GTC
Global Technology Community

SAN FRANCISCO AIRPORT MARRIOTT WATERFRONT,
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JULY 9-10, 2012

9th Anti-Infectives Partnering and Deal-Making

KEYNOTE SPEAKER

Brad Spellberg, M.D., FIDSA, FACP
Associate Professor, Medicine
Los Angeles Biomedical Research Institute at
Harbor-UCLA Medical Center

FEATURED SPEAKERS

Barry Eisenstein, M.D., FACP, FIDSA, FAAM
Senior Vice President, Scientific Affairs
Cubist Pharmaceuticals

Joseph Larsen, Ph.D.
Chief, Broad Spectrum Antimicrobials Program
Biomedical Advanced Research Development Authority

Rosemarie Aurigemma, Ph.D.
Chief, Drug Development Section;
Office of Biodefense Research Affairs
DMID, NIAID, NIH

Shing Chang, Ph.D.
R&D Director
Drugs for Neglected Diseases initiative

Part of the *2nd Infectious Diseases World Summit*

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10th Vaccines Research & Development: All Things Considered
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Day 1 - Monday, July 09, 2012

8:00 Welcome & Opening Remarks

Session: Regulatory Guidance and Overcoming Challenges in Anti-infectives Development

KEYNOTE PRESENTATION

8:05 The Future of Antibiotic R&D

Brad Spellberg, M.D., FIDSA, FACP
Associate Professor, Medicine
Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center

Ever-rising antibiotic resistance continues to plague public health systems all over the world. Meanwhile, new discovery and development of antibiotics continues to face scientific, regulatory, and economic challenges. What does the future hold? The medical need for new antibiotics will continue to worsen. Rapid diagnostics, changes in the regulatory landscape, public private partnerships, improved biological technologies, and expansion of international markets will have major impact on what antibiotics are developed and how.

Benefits:
1) Review the unmet medical need of antibiotics
2) Discuss recent economic and legislative developments
3) Discuss current and future regulatory environments
4) Review the concept of public private partnerships

FEATURED PRESENTATION

8:40 The Antibiotic Pipeline: Where Is It and What Needs Fixing

Barry Eisenstein, M.D., FACP, FIDSA, FAAM
Senior Vice President, Scientific Affairs
Cubist Pharmaceuticals

The continued increase in antibiotic resistance makes all antibiotics "wasting assets" with limited life span. To maintain the life-preserving armamentarium against bacterial infections, therefore, new antibiotics must be developed on a regular basis. Given the relatively low return on antibiotics, compared with drugs for more chronic conditions, investment in new ATB development has waned. Adding to the difficulty of new ATB development has been the inherent challenge of developing such drugs in patient populations with resistant pathogens. Thus, regulatory hurdles to approval present an additional disincentive to new ATB development. My talk will explore these issues and offer several approaches at both the regulatory and public policy level to attempt to overcome this "market failure".

Discussions that follow will, hopefully, enhance our understanding of the problem and our commitment to seek change in the environment we face, resulting in new, life-saving drugs that are also reasonable business investments for interested stakeholders.

9:15 A Long and Winding Road

Roger Echols, Principal Member, **ID3C - Infectious Disease Drug Development Consulting**

Since 2005, the reality of "regulatory risk" has had a major impact on the willingness to invest in antimicrobial drug development. Understanding how this situation came about may provide some answers going forward. Early antimicrobial development was targeted to treat specific pathogens (sulfanilamide-streptococci; streptomycin-tuberculosis; penicillin-pneumococcus). Once the principle of antimicrobial treatment was accepted, there were additional drug classes (mechanisms) with different spectra (tetracyclines, chloramphenicol) and modifications to the basic structure of active moieties led to a proliferation of antimicrobials, especially among the beta-lactams (penicillins, cephalosporins, penems). NDA regulatory packages became routine with a high rate of approval. Randomized controlled clinical trials were the exception prior to the 1970s. Indication specific clinical trials developed in the 1990s with considerable input from the IDSA. Physician clinical judgment supported by objective laboratory and physical signs determined the outcome establishing treatment benefit. Standard of care active control drugs were used to benchmark efficacy and safety of new agents. Determining "non-inferiority" margins and statistical power were managed by consensus. In the early 2000s, however, the justification of NI margins became topical and by 2005 became the new regulatory hurdle, most notably providing the withdrawal of certyain indications of Ketek (telithromycn) essentially killing the product. Since then few new antimicrobial drugs or even supplemental indications have been approved, and not due to safety concerns. Efforts by the FDA to provide new clinical trial guidelines (ABOM, CABP, ABECB, ABS, NP) have largely failed due to ethical concerns for placebo controls or investment costs. In the face of increasing antimicrobial drug resistance, particularly among gram-negative bacteria, the development pipeline is bare. Fortunately, both the FDA and Congress recognize the urgency of stimulating the discovery and development of new drugs. Interestingly, the focus has returned to targeted development. The question remains how to make these new efforts commercially viable.

