Final Agenda

2016

3RD ANNUAL

RE-ENTERING

ANTIBACTERIAL

DISCOVERY AND DEVELOPMENT SUMMIT

Filling the Antibacterial Pipeline to Combat the Multidrug Resistance Crisis

DECEMBER 7-9, 2016 | THE REVERE HOTEL | BOSTON, MA

TRACK 1:
Antibacterial Discovery
DECEMBER 7-8

TRACK 2:
Antibacterial Development and Market Access
DECEMBER 8-9

Recommended Short Courses

DECEMBER 7, 6:30 PM – 9:30 PM

From "White Powder" to Drug: The Path from Antibacterial Discovery to the Clinic

DECEMBER 8, 6:00 PM – 9:00 PM

Funding Opportunities for Antibacterial Research

Featured Speakers

Ruben Tommasi, Ph.D.
CSO, Entasis

Todd A. Black, Ph.D.
Executive Director, Infectious Diseases Merck Research Laboratory

Olga Lomovskaya, Ph.D.
Vice President, Biology, The Medicines Company

Nicole Mahoney
Director, Global Policy, Merck

Tyler Merkeley
(Acting) Chief of Staff, Head, Special Projects & Portfolio Management, Biomedical Advanced Research and Development Authority (BARDA)

Cristina Larkin
Chief Commercial Officer, Spero Therapeutics

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AntibacterialDrugDevelopmentSummit.com

Antibacterial Discovery

New discovery platforms, novel screens and approaches are vital for development of new antibacterials and for ceasing the dangerous trends of multidrug microbial resistance. Clostridium Difficile, Carbapenem-Resistant Enterobacteriaceae and Neisseria gonorrhoeae, the urgent threats according to CDC, each provides specific scientific challenges for researchers. The third annual Antibacterial Discovery conference will be focusing on platforms, targets and preclinical approaches for new antibacterial agent discovery and development.

WEDNESDAY, DECEMBER 7

7:15 am Registration Open and Morning Coffee

ADDRESSING MULTIDRUG RESISTANCE

7:50 Chairperson's Opening Remarks
Lynn Silver, Ph.D., Silver Consulting, LLC

8:00 Improving Our Understanding of Porin Permeability in Gram-Negative Bacteria
Ruben Tommasi, Ph.D., CSO, Entasis
Studies on the permeation of carbapenems, including analogs which explore polarity differences, as well as the placement of charge are explored. Results which we have obtained so far suggest that not only is proper polarity important, but also the proper placement of charge about the molecule. Ultimately, our goal is to establish structure permeation relationships that could be used to proactively design molecules with superior permeation into Gram-negative pathogens across multiple chemotypes.

8:30 Assessing Compound Permeability in Gram-Negative Bacteria to Enable Rational Drug Design
Thomas Krucker, Ph.D., Group Leader, New Technologies, Infectious Diseases Novartis Institutes for BioMedical Research
Accessing drug targets in the cytoplasm of Gram-negative pathogens is difficult because of the permeability barrier that limits the accumulation of promising antibiotics to effective levels within the cell. The ability to measure compound permeation and accumulation in Gram-negative bacteria is potentially an enabling component of structure-activity-relationships which guide rational drug design and optimization. Strategies addressing these challenges and the development of enabling technologies will be discussed.

9:00 Filling in the Gaps in the MDR Gram-Negative Pipeline
Todd A. Black, Ph.D., Executive Director, Infectious Diseases, Basic Research, Merck Research Laboratories
Antibiotic-resistant Gram-negative bacteria are increasing in prevalence. Some strains are now resistant to all classes of antibiotics, including polymyxins. The discovery of new classes of agents that are effective against Gram-negative pathogens have thus far proven to be an insurmountable challenge despite years of intensive efforts. The recent development of compounds that address specific subsets of resistance mechanisms have thus far been the only effective response. However, this approach provides only incremental improvements in strain coverage and presents challenges identifying the right patients and strategies to ensure appropriate use to reduce rapid development of resistance.

9:30 Novel Macrolides for Serious Infections
Larry Miller, CEO Macrolide Pharmaceuticals
Macrolide antibiotics are among the safest and most effective classes of antibacterials, but the use of the class has been limited by increasing resistance in Gram-positive bacteria and longstanding resistance in Gram-negative bacteria. A complete synthesis developed by Prof. Andrew Myers at Harvard University allows for the first time the synthesis of a wide range of macrolides and insight into structure/activity relationships. Macrolide Pharmaceuticals has synthesized more than 600 novel macrolides, with excellent Gram-positive activity and encouraging activity against multi-drug resistant Gram-negatives.

