Collaborative Models for Antibacterial R&D

3 June, 2015
James Anderson, Head of Corporate Government Affairs, GSK
• Antibiotic discovery has a higher attrition than other areas
  – Vast majority of historic antibacterial R&D effort focused on ‘small molecule kill the bug’
  • Same science base since Fleming

Discovery programs on novel classes can be very long and resource intensive: eg....

**Novel Bacterial type II Topoisomerase Inhibitors (NBTI) class of AB, different mechanism to quinolones**

*GSK203815

*GSK966587

*GSK945237

*GSK2140944

Started 1998. Initial focus to overcome CV liabilities

Focus on addressing risk

Focus on addressing risk

Focus on addressing risk

Focus on addressing risk

Passed 3 month tox

*MICs, efficacy & initial tox all excellent

Program focused on Gram –ve and Gram +ve, but only Gram +ve delivered

GSK Antibiotic PPP Experience in US

- DTRA’s primary focus is to protect the warfighter
- Since 2007 GSK/DTRA sharing the cost of pursuing the dual use potential of a new class of antibacterials that inhibit gyrase via a novel mechanism
- GSK944 (Phase 1) being pursued for conventional and biothreat indications

- GSK and BARDA to address need for new antibacterials
- May 2013 created a 5 year $200M partnership for AB development
- Funding is milestone driven and enables funding to be moved across a portfolio of compounds, including compounds added via alliances
- Governance is through a BARDA: GSK Joint Oversight Committee

- Anthrax is one of the most likely agents to be used in a bioterrorist attack
- Sept 2013, GSK will provide 60,000 doses of the inhalation anthrax treatment Raxibacumab to the US government over four years, at a value of approximately $196m. This forms part of a broader five year base contract.
- First monoclonal antibody to gain the FDA’s nod under the animal rule
ND4BB vision: Delivering a pipeline of new antibiotics to patients via PPPs

Filling the pipeline

Discovery

Early Discovery

Discovery & Preclinical

Phase I

Phase II

Phase III

Regulatory Review

Phase IV

Patients

TRANSLOCATION (Jan 2013)

ENABLE (Feb 2014)

COMBACTE (Jan 2013)

DRIVE-AB (Oct 2014)

COMBACTE-CARE (Mar 2015)

COMBACTE-MAGNET (2015)

Topic 7 (2015)

Basic science & Drug Discovery

Clinical development

Economic models
ENABLE – who is involved

European Gram Negative Antibacterial Engine (ENABLE)

- Consortium with 32 partners:
  - Uppsala University managing entity
  - 11 academic/institute/hospital organizations
  - 5 non-profits
  - 12 SMEs
  - 4 EFPIA partners

- Launched Feb 2014, 6 year run time
  - Projected budget: €100M

Goals

- Create a collaborative drug discovery platform
- Kick start pipeline for systemic treatment of infections due to resistant Gram-negative
  - identifying three Leads
  - identifying two development Candidates
  - progressing at least one compound into Phase 1
Looking into the Future

• Role for “Open labs” in antibiotic R&D?

• O’Neill Commission recommendations (Innovation Fund; attract and retain skills base)

• Possibilities for PPPs (for Discussion)
  – Purchasing and controlling distribution/use of certain antibiotics?
  – Encouraging investment in diagnostic tests?
  – Driving use of diagnostics globally?
Thankyou