9:50 Morning Break

Panel Discussion: Current Trends and Future in Anti-infectives Development

10:30 *Moderator: Robert Guidos, Vice President, Public Policy & Govt. Relations,* **Infectious Diseases Society of America (IDSA)**

Panelist: Brad Spellberg, M.D., FIDSA, FACP, Associate Professor, Medicine, **Los Angeles Biomedical Research Institute at Harbor-UCLA Medical Center**

Panelist: Barry Eisenstein, M.D., FACP, FIDSA, FAAM, Senior Vice President, Scientific Affairs, **Cubist Pharmaceuticals**

Panelist: Prabhavathi Fernandes, Ph.D., Founder, President and Chief Executive Officer , **Cempra Pharmaceuticals**

Panelist: Peter Hammann, TSU Infectious Dieseases; Head of External Opportunities and Innovation Research & Development, **Sanofi Deutschland**

• In the face of increasing antimicrobial drug resistance, particularly among gram-negative bacteria, the development pipeline is bare. FDA has published several clinical trial guidelines for industry that many have called infeasible. Both FDA and Congressional leaders have made statements recently demonstrating a recognition of the urgency of the antibiotic R&D problem and the need for FDA to take immediate steps to resolve the clinical trial dilemma. What are the macro and micro reasons FDA's efforts to provide feasible clinical trial guidance have failed?
• Some in PhRMA are proposing a tiered approach to antibiotic approvals that allows for pathways in addition to the traditional (2 study) approach, while others in industry have proposed a graduated approval approach. What are these approaches? Are they mutually exclusive? What is the right model and why? Can FDA implement these various approaches using existing authority or is new statutory authority needed?
• Regarding IDSA's proposed Limited Use Antibacterial Drug (LPAD) approval mechanism, during lobbying around the FDA Prescription Drug User Fee Act (PDUFA) reauthorization, there appeared to be a bright line drawn as far as industry support/opposition to the concept with large companies appearing to line up in opposition to the concept while many small companies (14 of them) lined up in support. Was this a temporary issue related to PDUFA politics or did a deeper policy-related divide? Might smaller companies stand to fare better if LPAD is established than large companies)? Would LPAD impact the practice of medicine?
• Looking in your crystal ball, what do you think the future holds? Which potential FDA-generated solutions hold the greatest promise for the field of antibiotic R&D? Which of the congressional solutions likely are most helpful and why? Will additional legislation be needed? Could transferrable (sellable) R&D tax credits provide a helpful push for both large and small companies?

• Are there other promising solutions being discussed among industry experts and other stakeholders?
• Is there a need for new antibiotics?
- What do we really need for gram positive?
- What do we really need for gram negative?
• Where are novel antibiotics coming from?
• The role of virulence factor inhibitors in the future.
• The role of neglected diseases in big pharma partnering with universities & initiatives in this field.

