DRUG REPOSITIONING SUMMIT
FINDING NEW ROUTES TO SUCCESS

October 10-11, 2007 • Loews Philadelphia Hotel • Philadelphia, Pennsylvania

FEATURED PRESENTATION
Lee E. Babiss, Ph.D., Global Head, Pharma Research, Roche Inc.

SESSIONS INCLUDE:
- OVERVIEW SESSION
- TECHNICAL APPROACHES
- REPROFILING DRUGS
- SCREENING AGAINST MULTIPLE TARGETS (Shared Session with Compound Profiling)

DON’T MISS:
Pre-Conference Short Course
Filing a 505 (B)(2) Application and Strategies for Gaining Approval
Kenneth V. Phelps, President and CEO, Camargo Pharmaceuticals Services, LLC

“...The meeting provided practical, theoretical, and successful examples of repositioning drugs. From Affy chip to animal models to clinical practice- all were covered.”
Senior Director, Pharmacology, GNF
(2006 Alumnus)

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Cambridge Healthtech Institute’s Second Annual

Cambridge Healthtech Institute, 250 First Ave, Suite 300, Needham, MA 02494
Phone: 781-972-5400 • Fax: 781-972-5425 • E-mail: chi@healthtech.com
8:00 am  Pre-Conference Short Course Registration

9:00am    Pre-Conference Short Course
Filing a 505 (B)(2) Application and Strategies for Gaining Approval

Kenneth V. Phelps, President and Chief Executive Officer, Camargo Pharmaceuticals Services, LLC

Obtaining FDA product approval via the 505(B)(2) route can be a terrific business strategy, but you must understand the benefits, risks and development steps. This course takes you, step-by-step, through the 505(B)(2) approval process. Equally important, this course provides the historical, legal and practical background you need for going go decisions. This 3-hour short course will greatly enhance your ability to identify 505(B)(2) candidates and pursue them with confidence.

Key learning goals:
- Define 505(B)(2)
- Compare and contrast 505(B)(2) with NDA/ANDA
- Identify 505(B)(2) opportunities (based on dosage form, strength, formulation, NME's)
- Evaluate the benefits and risks of 505(B)(2)
- Explain key legal challenges and their potential implications
- Describe the 505(B)(2) drug development steps and application process (Phases 1-4 and Submission)

12:00 pm Conference Registration

1:00      Chairperson’s Opening Remarks
Christopher A. Lipinski, Ph.D., Scientific Advisor, Melior Discovery Inc.

1:15      Drug Repurposing via Phenotypic Screening
Christopher A. Lipinski, Ph.D.

Screening of mechanistically defined targets accounts for 95% of today’s drug discovery efforts and lack of efficacy is a major cause of current clinical failure. These two phenomena are linked if there is a flaw in the logic for the target mechanism. In the 1970’s, phenotypic screening was the rule rather than the exception and failure rates were arguably better than today. So there is merit in a back to the future approach. Namely, capitalize on the known success of in vivo mouse phenotypic screening but do it much more efficiently than in the 1970’s. An intriguing, and only partly understood, phenomenon is the incredibly high success rate ranging from 10-90% in the initial stage in searching for a new use for an old drug, especially for an orally active drug that succeeded quite far into the clinic before failing for efficacy as opposed to safety. Partial explanations include the non diversity of biologically active chemistry space; the non diversity in ligand binding protein motifs; the great restriction in the properties of compounds advanced in clinical study and the orders of magnitude improvement in target opportunity space that phenotypic screening holds over mechanistic screening. An additional success increment can be added if the compound to be repurposed is subjected to absolutely brutal chemical examination so that nothing in the chemistry suggests even the slightest possibility of a medicinal chemistry or drug metabolism problem.

1:45    The Use of Integrative Pharmacology in Drug Repositioning
Thomas Barnes, Ph.D., Senior Vice President of Discovery, Gene Logic Inc.

