One poster discount per registration.
(You must be registered for a Symposium to present at the Symposia Poster Session; You must be registered for a Core Program to present at the Core Program Poster Session)

Symposia Posters

At the InterContinental San Francisco Hotel
February 19-20, 2012

- Topic-specific poster sessions
- Targeted audience

Core Program Posters

At the Moscone North Convention Center
February 21-22, 2012

- Your poster will be available to over 3,000 delegates
- Posters will be on display for two full days in the exhibit hall
- Core Program poster competition with two $500 prizes