
WORLD ANTI-MICROBIAL
RESISTANCE CONGRESS US | 2017

2017 EDITION – DRAFT CONFERENCE AGENDA
SEPTEMBER 14TH & 15TH, 2017 – JW MARRIOTT, WASHINGTON D.C.

Day One – September 14th, 2017

8:00	**Registration & Networking breakfast**
8:20	**Terrapinn Welcome Remarks**
8:25	**Chairperson's Opening Remarks** **Manos Perros,** President and Chief Executive Officer, **Entasis Therapeutics**
	FUTURE OF ANTIBIOTICS
8:30	**Keynote address: Reinvigorating Antibiotic and Diagnostic Innovation (READI) Act of 2017** • Tax credit for new antibiotics modeled after the Orphan Drug tax credit • Incentives for pharmaceutical companies to invest in the development of novel antibiotics and rapid diagnostic tests for infections • Bipartisan initiative to help drive research and development in antibiotics and reestablish the U.S. as a leader in this area **Congressman Erik Paulsen,** (MN-03), **United States House of Representatives**
8:50	**Keynote co-presentation: Current initiatives to drive legislative efforts and implementation of policies to spur antibiotic and diagnostics development and help curb antimicrobial resistance** • Fostering cutting edge scientific discoveries and identifying needs and opportunities for addressing AMR across the microbial sciences • Efforts to assess surveillance on how AMR is spread and the use of data to inform prevention activities • Initiatives and legislative efforts to support the funding and research of antimicrobial drugs • Strengthening diagnostics development and stewardship practices to fight resistance **William Powderly,** President, **Infectious Diseases Society of America (IDSA)** **Susan Sharp**, President, **American Society for Microbiology (ASM)**
9:20	**Keynote address: Convening interagency partners around CARB - progress towards the year 3 goals for implementation of the National Action Plan** • Overall progress on the National Action Plan • Programs and policies intended to improve stewardship in different healthcare settings, increase surveillance and unlock research • Progress of the deliverables to incentivize development of drugs and diagnostics • Looking to the future and how we continue to respond to the evolving issue of antimicrobial resistance **Christopher M. Jones,** Acting Associate Deputy Assistant Secretary (Science and Data Policy), Office of the Assistant Secretary for Planning and Evaluation, **U.S. Department of Health and Human Services**
9:40	**Keynote Panel: Igniting continuous support – how can industry keep the antibiotic pipeline afloat?** • Commitment from small, medium and big sized pharmaceutical companies to keep investing in the antibiotic field