Novel Diagnostics Against Drug Resistance

11:15 Molecular Methods for Rapid Detection of Antimicrobial Resistant Organisms

Fred C. Tenover, Ph.D., D(ABMM), F(AAM), F(IDSA), Executive Director, Scientific Affairs, **Cepheid**

Nucleic acid amplification methods can provide data on the presence of antimicrobial resistant microorganisms directly from clinical specimens often in less than 1 hour. Bacteria causing sepsis, respiratory tract infections (including tuberculosis), and wound infections (such as Staphylococcus aureus) are all amenable to rapid detection and reporting. Several studies have demonstrated that rapid detection of resistant bacteria, especially in positive blood cultures, can improve patient outcomes and reduce the overall cost of healthcare by optimizing therapy early in the course of disease. Commercial molecular diagnostic assays to detect resistant organisms are already in use in microbiology laboratories around the world. These include assays that detect rifampin-resistant strains of Mycobacterium tuberculosis directly in sputum samples in less than 2 hours. Implementation of the new assays often requires education programs for physicians to assist them in understanding how to use the molecular data to optimize antibiotic treatment regimens. It is likely that molecular assays will have a substantial impact on addressing the critical issue of antimicrobial resistance.

After listening to this presentation on rapid diagnostics, attendees will be able to:
- identify at least three molecular assays for resistant bacterial infections that will decrease the time to optimizing therapy for bacterial infections by at least 48 hours.
- Describe three molecular technologies that can be used to identify resistant bacteria present in positive blood culture vials to decrease time to identification in at least 80% of cases
- Describe at least 2 molecular methods for identifying mutations in Mycobacterium tuberculosis that result in rifampin resistance in >95% of strains.

11:40 Lunch on Your Own

Government Collaborations and Non-dilutive Funding

1:00 FEATURED PRESENTATION

Joseph Larsen, Ph.D.
Chief, Broad Spectrum Antimicrobials (BSA) Program; Division of CBRN Countermeasures
DHHS/ASPR/BARDA

The Biomedical Advanced Research Development Authority (BARDA) is responsible for developing and acquiring medical countermeasures directed against microbes of biodefense interest. BARDA is a component of the Department of Health and Human Services, under the Assistant Secretary for Preparedness and Response (ASPR). BARDA initiated its program for the development of novel antibacterial and antiviral drugs in January 2010. The goals of BARDA's Broad Spectrum Antimicrobials program are to enable the U.S. Government to acquire medical countermeasures to protect the American public against bioterrorist threats and to develop additional antimicrobial treatment options needed to counter the growing threat of antimicrobial resistance in common

FEATURED PRESENTATION

1:30 Gov't Collaborations and Non-dilutive Funding

Rosemarie Aurigemma, Ph.D.
Chief, Drug Development Section; Office of Biodefense Research Affairs
DMID, NIAID, NIH

The Division of Microbiology and Infectious Diseases (DMID) within the National Institute of Allergy and Infectious Diseases (NIAID) supports development of countermeasures for diseases of global health significance, including malaria, drug resistant tuberculosis, and influenza by developing new drugs, vaccines and point-of-care diagnostics. DMID also promotes basic and clinical research aimed at the development of antimicrobials and vaccines for emerging and re-emerging infectious diseases, including antibiotic-resistant bacteria and supports the development of medical countermeasures for biodefense and emerging infectious diseases in support of the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) mission. To achieve the goals of bringing new products through the translational pipeline, DMID offers a range of support, from grants to contracts as well as providing access to development services that can fill gaps in the product development pipeline.

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Panel Discussion: Finding the Middle Ground in Partnerships with Big Pharma and Govt.

2:00 *Moderator: Joyce Sutcliffe, Senior Vice President, Biology,* **Tetraphase Pharmaceuticals**

Panelist: Richard J. Hatchett, M.D., Chief Medical Officer and Deputy Director, **Biomedical Advanced Research and Development Authority (HHS/ASPR/BARDA)**

Panelist: Ed Moran, Vice President R&D Projects, **Theravance**

Panelist: TBA, **Novartis (NIBR)**

Panelist: John Doyle, Chief Operating Officer, **Achaogen**

2:45 Afternoon Break

Session: Recent Advances in Anti-Infectives - Part 1: Short Presentations

3:15 NZ2114, a Novel Plectasin Analogue, Aiming at Resistant Gram Positive Bacteria

Itzchak Angel, Ph.D., President and Chief Executive Officer, **Pharmaceutical Consulting and technologies / Novozymes**

NZ2114 is an improved 'engineered' variant of Plectasin, a fungal antimicrobial peptide developed by Novozymes. It is a next generation antibiotic drug, for treatment of gram positive infections with a novel mode of action: it inhibits cell wall biosynthesis through sequestering of Lipid-II.

