Overcoming the Challenges of Developing New Antibiotics for Resistant Bacteria

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Disclosures and Agenda

Disclosure

• I am a compensated employee of Merck and Co., Inc.
• The content of this presentation does not necessarily represent the opinions of Merck and Co., Inc.

Agenda

• The unique public health threat posed by growing bacterial resistance to antibiotics
• The present challenges of the R&D investment model for antibacterials
• The associated public policy imperatives
• The role of rapid diagnostics in both antibiotic development and optimized use ("stewardship")
RECENT Cubist (now Merck) Experience In ANTIBIOTIC DEVELOPMENT

- Completed four phase 3 studies in three different indications leading to two FDA approvals in 2014 (Sivextro and Zerbaxa), one EMA approval in 2015 and one EMA application pending

- Three additional phase 3 studies (each with a separate drug) ongoing for two indications

- Joined industry rapid diagnostics collaboration project convened by Cepheid (with GSK and Shionogi) for the adaptation of the X-pert CARBA-R test to aid in the detection of carbapenem-non-susceptible bacteria in urine and deep respiratory infections

- Contributing to the FNIH, CTTI, IMI, and Brookings efforts to improve antibiotic development
Why New Antibacterials?

“We can close the book on infectious disease”
-United States Surgeon General

1969

2010

“There are strains out there and they are becoming more and more common, that are resistant to virtually every antibiotic we have”
-Dr. Lou Rice as quoted in February 2010 NY Times article by Andrew Pollack
Infections are #3 cause of death in the US

Infections are #2 cause of death in the world
- 14.9 million in 2004 (29% of all deaths)

Hospital acquired infections: 2 million per year in US
- At least 23,000 deaths due to drug resistant bacteria

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