	• From push to pull incentives- what can industry do to keep driving the conversation and tangible outcomes? • Striving in R&D, balancing risk- benefit assessments and overcoming regulatory setbacks. What is the key? **Moderator: Barry Eisenstein,** Chair of the Scientific and Business Advisory Board, **CARB-X** **Clive Meanwell**, Chief Executive Officer, **The Medicines Company** **Jeff Stein,** Chief Executive Officer, **Cidara** **Manos Perros,** President and Chief Executive Officer, **Entasis Therapeutics** **Christopher Houchens,** Branch Chief (Acting), Antibacterials Program, **BARDA** **Dolca Thomas**, Vice President Translational Medicine for Immunology, Inflammation and Infectious Disease, **Roche**		
10:20	**Networking coffee break**		
	Track I: Antibiotic R&D	**Track II: Diagnostics**	**Track III: INNOVATION SHOWCASE**
	DEVELOPING ANTIBIOTICS	**DEVELOPING DIAGNOSTICS**	**NON TRADITIONAL AND NEW**
	Chaired by Barry Eisenstein, Chair of the Scientific and Business Advisory Board, **CARB-X**	**Chaired by**	**Chaired by Joe Thomas, Associate,** Antibiotic Resistance Project, **The Pew Charitable Trusts**
11:20	**Development strategies in rare fungal infections: Experience from the Cresemba® Development program** • Overcoming challenges developing therapies for rare fungal infections • Demonstrating efficacy using uncontrolled clinical trial data • Fostering collaboration between investigators, clinical sites with adequate expertise, industry and regulatory agencies **Bernhardt Zeiher**, President, Global Development, **Astellas Pharma**	**Incentivizing diagnostic development and reimbursement to promote stewardship - Where is the answer?** • Current incentives for diagnostics development and the influence drug R&D can have in the diagnostics pipeline • What about reimbursement? Can we achieve a value based assessment for diagnostics? • Global public health efforts to promote diagnostics R&D **Gregory Daniel,** Deputy Director, **Duke Margolis Center for Health Policy**	**New pipeline analysis for the development of nontraditional therapies to treat bacterial infections** • Overview of nontraditional products including well known medical interventions (vaccines and immunotherapies) and entirely new types (virulence inhibitors and lysins) • Key findings from The Pew Charitable Trusts' assessment of nontraditional products in development to treat or prevent systemic bacterial infections Scientific and regulatory hurdles to bringing these products to patients **David Visi,** Senior Associate, Antibiotic Resistance Project, **The Pew Charitable Trusts**
11:40	**Are existing antibiotics really worthless? – demystifying antibiotic resistance breakers** • Identifying antibiotic resistance breakers of clinical relevance and exploring synergistic potential with existing antibiotics	**Payer perspective - Evidence requirements and the road to value based reimbursement of diagnostics** • Overview of employing the proper diagnostics to guide therapeutic stewardship in the	**Anti-infective monoclonal antibodies and the use of rare, protective antibody producing B-cells to fight antimicrobial resistance** • Leveraging mAbs strong safety profile in

	• Clinical experience with the first Antibiotic Adjuvant Entity • An orthogonal approach to keep the pipeline afloat: winning the war against time expansions to address unmet medical needs **Manu Chaudhary,** Joint Managing Director and Director of Research, **Venus Remedies**	management of infections • Assessment of medical efficacy, peer reviewed data and patient numbers for the disease state • Effectively building on the clinical policy the right pre-requisites to manage the stewardship • Working together with diagnostic developers, industry and regulators to support reimbursement decisions and the overall diagnostics R&D landscape **Catharine Moffitt,** Senior Medical Director, **Aetna**	humans, long plasma half-life and low risk of drug resistance • Designing phase II trials for infectious diseases that have a significant impact on life expectancy • Opportunities and challenges of using mAbs to treat infectious diseases and chronic conditions **Vu Truong,** Chief Executive Officer and Director, **Aridis Pharmaceuticals**
12:00	**Addressing AMR and fostering innovation through alternative approaches to identify novel agents in the gram-negative space** • Overcoming the challenges of finding new classes of broad spectrum gram negative antibiotics when no new molecules have been discovered in decades • From early stage discovery strategies to clinical and regulatory approaches for late stage development • Exploring non-traditional biologic therapies to treat bacterial infections – will this be the key to innovation? **Todd Black,** Executive Director, Infectious Diseases, **Merck Research Laboratory**	**The health economics and patient outcomes of antimicrobial rapid diagnostics** • Health economic and patient outcomes (HEOR) supported to rapid diagnostics • Measurement and evaluation of rapid diagnostics on HEOR endpoints • How to break out of silos - cost vs. gain **Ami Claxton,** Global Director, Health Economics and Outcomes Research, **bioMérieux**	**A cross-kingdom vaccine against fungal (Candida) & bacterial (Staph aureus) AMR pathogens** • First efficacy established for an anti-fungal vaccine: Ph IIa results with NDV-3A • US Army collaboration using NDV-3A to prevent Staph aureus skin & soft tissue infections • NIH clinical study: Hyper-IgE Syndrome patients with recurrent Candida & Staph infections **Tim Cooke,** Chief Executive Officer, **NovaDigm Therapeutics**
12:20	**ROUNDTABLES** **Roundtable 1**: **Partnerships –** collaborations with smaller companies and academics to identify new drug candidates that can move into the clinic **Michal Draper,** Senior Director, External Science & Partnering, East Coast, **Sanofi**		**Pre-clinical development of novel cationic peptides as anti-infectives for serious multidrug-resistant bacterial infections** • Synthetic, engineered peptide sequences overcome systemic efficacy and toxicity concerns