Reduced hurdles in lead identification are resulting in the screening of druggable targets with weaker disease hypotheses, increasing the risk and thus incidence of programs that fail in the intended therapeutic area due to lack of efficacy. Nevertheless, the high-quality chemical matter that results can be used to probe target function and thereby link the corresponding compounds to new therapeutic utility. What is required is sufficiently high throughput methodologies to make de novo links between specific compounds and disease. We have integrated a set of technologies that provide the means of efficiently associating compounds with potential new therapeutic utility. This is in contrast to the unsystematic observations classically relied upon to reveal alternative or new drug indications. The promise of these technologies is to expeditiously reduce pipeline gaps within a pharmaceutical industry whose growth is threatened by reduced (and increasingly costly) new product flow.
Beyond drug repositioning, the Pfizer Indications Discovery Unit seeks to identify additional indications for active clinical candidates. A coordinated, systematic approach is being developed and implemented. The unit is dependent on extensive internal and external partnerships. Challenges and opportunities will be discussed.

2:45 Product Life Cycle Management: Drug Repositioning
Mr. Edward Grieff, Partner, Intellectual Property, Venable LLP

Corporations need to provide the maximum patent protection for commercial products. Several methods for life cycle management include FDA pediatric exclusivity, new formulations, and drug repositioning. Drug repositioning is an excellent way to maximize the life cycle of a product without changing the original dosage and formulation of a compound that is or will soon be off patent.
Thursday, October 11

8:00 am  Morning Coffee

8:30  Chairperson’s Remarks
Marcel van Duin, Ph.D., Executive Director and Head,
Department of Pharmacology, NV Organon

8:40  Uncovering Unexploited Biology on Halted Drugs
Chizuko Koseki, Ph.D., Vice President, Drug Profiling
Platform Unit, Sosei Co. Ltd.

In order to look for the potential of second biological target on halted drug candidates, Sosei has established a unique business model, the Drug Reprofiling Platform. Our efforts in the last several years are giving some answers to our original questions, is there any possibility to identify a new use on halted drugs, if so, how? Can we develop it for a new indication which was originally un-identified? Our DRP business model and some outcomes will be introduced.

9:15  Repositioning at Organon - Just for Halted Drugs?
Anja Garritsen, Ph.D., Executive Director Target
Discovery, NV Organon

Repositioning at Organon started with the identification of drugs that were discontinued at various stages of the development process. Based on this compound list, we established a number of collaborations with repositioning companies. This allowed us to exploit a range of philosophies and technologies and explore the possibilities in various therapeutic areas to the fullest. Currently, the concept of exploring the full therapeutic potential of our compounds, also in earlier phases of discovery, is catching on. Efforts range from cross-screening sets of compounds on a variety of targets to a focus search for new indications for compounds.

9:45  CIPRO: The Creation of a New Blockbuster
Hans-Joachim Zeller, Ph.D., Consultant, Innovation,
Bayer/HighTech Private Equity

Ciprofloxacin was identified in 1981 as a new, highly attractive antimicrobial agent. The use of knowledge about properties of older drug classes and the creation of a chemical niche allowed Bayer to build in new properties into such a molecule which made it useful for the treatment of severe systemic infections. This drug became one of the biggest successes in the field of antimicrobial therapy.

10:15  Poster Session, Exhibit Viewing and Coffee Break

10:45  Drug Repositioning Using a Multiplexed In Vivo Platform: Discovery of MLR-1023, A Repositioned Drug Candidate for Type II Diabetes
Michael S. Saporito, Ph.D., Vice President, Research,
Melior Discovery Inc.

We have developed a unique repositioning approach involving a platform comprised of multiple in vivo models representing diverse therapeutic areas. The power of this platform is illustrated by our lead compound, MLR-1023. This compound, originally developed for ulcers, exhibits robust activity in a panel of clinically relevant models of type II diabetes and is currently being developed for this indication. Of importance was the identification of a previously unknown molecular target for type II diabetes. This example of Melior Discovery’s approach demonstrates the potential for capturing new indications from existing molecules, and the potential for expanding our understanding of the underlying biological basis of disease.