10:00 Antibiotic Collaborative Drug Discovery Secure Data Sharing
Sponsored by CDD VAULT
Barry Bunin, Ph.D., CEO, Collaborative Drug Discovery, Inc.
With the resurgence of interest in the Antibiotic Drug Discovery field, it is critical that we learn from the past. Not just at the conceptual level, but at the detailed data level too. Towards that end, CDD has curated antibiotic data from Challenges of Antibacterial Discovery (Silver, L. Clin Microbiol Rev. 2011), Physicochemical Properties of Antibacterial Compounds: Implications for Drug Discovery (O'Shea, R., Moser. H. E. J. Med. Chem. 2008), A Gestalt approach to Gram-negative entry (Silver, L. Bioorganic & Medicinal Chemistry, June 2016), and Public ChEMBL Antibacterial Permeability with both Ki/IC50 and MIC data (courtesy of Sherborne, B.). To attack resistance smarter, we need new technologies, new modes of collaboration, and new ways to leverage historical data. Conceptually, by collaborating together we mimic with ideas and data, the processes bacteria use to transfer genomic and mechanistic information. One advantage we have is that the internet allows partial and widespread transfer of information, simultaneously or with temporal control. Emerging models (TBDA, NIH Neuroscience Blueprint, MLPCN, and molecular probes) hold lessons for future industry and academic collaborations.

10:30 Coffee Break in the Exhibit Hall with Poster Viewing

11:00 Host-Directed Therapeutics to Regulate Bacterial Infection and Overcome Antimicrobial Resistance
Rekha G. Panchal, Ph.D., Branch Chief, Molecular and Translational Sciences Division, US Army Medical Research Institute of Infectious Diseases
Antimicrobial resistance is one of the greatest threats to human health worldwide. Despite the general recognition of the important role of the host's defenses, most studies of antibiotic resistance focus on the interaction between the pathogen and the antibiotics and neglect the contribution of the host response. The host response to the pathogen is critical in the control of the emergence of antimicrobial resistance and the effective clearance of the pathogen. This presentation will focus on development of host-directed therapeutics as an adjunct treatment option for select Gram negative bacteria.

11:30 Antibacterial Discovery and Development in Veterinary Medicine
Jeff Watts, Ph.D., Research Director, External Innovation, Zoetis, Inc
Veterinary medicine is confronted with distinct antimicrobial resistance issues that include both foodborne and target animal pathogens. The discovery and development of novel antibacterials for use in treating animal diseases has unique challenges distinct from those in human health. For example, veterinary medicine will need novel, non-shared antibacterials that are effective in treating disease while addressing the unique cost limits and human food safety necessary for approval of a new agent.

12:00 pm Luncheon Presentation *(Sponsorship Opportunity Available)* **or Enjoy Lunch on Your Own**

12:30 Session Break

MEDCHEM APPROACHES

1:10 Chairperson's Remarks
Olga Lomovskaya, Ph.D., Vice President, Biology, The Medicines Company

1:15 Inhibitors That Target Serine and Metallo-Beta-Lactamases: Challenges and Opportunities
Olga Lomovskaya, Ph.D., Vice President, Biology, The Medicines Company
Earlier work in cyclic boronic acid beta-lactamase inhibitors (BLIs) identified vaborbactam, a potent inhibitor of the KPC (serine, Class A) carbapenemase that is now in clinical trials in combination with meropenem. More recent efforts that combined molecular modelling with traditional medicinal chemistry led to the discovery of a new series of potent cyclic boronic acid BLIs capable of inhibiting both serine and metallo carbapenemases.

1:40 Novel Inhibitors of Dihydrofolate Reductase – The Quest for G- Activity
Aileen Rubio, Ph.D., Head of Biology, Spero Therapeutics
Spero Therapeutics is working on novel inhibitors of dihydrofolate reductase (DHFR), a well-validated antibacterial target. The first-in-class DHFR inhibitor, trimethoprim (TMP), has had a long history of safe and effective use for the treatment of urinary tract infections, but its use has been eroded by the emergence of resistance. Our approach utilizes novel chemical matter, propargyl-linked antifolates, in a structure enabled drug discovery project to identify compounds with expanded spectrum to include MDR G- and TMP resistant organisms

2:05 Chemical Property Space – Considerations for Antibacterial Drug Discovery
Folkert Reck, Ph.D., Senior Investigator, Global Discovery Chemistry, Novartis Institutes for BioMedical Research
A discussion of impact of chemical property space on the challenges for Antibacterial Drug Discovery, namely safety, permeability into Gram-negative bacteria, and the quality of hits from screening.

2:30 Redesign of Biotin Carboxylase Inhibitors to Enhance Gram-Negative Membrane Penetration
Frederick Cohen, Ph.D., Director of Chemistry, Medicinal Chemistry, Achaogen
We present a case study in prospectively designing small-molecule inhibitors for penetration to the cytoplasm of Gram-negative bacteria. Careful optimization of molecular properties has allowed >100 fold improvement in antibacterial potency, while maintaining target binding potency. We also

present data on the biology of AccC in Pseudomonas aeruginosa, including essentiality and mutation frequency.