	Roundtable 2: Anti-fungal resistance —- state of the art of intrinsic and acquired antifungal resistance and how can we bring antifungal resistance to the forefront of the conversation? **Oren Cohen,** Chief Medical Officer, **Viamet Pharmaceuticals**	• Risk-assessment considerations for funding of promising early stage non-traditional approaches • Partnership opportunities for collaboration and co-development to expedite pre-clinical and clinical development **Jonathan Steckbeck,** Co-Founder and CEO, **Peptilogics**
	Roundtable 3: Continuous investment – how can companies strive in the antibiotic space and achieve non-diluted funding that supports clinical development **Andrew McCandlish**. Director, Corporate Development, **Achaogen**	
	Roundtable 4: Incentives – value based pricing, pull incentives and legislative efforts that can come close to guaranteeing ROI **Melissa Stundick,** Head of Strategic Alliances, **Spero Therapeutics**	12.40 **Forging new chemistry – metalloprotein technology to discover a new class of antibiotics that target gram negative pathogens** • Novel metal-binding chemistry & process to rationally design effective metalloenzyme inhibitors • Small molecules that inhibit LpxC with broad-spectrum effectiveness against drug resistant gram-negative bacteria • Advancing pre-clinical development and lead optimization through collaborations and non-dilutive funding **Zachary Zimmerman,** Chief Executive Officer, **Forge Therapeutics**
	Roundtable 5: Government partnerships – maximizing funding opportunities through BARDA partnerships to advance R&D, regulatory approval and commercialization **Christopher Houchens,** Branch Chief (Acting), Antibacterials Program, **BARDA**	
	Roundtable 6: Creating real change – fundamentally changing how we discover, develop, use, and protect antibiotics **Brad Spellberg,** Chief Medical Officer, **LAC+USC Medical Center**	
	Roundtable 7: HEOR – how to evaluate and measure health economic and patient outcome data generated by rapid diagnostics **Ami Claxton,** Global Director, Health Economics and Outcomes Research, **bioMérieux**	
	Roundtable 8: available for sponsorship	
1:00	**Networking lunch**	