11:15  Panel Discussion: IP and Practical Issues of Drug Repositioning and Repurposing
Moderator: Kevin Davies, Editor-in-Chief, BioIT World
 Strategies for partnering, gaining patent protection and freedom to operate
Cultural and organizational obstacles in repositioning and repurposing
Best practices and success stories for gaining approval

Additional Panelists
Donald E. Frail, Ph.D.
Thomas Barnes, Ph.D.
Richard B. Smith, Partner, Technology Group, Edwards
Angeil Palmer & Dodge LLP

12:00 Luncheon Workshop (Sponsorship Available)
or Lunch on Your Own

(Shared Session with Compound Profiling)

1:30  Chairperson’s Remarks

1:40  Featured Presentation
Is Repositioning a Viable Option for Creating Differentiated Medicines?
Lee E. Babiss, Ph.D., Global Head, Pharma
Research, Roche Inc.

- How do we create internal buy-in for this concept and how do we establish partnerships with biotech and academia to create a case for investing in repurposed drugs?
- What are the best wet-lab and in silico technologies that can be applied to identify new disease indications for promising drugs?
- Once the data suggests a new way forward, how can we make such assets a high priority in our companies and/or use these to gain access to other types of external innovation?
2:15 Automated Robotic Molecular Profiling in Cells for New Therapeutic Directions
Jeremy S. Caldwell, Ph.D., Director of Molecular and Cell Biology, Genomics Institute of the Novartis Research Foundation

Small molecule cross reactivity against multiple targets can simultaneously afford broad therapeutic utility and problematic non-specific effects. Xin man Quantitative methods to rapidly characterize molecules in a broad array of cellular assays would reveal the range of functions associated with small molecules and impart a more thorough profile of drug candidates early in the drug development process. Here we describe a high-throughput approach to discover the multiple activities of small molecule libraries analyzed in parallel against a broad array of phenotypic cellular assays, and the robotic infrastructure necessary to perform these measurements.

2:45 Poster Session, Exhibit Viewing and Refreshment Break

3:15 An Efficient Platform for Genetic Target and Compound Positioning
David Grass, Ph.D. Vice President Scientific Operations, Caliper Discovery Alliances and Services, Caliper Life Sciences

Given the challenges facing the biopharmaceutical industry, including increased drug discovery and development timelines, fewer IND and NDA submissions per R&D dollar investment, and diminishing drug exclusivity timelines, it has become extremely important to identify potential indications for both genetic targets and compounds as early and as efficiently as possible. Caliper Discovery Alliances and Services (CDAS) Xenogen Biosciences has created a broad platform which uses mice to comprehensively characterize genetic targets and compounds. This platform utilizes in vivo assays that are relevant to most of the major therapeutic areas. For genetic targets, this platform allows for efficient target validation and early positioning of potential therapeutics. For compounds, this platform identifies unanticipated pre-poststage opportunities for earlier stage compounds as well as repositioning opportunities for existing therapeutics and clinical development compounds.

3:45 Characterizing the Multiple Activities of Kinase Inhibitors
Petra Ross-Macdonald, Ph.D., Senior Research Investigator, Applied Genomics, Bristol-Myers Squibb Co.

Using a novel approach to identify genes that exhibit dose-response behavior, we can examine compound potency, selectivity, on- and off-target activities, and underlying biology across the therapeutic dosing range. This strategy is being employed to identify distinct activities within and between compounds.

4:15 Ceftriaxone and Results of Large Scale Screening Efforts
Jill Heemskerk, Ph.D., Extramural Research Program Neuroscience, National Institute of Neurological Disorders and Stroke

4:45 Close of Conference

“Provided very useful insight into this developing area. Very good mix of company and academic speakers—providing distinct and complementary approaches to drug repositioning”

Director, Science and Technology
Alliances, AstraZeneca
(2006 Alumnus)

2:45 Close of Conference

Camargo Pharmaceutical Services provides turnkey drug development solutions for pharmaceutical companies seeking to reposition drug candidates. Team Camargo has realized over 150 FDA approvals for NDAs, both 505(b)(1)s and 505(b)(2)s, in many therapeutic areas. Working in close collaboration with service partners, Camargo streamlines the development process increasing speed-to-market cost-effectively and efficiently for clients in the U.S. and abroad.

Gene Logic has an on-going commitment to enhance the productivity of the pharmaceutical industry by reducing the attrition rate of drug development. Over the past 10 years, our pharmaceutical customers and partners have relied on our Genomics Services to enhance their drug discovery & early development processes and on our Drug Repositioning Program to find new therapeutic uses for discontinued drug candidates.