2:55 Update on β-Lactam/β-Lactamase Inhibitors

Patricia A. Bradford, Ph.D., Antimicrobial Development Specialists, LLC

β-lactam/β-lactamase inhibitor combinations have been a mainstay of the antimicrobial armamentarium for many years. However, new β-lactamase in Gram-negative pathogens have diminished their usefulness. This presentation will discuss several new β-lactamase inhibitor combinations have been approved in recent years and others are in the development pipeline.

3:15 Bisphosphocins® – Antimicrobials for Broad Spectrum Indications Including Antibiotic-Resistant Bacterial, and Yeast, Fungal and Protozoan, Infections

Sponsored by

Steve Parkinson, President, CEO, Lakewood-Amedex Inc.

3:30 Sponsored Presentation *(Opportunity Available)*

3:45 Refreshment Break in the Exhibit Hall with Poster Viewing

METAGENOMICS AND GENOME MINING

4:10 Chairperson's Remarks

Joyce Sutcliff, Ph.D., Former Senior Vice President, Biology, Tetraphase Pharmaceuticals, Inc.

4:15 Antibiotics from Metagenomes

Sean F. Brady, Ph.D., Head, Laboratory of Genetically Encoded Small Molecules, The Rockefeller University

Uncultivated microorganisms are a very attractive source of potentially new natural products. Although there appears to be no easy way to culture this collection of unstudied microorganisms, it is possible to isolate large fragments of microbial DNA directly from environmental samples and clone this DNA into model bacterial systems in the lab. We are using both functional and sequence-based screening strategies to access new natural products from large environmental DNA libraries.

4:45 Genome Mining the Full Diversity of the Actinomycete Universe for Novel Antibiotic Discovery

Laurence E. Reid, Ph.D., CEO, Warp Drive Bio, LLC

Genome mining for novel natural products is an emerging approach to drive the discovery of new antibiotics. Actinomycetes have been the source of over two-thirds of clinically useful antibiotics of natural origin. However, the capability of actinomycetes to synthesize novel antibiotics has barely been tapped. Warp Drive Bio has sequenced over 135,000 actinomycete genomes to generate a proprietary database containing ~3.5 million biosynthetic gene clusters. Importantly ~75% of cluster families identified in our database have yet to be reported in the literature. Warp Drive is identifying biosynthetic clusters that produce new members of known antibiotic families (e.g. beta-lactams) as well as truly novel ("neomorph") antibiotics

5:15 PANEL DISCUSSION: Host vs. Microbe Approaches

- How can resistance erosion be part of the design of small molecules or host-pathogen approaches?
- Contrasts between pathogen-specific, host-microbe and small-molecule approaches
- How can guidance in the clinical microbiology lab be provided for host-specific or combinations of small-molecule and host-specific approaches?

Moderator: Joyce Sutcliff, Ph.D., Former Senior Vice President, Biology, Tetraphase Pharmaceuticals, Inc.

Panelists: Speakers of the Day

5:45 Welcome Reception in the Exhibit Hall with Poster Viewing

6:45 Dinner Short Course: SC1: From "White Powder" to Drug: The Path from Antibacterial Discovery to the Clinic*

*** Separate Registration Required***

THURSDAY, DECEMBER 8

7:15 am Interactive Breakout Discussion Groups with Continental Breakfast

This session features various discussion groups that are led by a moderator/s who ensures focused conversations around the key issues listed. Attendees choose to join a specific group and the small, informal setting facilitates sharing of ideas and active networking. Continental breakfast is available for all participants. Details on the topics and moderators are available on the conference website.

ANTIBACTERIAL BIOLOGICS

8:00 Chairperson's Remarks

Eszter Nagy, M.D., Ph.D., Co-Founder and CSO, Arsanis, Inc; Managing Director, Arsanis Biosciences GmbH

8:10 A New Paradigm in the Infectious Disease Field: Preemptive Therapy of Severe Infections with Highly Potent Monoclonal Antibodies

Eszter Nagy, M.D., Ph.D., Co-Founder and CSO, Arsanis, Inc; Managing Director, Arsanis Biosciences GmbH

Severe bacterial infections are associated with high healthcare costs and mortality even with appropriate antibiotic therapy; the emerging antibiotic resistance further exacerbates this problem. Antibodies, induced by active immunization are proven to be the effector molecules in preventing bacterial infections. Even more powerful "designer" antibodies can be generated recombinantly and used in a preemptive approach for patients with high risk to develop severe infections, such as pneumonia and bacteremia.

8:30 Antibody-Antibiotic Conjugate for Treatment of Bacterial Infections

Man Wah Tan, Ph.D., Director and Senior Scientist, Infectious Diseases, Genentech

To fight infections, Mother Nature has generously gifted us with a huge array of chemical matter, including antibodies and natural products. To further harness Nature's gift, Genentech has engineered Antibody-Antibiotic Conjugates (AAC) that exploit the key features of both antibody and antibiotic to treat bacterial infections. Features of an AAC for treatment of severe Staphylococcus aureus infections and the potential of AAC as a therapeutic platform will be discussed.