1:30	**Keynote address: Strategies for preventing antibiotic-mediated secondary infections and antimicrobial resistance by protecting the gut microbiome** • Clostridium difficile continues to be an urgent threat and IV beta-lactams antibiotics are a significant risk factor for this opportunistic infection • SYN-004 (ribaxamase) degrades excess beta-lactam antibiotics in the upper GI thus protecting the gut microbiome from disruption and preventing C. difficile infection • SYN-004 (ribaxamase) significantly reduced C. difficile infections in patients being treated with ceftriaxone in a Phase 2b clinical study • SYN-004 (ribaxamase) protected the integrity of the gut microbiome and reduced the emergence of antimicrobial resistance **John Kokai-Kun,** Vice President, Non-Clinical Affairs, **Synthetic Biologics**		
1:50	**Networking lunch resumes**		
	CLINICAL DEVELOPMENT 2.0	**DIAGNOSTICS 360°**	**NON-TRADITIONAL AND NEW**
2:30	**A vision for the future of antimicrobial clinical trials - using outcomes to analyze patients rather than patients to analyze outcomes** • Changing the antibiotics clinical trial paradigm – Desirability of Outcome Ranking (DOOR) and the partial credit strategy • Using outcomes to analyze patients rather than patients to analyze outcomes particularly in late stage development • Pragmatic impact on benefit-risk decision-making **Scott Evans,** Director of the Statistical and Data Management Center (SDMC) for the Antibacterial Resistance Leadership Group (ARLG), **Harvard University**	**A prospective randomized controlled trial evaluating outcomes associated with rapid diagnostics for pathogen and resistance gene detection** • Impact of rapid diagnostics on antibiotic utilization and time to antibiotic escalation and de-escalation • Effect of rapid diagnostics on stewardship and overall hospital stay length, mortality and cost • Increasing implementation science around diagnostics in the hospital setting **Ritu Banerjee,** Associate Professor of Pediatrics and director of **Vanderbilt Antimicrobial Stewardship Program (VASP)**	**Lysins as narrow spectrum anti-infectives for the treatment of serious drug resistant bacterial infections** • Using bacteriophage enzymes to cleave the bacterial cell wall, clear biofilms and prevent resistance • How can lysins be used synergistically with standard of care antibiotics? • Current data and future development plans **Steven Gilman,** Chairman & CEO, **ContraFect Corporation**
2:50	**Clinical trial networks (CTN) in antimicrobial drug development- how can networks revolutionize approval and treatment of MDR infections** • Investigator-initiated randomized controlled trials for gram positive and gram negative pathogens • How does information sharing between the sites work?	**Coordinated development of antimicrobial drugs and antimicrobial susceptibility test devices – FDA Guidance** • Closing the gap between antibacterial drug approval and the availability of susceptibility tests through information sharing between drug and device manufacturers, CDER & CDHR • Working with physicians to provide education on the importance of susceptibility testing	**Microbiota-based drug candidates to suppress or reverse colonization with multi-drug resistant organisms (MDROs)** • Microbiota Restoration Therapy (MRT)-delivering a broad spectrum of live microbes to the intestinal tract, to rehabilitate the microbiome to treat bacterial infections and drug resistant

	• Evaluating multiple drug candidates simultaneously, pre-identifying sites and continuously enrolling patients in the network to create robust data repositories • Available network examples and the feasibility for the creation of CTN in the United States **David Paterson,** Professor of Infectious Diseases, **University of Queensland**	• Will providing susceptibility data in the gap period before AST approval • Improving communication between industry, device manufacturers and regulators **Ribhi Shawar,** Branch Chief, Division of Microbiology, CDRH OIVD, **FDA**	pathogens • Microbiome based therapies vs. fecal transplantation and the regulatory considerations to advance clinical programs • Planning for commercialization by carefully looking into IP of formulation, storage, delivery and disease targets **Lee Jones,** Founder, President & CEO, **Rebiotix**
3:10	**Panel: The big challenge – pathogen specific trial design to target multi-drug resistant bacteria (MDR)** • Screening hundreds of patients to enroll 1. How to overcome this while keeping trials ethical and producing robust statistical data? • Getting patients to MDR clinical trial centers when they have life threatening infections • Identifying the best comparator drug • Using Bayesian statistical analysis and exploring the creation of clinical trial networks **Moderator: Maria Ascano,** Director, Infectious, Niche, and Rare Diseases**, Decision Resources Group** **Michael Dudley**, Senior Vice President of Research and Development and Chief Scientific Officer, **The Medicines Company** **Gareth Morgan,** Senior Vice President, Head, Global Portfolio Management, **Shionogi** **Adrian Jubb,** Vice President and Head of Early Development, **Achaogen** **Glenn Dale**, Head of Early Development, Antimicrobials, **Polyphor**	**Panel: Susceptibility testing – we all know it's important, but how tangible is it?** • Regulatory barriers for the development and adoption of susceptibility tests in the hospital setting • Pairing up newly approved antibiotics with susceptibility tests to prevent off-label antibiotic use – how can this be optimized? • Integrating laboratories, healthcare practitioners, regulators, public health officials and manufacturers to optimize susceptibility tests development and implementation • Technologies in development - real-time microscopy, real time bacterial weighing, bacterial counting and bacterial gene acquisition detection **Moderator: available for sponsorship** **Jean Patel,** Deputy Director, Office of Antimicrobial Resistance, **CDC** **Romney Humphries,** Section Chief, Clinical Microbiology, **UCLA Health System** **Ribhi Shawar,** Branch Chief, Division of Microbiology, CDRH OIVD, **FDA** **Ian Critchley,** Vice President of Clinical Microbiology, **Allergan Pharmaceuticals**	**Fighting antibiotic resistance by protecting the gut microbiome from the unintended effects of commonly used intravenous antibiotics** • Evaluating how selective pressure from IV antibiotics may lead to the emergence of antibiotic resistance in the gut microbiome • Regulatory considerations to advance microbiome based products into commercialization • Results from several exploratory endpoints from a phase 2b study focused on ribaxamase's ability to prevent the emergence of antimicrobial resistance in the gut microbiome **Jeffrey Riley,** Chief Executive Officer, President and Director, **Synthetic Biologics** 3.30 **Innate defense regulators (IDRs) as an agnostic therapy to treat bacterial infections and fight resistance** • Using innate immunity to fight infections irrespective of the pathogen (gram positive, gram negative, antibiotic sensitive or resistant, intra or extracellular)

