Duke | MARGOLIS CENTER *for* Health Policy

Understanding the Development Challenges Associated with Emerging Non-Traditional Antibiotics

JW Marriott • Washington, DC
June 14, 2018

8:30 am **Registration opens**

9:00 am **Welcome and overview**

- Gregory Daniel, Duke-Margolis Center for Health Policy

9:05 am **Opening remarks**

- Ed Cox, U.S. Food & Drug Administration

9:15 am **Introduction to non-traditional antibiotics**

This presentation will provide an overview of non-traditional antibiotics, describing their importance, the variety of technologies, and why they are difficult to develop.

Speakers:

- Kevin Outterson, CARB-X, Boston University
- John Rex, F2G Ltd., Wellcome Trust, Advent Life Sciences

9:45 am **Session 1: Developing non-traditional antibiotics with the potential to be studied in clinical trials as monotherapies**

Objective: This session will cover non-traditional agents that have a direct, narrow spectrum impact on infecting bacteria, and that could be used as a monotherapy in clinical trials. Speakers will review the technologies being developed, then discuss some of the challenges of developing scientific evidence that supports efficacy against a limited set of bacteria.

Speakers (10 min per):

- Greg Merril, Adaptive Phage Therapeutics
- Paul Garofolo, Locus Biosciences, Inc.
- Alan Joslyn, Oragenics, Inc.

Panel Discussion (25 min)
Moderator: Gregory Daniel, Duke-Margolis
Panelists:

- Greg Merril, Adaptive Phage Therapeutics
- Paul Garofolo, Locus Biosciences, Inc.
- Alan Joslyn, Oragenics, Inc.
- Scott Stibitz, U.S. Food & Drug Administration

(Session 1 continued)

Audience Q&A (20 min)

Questions may include:
- What are the most challenging issues in development?
- How does development differ from traditional antibiotics?
- What are the challenges associated with developing a narrow spectrum agent?

11:00 am **Break**

11:15 am **Session 2: Generating agents that restore activity to – and are used in combination with – existing antimicrobials**

Objective: This session will examine non-traditional antibiotic agents that can restore the activity of existing antibiotics, and that are not administered as monotherapies. Speakers will review the technologies, followed by a panel that will discuss some of the scientific challenges that are encountered during development.

Speakers (10 min per):
- Troy Lister, Spero Therapeutics
- Greg Mario, TAXIS Pharmaceuticals

Panel Discussion (25 min)
Moderator: Gregory Daniel, Duke-Margolis
Panelists:
- Troy Lister, Spero Therapeutics
- Greg Mario, TAXIS Pharmaceuticals
- Ed Cox, U.S. Food & Drug Administration
- Vance Fowler, Duke University

Audience Q&A (20 min)

Questions may include:
- What are the key scientific challenges to developing this type of product?
- How does development differ from traditional antibiotics?
- What are the challenges of demonstrating an impact on resistance?

12:30 pm **Lunch**

1:30 pm **Session 3: Developing agents that are studied in combination with existing antimicrobials to enhance elimination of bacteria**

Objective: This session will cover agents that improve the function of existing antibiotics in an incremental manner. Speakers will give an overview of the technologies, along with associated scientific development challenges that will be followed by a moderated discussion.

Speakers (10 min per):

- Cara Cassino, Contrafect Corp.
- Wayne Dankner, AtoxBio
- Vu Truong, Aridis Pharmaceuticals, Inc.

Panel Discussion (25 min)
Moderator: Gregory Daniel, Duke-Margolis
Panelists:

- Cara Cassino, Contrafect Corp.
- Wayne Dankner, AtoxBio
- Vu Truong, Aridis Pharmaceuticals, Inc.
- Sumathi Nambiar, U.S. Food & Drug Administration
- Dennis Dixon, National Institute of Allergy & Infectious Disease

Audience Q&A (20 min)

Questions may include:

- What are the challenges with developing a product that does not kill bacteria?
- What are measures that can be used to distinguish impact of new agent from SOC?
- What are the differences between single antibodies and antibody cocktails?

2:45 pm **Break**

3:00 pm **Session 4: Preventing infections using non-traditional antibiotic agents**

Objective: This session will cover non-vaccine agents that can be used to prevent bacterial infections. Speakers will give an overview of the technologies, along with associated scientific development challenges that will be followed by a moderated discussion.

Speakers (10 min per):

- Dave Mantus, Arsanis, Inc.
- Lee Jones, Rebiotix, Inc.
- Michael Bevilacqua, Amicrobe, Inc.

(Session 4 continued)

Panel Discussion (25 min)
Moderator: Gregory Daniel, Duke-Margolis
Panelists:

- Dave Mantus, Arsanis, Inc.
- Lee Jones, Rebiotix, Inc.
- Michael Bevilacqua, Amicrobe, Inc.
- Deverick Anderson, Duke University
- Joe Larsen, Biomedical Advanced Research and Development Authority

Audience Q&A (20 min)

Questions may include:

- What are the challenges in demonstrating successful prevention?
- What are potential endpoints and timeframe for measuring prevention?
- What tools are needed for these products to be successful?

4:15 pm **Session 5: Wrap-up panel to discuss remaining needs and next steps**

Objective: This session will react to the day's discussions, discuss the most pressing issues facing non-traditional antibiotic approaches, and outline desired next steps to address these issues.

Panel Discussion (45 min)
Moderator: Gregory Daniel, Duke-Margolis
Panelists:

- Jonathan Darrow, Harvard University
- Scott Evans, George Washington University
- Marc Gitzinger, BEAM Alliance
- John Rex, F2G Ltd., Wellcome Trust, Advent Life Sciences

Audience Q&A (20 min)

5:00 pm **Closing remarks and adjournment**

Funding for this workshop was made possible in part by a cooperative agreement from the U.S. Food and Drug Administration Center for Drug Evaluation and Research. The views expressed in written workshop materials or publications and by speakers and moderators do not necessarily reflect the official policies of the Department of Health and Human Services nor does mention of trade names, commercial practices, or organizations imply endorsements by the U.S. Government.