8:50 Target Discoveries for Immunotherapy against Antibiotics-Resistant Klebsiella Pneumoniae

Xiaodong Xiao, Ph.D., Senior Scientist, MedImmune

Immunotherapy represents a promising strategy against antibiotics-resistant Klebsiella pneumoniae. Critical to this strategy are the identifications of appropriate molecules that can serve as either vaccine antigen or antibody targets. Using a target-agnostic approach, we isolated a group of antibodies that displayed anti-Klebsiella pneumoniae activities. We went on to identify their common target as MrkA, a major type III fimbrial complex protein. The significance of the molecule and the method will be discussed.

9:10 Bezlotoxumab: A Biologics-Based Approach to Prevent Recurrent CDI

Alex Therien, Ph.D., Director, Biology-Discovery, Infectious Diseases, Merck

A novel approach to the prevention of recurrent CDI is the use of monoclonal antibodies(mAbs) directed against the toxins produced by C. difficile in patients receiving antibiotic therapy for CDI. Bezlotoxumab is a fully human mAb of that binds and neutralizes toxin B activity. Clinical trials have validated this approach as a means to reduce the recurrence of CDI.

9:35 Sponsored Presentation *(Opportunity Available)*

10:05 Coffee Break in the Exhibit Hall with Poster Viewing

10:30 Chairperson's Remarks

Menachem Shoham, Ph.D., Associate Professor, Biochemistry, Case Western Reserve University

10:35 Quorum-Sensing Inhibitors as Antibacterial Agents

Menachem Shoham, Ph.D., Associate Professor, Biochemistry, Case Western Reserve University

Quorum-sensing inhibitors curtail the ability of the pathogen to produce disease-causing toxins and virulence factors without killing the pathogen. No emergence of resistance has been reported so far. Interestingly, these agents also sensitize pathogens to antibiotics and inhibit biofilm formation.

11:05 Busting Silos: Host-Microbe Interactions in Infectious and Chronic Diseases

James R. Brown, MSc, Ph.D., Director, Computational Biology Infectious Disease and Oncology, GlaxoSmithKline

Traditionally, infectious and chronic diseases were separate silos in drug discovery. However, recent advances in genomics and bioinformatics are opening new dialogues between these fields. Understanding the microbiome in human health could provide new therapeutics for chronic diseases including respiratory and inflammatory diseases. Furthermore, new insights are emerging about the host-pathogen interactome. This presentation will discuss the opportunities and challenges for translation medicine using specific examples from our efforts.

11:35 Engineered Synthetic Peptides to Combat Infectious Diseases

César de la Fuente, Ph.D., Postdoctoral Associate, Synthetic Biology Group, Center for Microbiome Informatics and Therapeutics, Massachusetts Institute of Technology

Antibiotic-resistant infections are predicted to kill 10 million people worldwide per year by 2050, costing the global economy $100 trillion. Specific biologically inspired synthetic peptides are potent at preventing biofilm formation and eradicating pre-formed biofilms of the most dangerous and drug-resistant pathogens in our society. Moreover, lead peptides potentiate the activity of several classes of conventional antibiotics, and protect against otherwise lethal infections in several animal models.

11:50 Enjoy Lunch on Your Own

THURSDAY, DECEMBER 8

12:00 pm Registration

RAPID DIAGNOSTICS FOR ANTIMICROBIAL STEWARDSHIP AND ENABLING CLINICAL DEVELOPMENT

12:55 Chairperson's Opening Remarks

Barry Eisenstein, M.D., FACP, FIDSA, FAAM, Distinguished Physician, Antimicrobials, Merck & Co., Inc.

1:00 New and Emerging Diagnostics for Antibiotic Stewardship and Clinical Trials

Kimberly E. Hanson, M.D., MHS, Associate Professor of Medicine and Pathology, University of Utah

Accurate and timely diagnosis can improve patient care and antibiotic stewardship initiatives as well as potentially facilitate enrollment in clinical trials of new antimicrobials. This session provides an overview of new and emerging diagnostic technologies for infectious diseases, with a focus on bacterial detection and drug resistance testing. The ways in which current assays may be optimally utilized along with potential barriers to the implementation of advanced technologies will be discussed.

1:30 It Takes Two: The Role of Rapid Diagnostics in the Success of Antimicrobial Stewardship

Kevin Alby, Ph.D., D(ABMM), Assistant Director Clinical Microbiology Lab, Hospital of the University of Pennsylvania; Assistant Professor, Pathology and Laboratory Medicine, Perelman School of Medicine, University of Pennsylvania

The talk will focus on the currently available rapid diagnostics for bloodstream infection, and how partnering with antimicrobial stewardship teams leads to improved outcomes.