			• Approach complimentary to the standard of care that can lead to combination therapies or extended patent protections • IDRs as an alternative to antibiotics and that can help combat antimicrobial resistance **Oreola Donini,** Chief Scientific Officer, **Soligenix**
3:50	**Networking coffee break**		
	STEWARDSHIP		
	Chaired by Elizabeth Dodds, President-elect, **Society of Infectious Disease Pharmacists**		
4:30	**Keynote Address: Establishing a vision for antimicrobial stewardship in a pharmaceutical company** • What antimicrobial resistance should be about • Why antimicrobial stewardship should matter to the pharmaceutical industry • Initiatives to improve stewardship through education, implementation, research and advocacy **Elizabeth D. Hermsen**, Head, Global Antimicrobial Stewardship, **Merck**		
4:50	**Keynote Address: Improving antimicrobial stewardship for the long-term benefits – challenges of implementing a global antimicrobial stewardship approach** • Overcoming challenges of national and international coordination by improving collaboration, concrete plans, multidisciplinary approaches and effective spending • How to influence healthcare providers and incentivize stewardship practices coupled with effective diagnostics? • Establishing a global international protocol for when a new a new resistance gene is discovered • Initiatives to tackle the use of over the counter antibiotics in countries where prescriptions are not strongly regulated **Lauri Hicks,** Director, Office of Antibiotic Stewardship, Division of Healthcare Quality Promotion, **CDC**		
5:10	**Keynote Stewardship Panel – How to effectively set up coordinated antimicrobial stewardship programs in community and academic medical centers** • Stewardship's role in bridging the gap between diagnostic tests and effective clinician decision making • Incorporation of adequate expertise, allocation of resources, education and monitoring & reporting practices • Main barriers, similarities and differences for implementation in academic vs. medical centers • How can stewardship programs address decision making with results from susceptibility testing? **Moderator: Elizabeth Dodds,** President-elect, **Society of Infectious Disease Pharmacists** **Debra Goff,** Founding Member of the Antimicrobial Stewardship Program (ASP), **American Society of Health-System Pharmacists,** Clinical Associate		

	Professor, College of Pharmacy, **The Ohio State University** **Keith Hamilton,** Director, Antimicrobial stewardship Program, **Pennsylvania University Hospital** **Jason Newland,** Director, Antimicrobial Stewardship Program at St. Louis Children's Hospital, **Washington University in St. Louis** **Daniel Uslan,** Director, Antimicrobial Stewardship Program, Division of Infectious Diseases, **UCLA**
5:50	Closing remarks
5:55	**Drinks reception**
7:00	**End of conference day one**