The objective of the development project was to develop an API for an iv antibiotic which target severe gram positive hospital infections caused by especially resistant staphylococcus and streptococci strains such as pneumonia, bacterimia, and skin infections.

After a comprehensive screening of more than 500.000 Plectasin variants the 3 most promising candidates have been investigated further with regard to safety/tox profile (in vitro and in vivo), efficacy (in vitro and in vivo infection models), manufacturing potential (fermentation yields, up-scaling potential, stability, formulation potential, and purification potential with process and product related impurities).

The Plectasin variant NZ2114 has been selected for pre-clinical and clinical development. NZ2114 is especially effective against Staphyloccoci and Streptococci and has show equivalent or superior effect in in vivo infection models compared to current benchmark compounds (Vancomycin, Linezolid).

It is at present time ready for phase-I clinical trials.

Oral Presentations from Submitted Abstracts

3:35 To be considered for an oral presentation, please submit an abstract here by June 9, 2012. Selected presentations will be based on quality of abstract and availability. Presentation slots fill up fast so please submit your abstract ASAP.

Panel Discussion: Investment Opportunities with Venture Capitalists

3:55 *Moderator: Malcolm Kendall, President and CEO,* **Indel Therapeutics**

Panelist: Chau Q. Khuong, Private Equity Principal, **OrbiMed Advisors**

Panelist: Kush M. Parmar, M.D., Ph.D., Principal, **5AM Ventures**

Panelist: Patrick Heron, General Partner, **Frazier Healthcare**

Panelist: Dov Goldstein, Partner, **Aisling Capital**

- Current state of VC investment in antibiotics? Are there many new companies?
- Deal climate with large pharma?
- Exit environment and IPO window for antibiotic development companies?
- Building an investment syndicate – more or less parties at the table?
- Attractiveness of anti-infectives from a VC perspective:
- The relatively strong translation of preclinical data to clinical POC w/ anti-infectives
- Relatively short time-frames to demonstrate efficacy, although regulatory bar is different depending on indications.
- Pharma has substantially move out of ID, therefore making this the best time to invest for when appetite strengthens and pipelines are thin.
- Challenges from a VC perspective:
- Regulatory challenges remain significant, despite language towards a more personalized therapy approach.
- Technology—inability to know up front whether a patient requires a truly novel drug presents a challenge for drug development.
- Pricing—the culture of commodity pricing for antibiotics is entrenched, although we are seeing strong examples recently that is moving towards "value-based" pricing. This will be critical.
- Areas we are watching as VCs:
- MDR gram(-) infections
- HBV
- RSV
- Orphan diseases (e.g., BK virus)
- Companion diagnostics that offer truly rapid susceptibility testing without first requiring positive cultures

Activity: Speed Meeting

4:45 3 minute speed meetings. Delegates can RSVP once they register.

Seated Delegates that do not change seats: **delegates from Big Pharma, Government Officials, Venture Capitalists**

Delegates that change seats every 3 minutes: **all other delegates**

5:30 Networking Reception and Poster Session

Day 2 - Tuesday, July 10, 2012

Panel Discussion: Licensing vs. Co-development Partnerships

Panelist: Brad Prosek, Senior Director, Corporate Development, **Cubist Pharmaceuticals**

Panelist: Yuan-Hua Ding, Senior Director, External R&D Innovation, **Pfizer**

Panelist: Neil Abdollahian, MS, MBA, Vice President, Corporate Development, **Trius Therapeutics**

Panelist: Bhooshitha de Silva, Vice President, Business Development & Strategy, **Optimer Pharmaceuticals**

1) What's the conceptual difference in value & risk between a co-development and out-licensing deal
2) trade-offs between licensing and co-development and when to consider
3) Alliance management and governance challenges with co-development deals
4) Recent deals commentary
5) Search strategies
6) Valuation strategies
7) Developing market perspectives / opportunities