REGULATORY AND CLINICAL DEVELOPMENT CHALLENGES

2:00 Global Bacterial Surveillance via Whole Genome Sequencing to Assess Genetic Diversity with Respect to Antimicrobial Drug Development and Resistance

David Tabor, Ph. D., Senior Scientist, Applied Immunology and Immunology, MedImmune, LLC

The presentation will discuss two global bacterial surveillance studies that employed whole genome sequencing in an effort to understand the genetic diversity within specific bacterial species. This was performed in an effort to guide antimicrobial target selection and to assess the potential for drug resistance. The use of next-generation sequencing to replace traditional methods will be highlighted.

2:30 Sponsored Presentation *(Opportunity Available)*

3:00 Refreshment Break In the Exhibit Hall with Poster Viewing

3:30 Regulatory Update: An Overview of New Pathways and Updated Guidance

Nicole Mahoney, Director, Global Policy, Merck

Regulators have recently introduced several new pathways to encourage innovation and expedite the development of drugs for serious or life-threatening conditions. While the Breakthrough Designation in the U.S., the SAKIGAKE Designation System in Japan and the new PRIority MEdicines (PRIME) program in the EU are all designed to speed patient access to promising new therapies, sponsors must understand the unique requirements and features of each in order to optimize their global development strategy. This talk will explore available pathways and other recent regulatory developments with a specific focus on their relevance to the development of new anti-infective drugs

4:00 Challenges with Antibiotic Drug Clinical Development: A U.S. Biotech Company Perspective

Patrick Horn, M.D., Ph.D., CMO, Tetraphase Pharmaceuticals

This presentation will discuss the many considerations and complexities involved when following traditional indication-specific pathways for the development of novel antibiotics that can play an important role in treatment of multidrug-resistant pathogens, as well as the challenges that influence the conduct of global clinical trials due to the rise of antibiotic resistance.

4:30 Challenges in the Development of Biologics for Bacterial Diseases

David S. Mantus, Ph.D., Chief Development Officer, Arsanis, Inc.

Despite more than 120 years of clinical use, biologics other than traditional vaccines have seen limited recent development for the prevention and treatment of bacterial diseases. The clinical, regulatory, technical and policy challenges of biologics development in this therapeutic space will be discussed.

5:00 Development, Regulatory, and Market Access Environments for Anti-Infectives in Animal Health

Raksha Tiwari, Ph.D., Research Director, Anti-Infectives Research, Zoetis

This presentation will focus on the challenges during both clinical trials and commercialization of antibacterials in animal health.

6:00 Dinner Short Course:
SC2: Funding Opportunities for Antibacterial Research*

**Separate Registration Required*

FRIDAY, DECEMBER 9

7:30 Interactive Breakout Discussion Groups with Continental Breakfast

This session features various discussion groups that are led by a moderator/s who ensures focused conversations around the key issues listed. Attendees choose to join a specific group and the small, informal setting facilitates sharing of ideas and active networking. Continental breakfast is available for all participants. Details on the topics and moderators are available on the conference website.

INVESTMENT AND FUNDING CHALLENGES

8:15 Chairperson's Remarks

Barrett Thornhill, Executive Director, Antibacterial Innovation Alliance

8:20 Industry Perspective on Finding, Getting, and Managing Non-Dilutive Funding

Andrew McCandlish, Director, Corporate Development, Achaogen

Non-dilutive funding from government grants and contracts can be a powerful "push" mechanism to advance the discovery and development of novel antibacterials. From the company perspective, this funding offsets R&D costs and supplements funding raised from private and public investors. However, factors such as long application review timelines and rigid contracting regulations represent challenges to companies in the dynamic biopharma industry, and maintaining compliance with reporting and other deliverables requires significant resources. This talk will review such challenges from the industry perspective, and offer mitigation strategies that companies can incorporate into their non-dilutive funding plans.

9:10 Panel Discussion: Venture Capitalists: What Are Investors Looking for?

Panelists: Vikas Goyal, Associate, SR One

Joshua Resnick, M.D., Partner, SC Life Science Advisers

Join two venture capitalists who will reveal the methods and metrics they use when investing in antibacterial companies. Understand the questions they ask of potential investments, and ask them your most pressing questions in turn.

9:40 Sponsored Presentation *(Opportunity Available)*

10:10 Coffee Break in the Exhibit Hall with Poster Viewing

SECURING FUNDING VIA PARTNERSHIPS AND COLLABORATIONS

10:30 NIH and the CARB Challenge

Rosemarie Aurigemma, Ph.D., Chief, Drug Development Section, Office of Biodefense, Research Resources, and Translational Research, DMID, NIAID, NIH

NIAID-supported research on antimicrobial drug resistance has helped facilitate translation of basic research discoveries from "bench to bedside". Since the start of the National Strategy for Combating Antibiotic Resistant Bacteria, all facets of this support have been boosted in order to drive greater interest and encourage investment and innovation in antimicrobial development. With the goal of breaking new ground and boosting momentum in the field, NIAID hopes that the investment made will result in an upwelling of novel products into the pipeline and lead to new licensed products to stem the surge of resistant infections. This presentation will describe NIAID programs that support antimicrobial product development, the results of the first year of the CARB initiative and the opportunities that lay ahead.