Day Two – September 15th, 2017

8:00	**Registration & Networking breakfast**
8:50	**Terrapinn Welcome Remarks**
8:55	**Chairperson's Opening Remarks**
	INCENTIVES IN ACTION
8:40	**Keynote address: Accelerating a diverse global portfolio of 20 innovative antibacterial products towards clinical development leveraging a public private partnership model** • Government can lead innovation through novel public private partnerships • Results from the first year of CARB-X and a recap of the antibacterial candidates that are now "Powered by CARB-X" • CARB-X vision for Year #2 as we continue to build and expand this Global Innovation Fund to accelerate global antibacterial innovation to address the threat of antibiotic resistant infections **Tyler Merkley,** Project Officer, **DHHS,** Program Manager**, CARB-X**
9:00	**Keynote address: 4 years of the Innovative Medicines Initiative's New Drugs for Bad Bugs program – European public-private partnerships for the development of new strategies to combat antibiotic resistance** • ENABLE, COMBACTE, TRANSLOCATION and DRIVE-AB. What are the measurable outcomes and progress of these programs? • What will happen with the funding for these initiatives and how is implementation being addressed? • Effective partnering to accelerate translational research worldwide and what lies ahead **Pierre Meulien,** Executive Director**, Innovative Medicines Initiative (IMI)**
9:20	**We now need the 'Pull' – Industry's role in creating new commercial models for antibiotics** • The impact of push incentives on investing in new antibiotics • What can industry do to help move from push to pull incentives

	• What would the implementation of pull incentives look like in pharma **David Payne,** VP Antibacterial Discovery Performance Unit, **GSK**
9:40	**Keynote panel: Paving the way - overcoming challenges of the overall development pathway in companies of all sizes to reach drug approvals** • How to plan and sequence activities in a logical way and that is also an efficient use of capital? • Managing expectations from investors, interactions with regulators, R&D decisions and internal company ecosystems to achieve operational fluidity • Leveraging current incentives and planning for commercially viable antibiotics • How to implement lessons learned from successes and failures in the antimicrobial space? **Moderator: Janet Hammond,** Vice President of Infectious Diseases, **Abbvie** **Larry Edwards,** Chief Commercial Officer, **Tetraphase Pharmaceuticals** **Kevin Finney,** Chief Operating Officer, **Zavante Therapeutics** **Deborah O'Neil,** Chief Executive & Scientific Officer, **NovaBiotics** **David Veitch,** Chief Commercial Officer, **Basilea Pharmaceutica**
10:10	**Networking coffee break**

	Track I: Antibiotic R&D	**Track II: Diagnostics**	**Track III: INNOVATION SHOWCASE**
	ANTIBIOTIC DISCOVERY	**BIOFILM**	**NON TRADITIONAL AND NEW**
	Chaired by	**Chaired by Tharini Sathiamoorthy,** Associate Vice President, **AdvaMedDx**	**Chaired by**
11:10	**An inter-disciplinary Collaborative Hub for Early Antibiotic Discovery (CHEAD) to advance therapeutic products through shared chemistry services** • Supporting early stage development of molecules identified by academic investigators • Partnerships to optimize molecules from a hit to a lead • Providing capabilities in medicinal chemistry, protein biochemistry, protein structural biology biochemistry, biophysics, analytical screening, in vivo ADME and in vivo pharmacokinetics **Deborah Hung,** Director of the Infectious Disease Program, **Broad Institute**	**Looking for new perspectives to fight bacterial biofilm infections** • Bacterial biofilm as a major source of infections in medical, leading to frequent therapeutic failures • Biofilms could display unique and targetable properties, suggested by the profound phenotypic differences between planktonic and biofilm bacteria • Exploring functions or molecules produced within bacterial communities could lead to new strategies to diagnose or limit biofilm-associated infections **Prof. Jean-Marc Ghigo**, Genetics of Biofilms	**Engineered bacteriophage platform to deliver biofilm dispersing enzymes to treat bacterial infections in prosthetic joints** • Using customized phages coding for biofilm-degrading enzyme payloads • Collaborations with academic hospitals and industry stakeholders to advance clinical development and regulatory approval • Applicability of phage therapy in the hospital setting and animal health