SPONSORSHIP and EXHIBIT INFORMATION
Showcase your company’s expertise, brand your solutions and develop revenue opportunities with qualified decision-makers by becoming an Exhibitor or Sponsor! We can customize any opportunity to meet your current marketing and sales objectives. To find out more about our comprehensive sponsorship and exhibit packages, please contact Carol Dinerstein at 781-972-5471, or email: dinerstein@healthtech.com

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Discounted Room Rate: $219 s/d
Discounted Room Reservation Cutoff Date: September 12, 2007

Please call the hotel directly to make your room reservation. Identify yourself as a Cambridge Healthtech Institute conference attendee to receive the reduced 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. Discount rooms are limited, so please book early.

Travel Information
Flight Discounts: Discount fares are available on United, United Express, United code share flights (UA*) operated by US Airways, and US Airways Express. Receive up to a 15% discount by calling United’s toll-free number 1-800-521-4041 and refer to the Meeting ID Number 579YS.

Car Rental Information
Special discount rentals have been established withAVIS for this conference. Please call AVIS directly at 800-331-1600 and reference the Avis Worldwide Discount (AWD) Number J868190

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**REGISTRATION INFORMATION**

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Would you like to receive event updates via fax?  
- Yes  
- No

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*Email*  
- Email is not a mandatory field. However, by excluding your email you will not receive notification about online access to pre-conference presenter materials, conference updates and networking opportunities.

**PAYMENT INFORMATION**

| Drug Repositioning & Compound Profiling Package:  
| Includes registration for the pre-conference short course, the Drug Repositioning Summit, and the Compound Profiling Conference (October 10-12)  
| Early Registration Discount until July 20, 2007  
| Advance Registration Discount until September 7, 2007  
| Registration after September 7, 2007  
| Single Conference Only:  
| Includes registration for the Drug Repositioning Summit (October 10-11) or the Compound Profiling Conference (October 11-12)  
| Early Registration Discount until July 20, 2007  
| Advance Registration Discount until September 7, 2007  
| Registration after September 7, 2007  
| Short Course Only:  
| Includes registration for pre-conference short course only (October 10)  
| Filing a 505 (B)(2) Application  
| Poster Discount  

- Commercial  
- Academic, Government, Hospital-Affiliated

| $1745  
| $1895  
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| $995  
| $1075  
| $545  
| $620  
| $695  
| $245  
| $50 off

- I cannot attend but would like to purchase the conference CD for $250 (plus shipping).  
- Massachusetts delivery will include 5% sales tax.

- Enclosed is a check or money order payable to Cambridge Healthtech Institute, drawn on a U.S. bank, in U.S. currency.

- Invoice me, but reserve my space with credit card information listed below.

  **Invoices unpaid two weeks prior to conference will be billed to credit card at full registration rate. Invoices must be paid in full and checks received by the deadline date to retain registration discount. If you plan to register on site, please check with CHI beforehand for space availability.**

- Please charge:  
  - AMEX (15 digits)  
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**PRESENT A POSTER AND SAVE $50**  
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 CD, your abstract must be submitted, accepted and registration paid in full by September 19, 2007. Register online to use the Poster Abstract Submission form or, if you register by phone, fax, or mail, you will receive Poster Abstract Submission guidelines via email.

I am interested in presenting a poster at  
Drug Repositioning Summit and will submit a completed one-page abstract by September 19, 2007. (Please Note: Registration must be paid in full to present a poster.)

Title

**ADDITIONAL REGISTRATION DETAILS**

- Each registration includes all conference sessions, posters and exhibits, food functions, and a copy of the conference CD.  
- To secure a poster board and inclusion in the conference CD, your abstract must be submitted, accepted and registration paid in full by September 19, 2007.

**SUBSTITUTION/CANCELLATION POLICY**

In the event that you need to cancel a registration, you may:

- Transfer your registration to a colleague within your organization.
- Credit your registration to another Cambridge Healthtech Institute program.
- Request a refund minus a $100 processing fee per conference.
- Request a refund minus the cost ($250) of ordering a copy of the CD.

NOTE: Cancellations will only be accepted up to two weeks prior to the conference.

Program and speakers are subject to change.

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