11:00 CARB Accelerator – A Novel Partnership to Promote Innovation and Foster a Robust Antimicrobials Pipeline

Tyler Merkeley, (Acting) Chief of Staff, Head, Special Projects & Portfolio Management, Biomedical Advanced Research and Development Authority (BARDA)

How will BARDA, NIAID and industry accelerate a portfolio of innovative early antimicrobial products to counter the threat of antimicrobial resistance (AMR)? Via the Combating Antibiotic Resistant Bacteria (CARB) Biopharmaceutical Accelerator! A novel public private partnership approach launched in 2016 to identify, assemble, and accelerate a portfolio of innovative early antimicrobial products to counter the threat of AMR.

11:30 Driving Re-Investment in Antibiotics: Update from Europe's DRIVE-AB

Kevin Outterson, J.D., Visiting Fellow, Chatham House, Professor, Law, Health Law, Bioethics and Human Rights, Boston University School of Law

DRIVE-AB is a public-private partnership funded by EFPIA and the European Union. The goal is to make recommendations so that antibiotics become a more promising drug class for drug developers, without stimulating inappropriate use and resistance. We will discuss the preliminary results reported in Amsterdam in June, together with the latest updates.

12:00 pm Enjoy Lunch on Your Own

MARKET ACCESS: PRICING AND REIMBURSEMENT

1:30 Chairperson's Remarks

Andrew McCandlish, Director, Corporate Development, Achaogen

1:35 Antimicrobial Market Incentives: State of Play in Washington DC

Barrett Thornhill, Executive Director, Antibacterial Innovation Alliance

In order to direct commercial attention to the areas where the threat of antimicrobial resistance is the highest, federal interventions must be multifaceted, substantial and sustained. Improving antimicrobial stewardship, considering the impact of antibiotic use in agriculture, and working more closely with global stakeholders and other countries is helpful, but to significantly counter drug resistant infections, establishing a strong and continuous R&D enterprise is paramount.

2:05 Antibiotic Commercial Market Dynamics and Evolving Antibiotic Pricing Model

Cristina Larkin, Chief Commercial Officer, Spero Therapeutics

The commercial model for antibiotics is evolving. Stewardship and going resistance has forced industry to reconsider the old model and reshape the thinking in product position and pricing.

2:35 Launching Antibiotics in the Global Market: Perspectives from a Biotech Company

Carl Foster, Executive Vice President, Business Development, Cempra Pharmaceuticals

Small or midsized pharmaceutical companies, approximately 50% of which are pre-revenue, are developing more than 80% of antibiotics currently in the pipeline. These companies typically lack the infrastructure and resources required for independently launching antibiotics in international markets, making it critical to identify a strategic partner(s). Selecting one global partner is often the preferred pathway, however, regional partnerships could serve as an alternate avenue to commercialize antibiotics in international markets. This presentation will highlight the commercialization challenges associated with launching antibiotics.

3:05 FEATURED PRESENTATION: Triple Threat – Doing Our Part to Address Antimicrobial Resistance

Elizabeth D. Hermsen, Pharm.D., M.B.A., BCPS-ID, Head, Global Antimicrobial Stewardship, Merck & Co., Inc.

According to the World Health Organization, the health and economic consequences of antimicrobial resistance are considerable and costly, making it a serious threat to societal health. In January 2016, Merck joined over 80 pharmaceutical, diagnostic, and biotechnology companies, as well as key industry bodies, to issue a declaration at the World Economic Forum, which called on governments and industry to work together to take action against antimicrobial resistance. As a next step, Merck has developed a Global Action Plan outlining the company's efforts to address antimicrobial resistance in three key areas: driving innovation to develop new antibiotics; promoting antimicrobial stewardship to ensure the responsible and appropriate use of antibiotics; and increasing access to antimicrobial medicines.