		Laboratory, Department of Microbiology, **Institut Pasteur**	**Jeff Wager,** Chief Executive Officer, **Enbiotix**
11:30	**The AMR Centre – supporting the development of new antibiotics and diagnostics through fully integrated development capabilities** • Incentivizing collaboration and funding of subject matter experts through public-private partnerships – From the UK to global approaches • Fostering antibiotic research and translational R&D from pre-clinical hits through to clinical proof of concept • Preliminary results and progress on national and international partnerships to fight AMR **Peter Jackson**, Chairman, **AMR Centre**	**When the biofilm is visible – the wound infections** • Biofilms found in wounds are suspected to delay healing • Electron microscopy of biopsies from chronic wounds found that 60% of the specimens contained biofilm structures in comparison with only 6% of biopsies from acute wounds • "Biofilm-based wound care" aims to reduce the biofilm burden and prevent reconstitution of the biofilm **Dr. Enea. Di Domenico**, Clinical Pathology and Microbiology, **S. Gallicano Institute**	**Targeted monoclonal antibody immunotherapies to treat infectious diseases** • Designing a Phase II trial for Staphylococcus aureus pneumonia in high-risk ICU patients • What are the clinical and regulatory challenges to the development of mAbs to treat infections? • Real and potential advantages of mAbs vs. traditional anti-infectives **Chris Stevens,** Chief Medical Officer**, Arsanis**
11:40	**Disruptive Antibiotic Drug Discovery solutions** **Sponsored session**	**A major clinical case: the diabetic foot ulcer (DFU)** • Characteristics of the Diabetic Foot Ulcer (DFU) as a recurring complication of diabetes and the requirement of long-term treatment • Societal burden and the high cost that DFU represents in healthcare systems of high-income countries (4 billion € yearly) • Importance of bacterial interactions on the skin surface in the pathophysiology of DFU and time to healing • Challenges of effectively diagnosing presence and role of biofilm in these infections and choosing the right treatment **Yannick Pletan**, Expert in Life Sciences, **ULTRACE Development**	**Developing type III secretion inhibitors to potentiate host defenses against resistant P. aeruginosa in critically ill pneumonia patients.** • What is the role for virulence factor inhibitors in antibacterial therapy? • A highly selective phenoxyacetamide series of type III secretion inhibitors • The effect of dimeric inhibitors on a polymeric target • What are the risks for resistance development? **Donald Moir,** Chief Scientific Officer, **Microbiotix**
12:00	**ROUNDTABLES**		