Old Drugs, New Drugs

8:45 Market Opportunities for Antibacterials Inside and Outside of the Hospital

Danielle Drayton, Ph.D., Chief Operating Officer, **Arlington Medical Resources**

The hospital antibacterial market represents a high-value, high-unmet-need segment of the overall antibacterial market. Characterized by an expanding population of at-risk patients and growing prevalence and diversity of antibiotic-resistant pathogens, the hospital is ripe with opportunity for novel therapies to treat not only MRSA but also Clostridium difficile infection (CDI) and gram-negative infections (GNIs). Additionally, the market for outpatient parenteral antibiotic therapy (OPAT) is also an area of increasing opportunity for antibacterial agents. As market competition increases, a granular understanding of the patients, indications, products, pathogens, and key prescribers will be paramount to the positioning and commercial success of current and emerging therapies.

Benefits of this Presentation:
- This presentation will explore the current market landscape for MRSA (including ABSSSIs), CDI, and GNIs in the context of the larger hospital antibiotics market
- Review promising near-term and long-term candidates in the pipeline and how key agents fit into the market.
- Review of key unmet needs and drug development opportunities in the hospital and for OPAT

9:20 IV/Oral Step-down Therapies for Serious Hospital Infections: Synthetically Novel Tetracyclines

Joyce Sutcliffe, Senior Vice President, Biology, **Tetraphase Pharmaceuticals**

The ability to deliver clinical candidates from any antibacterial program is challenging, especially in the face of multidrug-resistant pathogens where combination therapies are rapidly becoming the norm. Tetracycline represented an early, broad-spectrum antibiotic and a valuable addition to the medical armamentarium. New molecules with advantageous IV/oral pharmacokinetics that retain activity against all mechanisms of tetracycline resistance, and are potent against contemporary multi-drug-resistant pathogens can be designed using a platform that allows for totally novel modifications to the scaffold. While many companies seek a novel compound that has an unexploited mechanism of action, this presentation provides an alternative approach for novelty. For example, we contend that the design of a novel tetracycline with a desirable pharmacokinetic and safety profile is innovative, faster-to-development, and provides a less risky than the identification and development of novel matter that hits an unexploited target. An update on TP-434, presently in phase 2 trials for complicated intra-abdominal infections, and data on discovery compounds that protect in Pseudomonas aeruginosa lung and thigh models will be presented.

9:45 Development of An Entirely New Class of Antibiotic: PMX-30063 Small Molecule Mimetic of Host-defense Proteins

Nicholas Landekic, President and Chief Executive Officer, **PolyMedix**

10:10 Morning Break

Neglected Infectious Diseases

10:45 EthR Inhibitors that Boost Ethionamide Activity

Marcel Tigges, Ph.D., Chief Scientific Officer, **BioVersys AG**

Up to 9 million people contract tuberculosis every year and 50 million people are presently infected with Mycobacterium tuberculosis resistant to both first-line drugs isoniazid and rifampicin (WHO, Fact sheet No. 104, March 2007). Ethionamide (2-ethylthioiso¬nicotinamide, 2-ethylpyrimidine-4-carbothioamide), a structural analogue of isoniazid, is currently the last line of defense in the treatment of multi-drug-resistant tuberculosis (MDR-TB). During 35 years of its clinical use, ethionamide has fortunately elicited little cross-resistance with isoniazid as both prodrugs have to be activated by different mycobacterial enzymes to develop their antimicrobial activity. Yet, ethionamide continues to be prescribed at hepatotoxic doses as a consequence of EthR repressing ethA, the monooxigenase that catalyses activation of the prodrug ethionamide into an anti¬mycobacterial nicotinamide adenine dinucleotide derivative. Up to a 1 g/day are required for an acceptable concentration in blood (Holdiness, M. R., Clin Pharmacokinet 1984, 9, 511-44), which is associated with severe side-effects including neurotoxicity and fatal hepatotoxicity.

The research groups of Prof. Alain Baulard, Prof. Benoit Deprez, Prof. Nicolas Willand and Prof. Fussenegger have identified compounds that overcome EthR-mediated resistance to ethionamide. Based on experiments performed in various assay modules, the in vitro efficacy and specificity of LEAD compounds could be validated in vivo. Together with the BioVersys AG these compounds have been further developed towards preclinical studies and restoring ethionamide as important therapeutic option in treatment of M.tuberculosis infections.