3:35 Close of Conference

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TheScientist EXPLORING LIFE, INSPIRING INNOVATION

Dinner Short Courses

December 7, 6:30 – 9:30 pm

SC1: From "White Powder" to Drug: The Path from Antibacterial Discovery to the Clinic*

Chairperson and Moderator:
Lynn Silver, Ph.D., Silver Consulting, LLC

The course will cover:

- **Compound validation**
  Aileen Rubio, Ph.D., Head of Biology, Spero Therapeutics
- **Preclinical development**
  Joyce Sutcliff, Ph.D., Former Senior Vice President, Biology, Tetraphase Pharmaceuticals, Inc.
- **Clinical phases**
  Robin Isaacs, MD, Chief Medical Officer, Entasis Therapeutics
- **Regulatory concerns and pathways**
  Nicole Mahoney, Director, Global Policy, Merck
- **Partnership seeking**
  Vikas Goyal, Associate, SR One

December 8, 6:00 – 9:00 pm

SC2: Funding Opportunities for Antibacterial Research*

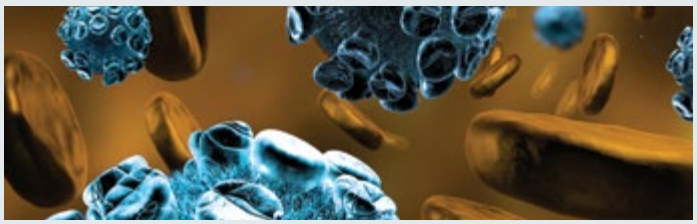
Instructors:
Rosemarie Aurigemma, Ph.D., Chief, Drug Development Section, DMID, NIAID
Christopher Houchens, Ph.D., Branch Chief (Acting), Antibacterials Program, Division of CBRN Countermeasures, Biomedical Advanced Research and Development Authority (BARDA)
Amanda Horstman Smith, Ph.D., Science and Technology Manager, Defense Threat Reduction Agency

The course will cover:

- From basic research to the clinic – How do we support the discovery & development of new agents?
- Grants, contracts and biodefense partnerships
- Preclinical, nonclinical, and clinical product development services

Co-Located Event | *December 7-9, 2016*

IMVACS
IMMUNIZATION & VACCINE SUMMIT



The Eleventh Annual Immunization and Vaccine Summit will cover a range of topics in this evolving field, including the latest advancements and applications of vaccine technologies, development of effective vaccine adjuvants, and progress in DNA- and RNA-based vaccines.

Learn more at ImVacS.com

HOTEL & TRAVEL INFORMATION

Conference Venue & Hotel:

The Revere Hotel
200 Stuart St.
Boston, MA 02116
Phone: 617-482-1800

Reservations: Go to the travel page of **AntibacterialDrugDevelopmentSummit.com**

Discounted Room Rate: **$229 s/d**
Discounted Room Cut-off Date: **November 9, 2016**

Go to the travel page of **AntibacterialDrugDevelopmentSummit.com** for additional info

SPONSORSHIP, EXHIBIT, AND LEAD GENERATION OPPORTUNITIES

CHI offers comprehensive sponsorship packages which include presentation opportunities, exhibit space, branding and networking with specific prospects. Sponsorship allows you to achieve your objectives before, during, and long after the event. Any sponsorship can be customized to meet your company's needs and budget. Signing on early will allow you to maximize exposure to qualified decision-makers.

PODIUM PRESENTATIONS
Available within the Main Agenda!

Showcase your solutions to a guaranteed, targeted audience. Package includes a 15- or 30-minute podium presentation within the scientific agenda, exhibit space, on-site branding, access to cooperative marketing efforts by CHI, and more.

BREAKFAST & LUNCHEON PODIUM PRESENTATIONS

Opportunity includes a 30-minute podium presentation. Boxed lunches are delivered into the main session room, which guarantees audience attendance and participation. A limited number of presentations are available for sponsorship and they will sell out quickly. Sign on early to secure your talk!

INVITATION-ONLY VIP DINNER/ HOSPITALITY SUITE

Sponsors will select their top prospects from the conference pre-registration list for an evening of networking at the hotel or at a choice local venue. CHI will extend invitations and deliver prospects, helping you to make the most out of this invaluable opportunity. Evening will be customized according to sponsor's objectives i.e.:

- Purely social
- Reception style
- Focus group
- Plated dinner with specific conversation focus

EXHIBIT

Exhibitors will enjoy facilitated networking opportunities with qualified delegates. Speak face-to-face with prospective clients and showcase your latest product, service, or solution.

ONE-ON-ONE MEETINGS

Select your top prospects from the pre-conference registration list. CHI will reach out to your prospects and arrange the meeting for you. A minimum number of meetings will be guaranteed, depending on your marketing objectives and needs. A very limited number of these packages will be sold.

ADDITIONAL BRANDING AND PROMOTIONAL OPPORTUNITIES
are available, including:

- Conference Tote Bags • Literature Distribution (Tote Bag Insert or Chair Drop)
- Badge Lanyards • Program Guide Advertisement
- Padfolios