	Roundtable 1: NIH partnerships – maximizing targeted funding opportunities and partnerships to advance *pre-clinical* development of antibiotics **Jane Knisely,** Program Officer, Bacteriology and Mycology Branch, **NIAID, NIH**
	Roundtable 2: VC investments – Non-conventional type approaches, de risking, licensing with academic instructions, managing intellectual property and potential acquisitions **Aleks Radovic-Moreno**, Senior Associate, **PureTech Health**
	Roundtable 3: Animal models – establishment and validation of animal models for the pre-clinical evaluation of novel antibacterials for drug resistant pathogens **Jennifer Hoover,** Chief Scientist, Antibacterial Discovery Performance Unit**, GSK**
	Roundtable 4: Susceptibility testing – speeding susceptibility testing availability to support the use of newly approved antibiotics **Nicole Mahoney,** Director of Government Affairs & Regulatory Policy, **Merck**
	Roundtable 5: Manufacturing – overcoming manufacturing outsourcing issues to prevent antibiotic shortages while maintaining quality and regulatory compliance **Evan Hecker,** Director of API Development, **Spero Therapeutics**
	Roundtable 6: Microbiome – leveraging defined regulatory pathways for advancing microbiome-based therapeutics through clinical development **Joseph Sliman,** Chief Medical Officer, **Synthetic Biologics**
12:40	**Keynote Investors panel: Investing in the infectious diseases space – targeting an increasingly incentivized sector** • Why this space is so attractive for investors once again? • Leveraging faster approval times, economic incentives, lower production costs, and emerging resistance • Risk assessment of potential market failure to drive successful investments • Investing in early vs. late stage antibiotic companies • What are common mistakes companies make when pitching for investment? **Heather Behanna**, Principal, Private Equity, **Sofinnova Ventures** **Joshua Resnick,** Partner, **SV Health Investors** **Josh Richardson,** Managing Director, **Longitude Capital** **Brian Dorsey**, Managing Partner, **MagnaSci Ventures** **Henry Skinner,** Managing Director, **Novartis Venture Fund**

1:20	**Networking lunch break**	
1:50	**Keynote address: Iclaprim – a well differentiated, targeted, potent and rapidly bactericidal antibiotic against multidrug resistant bacteria** • Exploring a novel mechanism of action different from any other antibiotic currently in development • Positive clinical outcomes among patients with ABSSSI and HAP/VAP through the concentration of Iclaprim at sites of infection. • Looking into safety data and what lies ahead to achieve FDA approval **David Huang,** Chief Medical Officer, **Motif Bio**	
2:10	**Networking lunch break continues**	
	Track I: Antibiotic R&D	**Track II: Diagnostics**
	PUBLIC HEALTH	**POINT OF CARE**
	Chaired by	**Chaired by Tharini Sathiamoorthy,** Associate Vice President, **AdvaMedDx**
3:00	**Spotlight on *Candida auris* – a transmissible fungus representing a new public health risk** • The emergence of multidrug-resistant (MDR) yeast that can cause invasive high-mortality infections • Controlling outbreaks of a pathogen difficult to identify with standard laboratory methods • How can industry, hospitals and public health officials prepare to fight this new and resistant fungus? **Brendan Jackson,** Epidemiology Team Lead, Mycotic Diseases Branch, **CDC**	**Combining C-reactive protein and a highly specific biomarker (MxA) to successfully detect viral vs. bacterial infections** • Supporting and guiding therapy decisions through a rapid and highly efficacious test • Leveraging point-of-care and outpatients settings • A rapid single use disposable diagnostics aimed to transform the way viral vs. bacterial infections are detected **Robert Sambursky,** President and Chief Technology & Medical Officer, **RPS Diagnostics**
3:20	**Development of ExPEC4V, a vaccine to prevent health care associated invasive disease caused by the most prevalent and drug-resistant extra-intestinal pathogenic *E. coli*** • Epidemiology and burden of extra-intestinal pathogenic E. coli (sepsis, morbidity, mortality, strains, resistance), • Progress to date with development of ExPECV4 • Conclusion on the potential role of vaccines in the fight against AMR **Valerie Oriol Mathieu,** Global Medical Affairs Lead, Vaccines**, Janssen Vaccines & Prevention**	**Bacterial vs. viral – the potential revolutionary point of care diagnostic to tackle the most common antibiotic miss-use** • Rapidly distinguishing viral vs. bacterial pneumonia to guide antimicrobial treatment decisions at the point of care • Re purposing a breath test for invasive aspergillosis for the detection of bacterial vs. viral pneumonia • Reaching the goal of providing better care for patients in a market where many promising diagnostics have failed • Barriers and opportunities to develop diagnostics when research begins in the hospital setting **Sophia Koo,** Assistant Professor of Medicine, **Harvard Medical School, Brigham and Women's Hospital**

3:40	Closing remarks
4:10	End of conference