Benefits of talk:
- Novel approach to overcome antibiotic resistance
- Restoring activity of existing drugs
- Close interaction of Start-Up with academic partners
- Drug-development in a small Start-Up company, hurdles and opportunities

FEATURED PRESENTATION

11:10 Building a Portfolio of Anti-infectives Against Neglected Diseases Through Industry-PDP Partnership

Shing Chang, Ph.D.
Director, Research and Development
Drugs for Neglected Diseases initiative [DNDi]

Product development partnerships (PDPs) are not-for-profit R&D organizations dedicated to address the health needs for developing countries. DNDi (Drugs for Neglected Diseases initiative) is one of the PDPs. Established in 2003 with the goal of delivering improved treatments for neglected patients suffering from diseases such as sleeping sickness, leishmaniasis, Chagas Disease, malaria, filariasis, and pediatric HIV infection.

To date, DNDi has delivered 6 new treatments, and has built a pipeline with many NCEs. The success is largely built on long-term partnerships with academia, the public sector, international agencies, and particularly, with pharmaceutical and biotech industry.

On 30 January 2012, leading pharmaceutical companies, the Bill & Melinda Gates Foundation, donor organizations, NTD-endemic country representatives and non-governmental organizations gathered in London to announce a series of coordinated commitments to help reach WHO goals to control or eliminate ten Neglected Tropical Diseases (NTDs) by 2020.

I will highlight the collaborative model of building the anti-infective portfolio to combat the neglected infectious diseases, which afflict 1.4 billion of the world's poorest, demonstrating power of PDP-Industry collaboration in address global health challenges.

Session: Recent Advances in Anti-Infectives - Part 2

11:35 *Malcolm Kendall, President and CEO,* **Indel Therapeutics**

12:00 The First Fluoroketolide, Solithromycin, in Development to Meet the Need for A New Macrolide

Prabhavathi Fernandes, Ph.D., Founder, President and Chief Executive Officer , **Cempra Pharmaceuticals**

The spectrum of activity, safety, anti-inflammatory properties, intracellular activity and tissue distribution have made macrolides the go-to antibiotic for treating respiratory tract infections. They are also widely used in many other infections, including bacterial urethritis. Widespread use of macrolides, primarily azithromycin, has led to greater than 30% resistance in the US and greater than 96% resistance in China for pneumococci, the primary pathogen in bacterial pneumonia. Solithromycin has multiple binding sites on the bacterial ribosome, overcoming pneumococcal resistance to older macrolides like azithromycin. It has been well tolerated in Phase 1 clinical trials and has completed a Phase 2 trial where it has demonstrated comparable efficacy to levofloxacin, even at the 72 hour early response end point, and has shown a favorable safety profile. It has been chemically, metabolically and mechanistically differentiated from telithromycin (Ketek). Phase 3 studies with oral tablets are planned. Macrolides are traditionally used orally because of tolerability issues. Solithromycin's intravenous formulation is also under development and has been well tolerated in a Phase 1 study. Phase 3 studies with intravenous to oral step-down therapy are planned and this dosing regimen is expected to provide a pharmacoeconomic advantage by providing broad coverage against respiratory bacterial pathogens and allowing the patient to be dosed intravenously and orally with the same product.

12:25 Lunch Provided by GTC

1:40 *Michael N. Dudley, Pharm.D., FCCP, FIDSA , Senior VP, Research & Development and Chief Scientific Officer,* **Rempex Pharmaceuticals**

2:05 Ceftobiprole – A Broad-spectrum Cephalosporin with Proven Clinical Efficacy in Pneumonia

Laurenz Kellenberger, CSO, **Basilea Pharmaceutica**

2:30 Heterodimer Antibiotics for Resistant Gram Positive Infections – Multi-Pharmacology Approaches to Treating Difficult Infections

Ed Moran, Vice President R&D Projects, **Theravance**

2:55 Closing Remarks

3:00 Conference Concludes

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