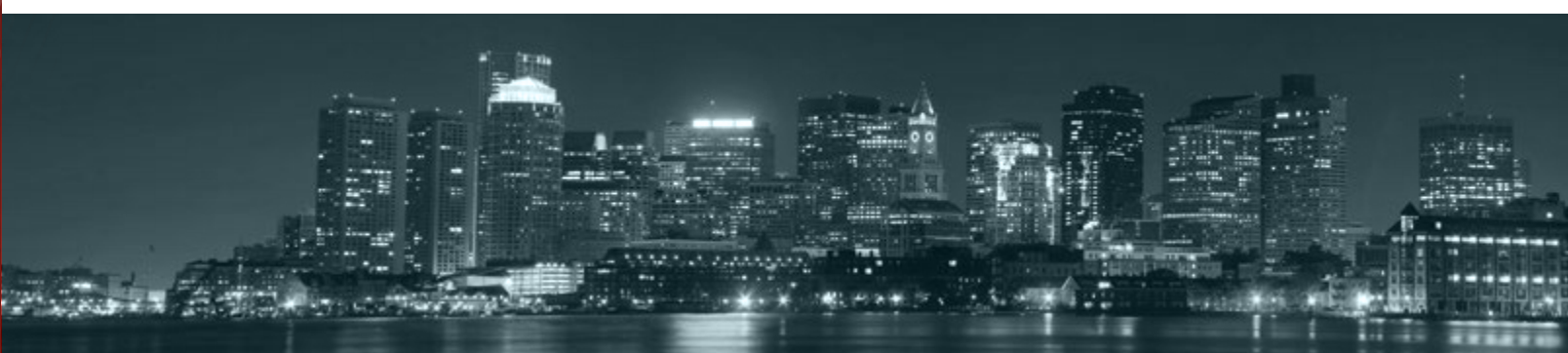
LOOKING FOR ADDITIONAL WAYS TO DRIVE LEADS TO YOUR SALES TEAM?

CHI's Lead Generation Programs will help you obtain more targeted, quality leads throughout the year. We will mine our database of 800,000+ life science professionals to your specific needs. We guarantee a minimum of 100 leads per program! Opportunities include:

- Whitepapers
- Custom Market Research Surveys
- Web Symposia
- Podcasts

FOR MORE INFORMATION ON SPONSORSHIP, PLEASE CONTACT:

Uma Patel | Business Development Manager | 781-972-1349 | upatel@healthtech.com



3RD ANNUAL

RE-ENTERING

ANTIBACTERIAL

DISCOVERY AND DEVELOPMENT SUMMIT

DECEMBER 7-9, 2016
THE REVERE HOTEL
BOSTON, MA

PRICING & REGISTRATION INFORMATION

SHORT COURSES

	Commercial	Academic, Government, Hospital-affiliated
One Short Course	$699	$399
Two Short Courses	$999	$699

December 7, 6:30 pm – 9:30 pm
SC1: From "White Powder" to Drug:
The Path from Antibacterial Discovery to the Clinic

December 8, 6:00 pm – 9:00 pm
SC2: Funding Opportunities for Antibacterial Research

CONFERENCE PRICING

STANDARD PRICING *(Includes access to two conference programs, excludes short courses)*

Early Registration by September 23, 2016	$2,449	$1,049
Advance Registration by November 4, 2016	$2,649	$1,149
Late Registration after November 4, 2016 and on-site	$2,849	$1,249

BASIC PRICING *(Includes access to one conference program, excludes short courses)*

Early Registration by September 23, 2016	$1,349	$579
Advance Registration by November 4, 2016	$1,549	$659
Late Registration after November 4, 2016 and on-site	$1,749	$729

CONFERENCE SELECTION (required)

Based upon your package selection choose the conference(s) you will most likely attend.
We do allow you to move between conferences occurring on the same dates

*If you selected...

Standard Package - Choose 1 each column (I + II)
Basic Package - Choose 1 from 1 column (I, or II)

I – Wednesday-Thursday	II – Thursday-Friday
Antibacterial Discovery	Antibacterial Development and Market Access

Poster Submission - Poster abstracts are due by November 4, 2016. Once your registration has been fully processed, we will send an email containing a unique link allowing you to submit your poster abstract. If you do not receive your link within 5 business days, please contact jring@healthtech.com. * CHI reserves the right to publish your poster title and abstract in various marketing materials and products.

Alumni Discount - SAVE 20%: CHI appreciates your past participation at Re-Entering Antibacterial Discovery and Development Summit . As a result of the great loyalty you have shown us, we are pleased to extend to you the exclusive opportunity to save an additional 20% off the registration rate.

REGISTER 3 - 4th IS FREE: Individuals must register for the same conference or conference combination and submit completed registration form together for discount to apply.

Group Discounts: Special rates are available for multiple attendees from the same organization.For more information on group discounts contact Jeff Knight, jknight@healthtech.com, 781-247-6264

**Alumni, Twitter, LinkedIN, Facebook or any other promotional discounts cannot be combined. Discounts not applicable on Event Short Courses.*

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 healthtech.com/regdetails

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

How to Register: **AntibacterialDrugDevelopmentSummit.com**
reg@healthtech.com • P: 781.972.5400 or Toll-free in the U.S. 888.999.6288

Please use keycode
BAC F
when registering!

Cambridge Healthtech Institute
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