TPOXX® – A Smallpox Antiviral

Challenges and achievements of a successful public-private partnership

Dennis E. Hruby, SIGA CSO
TPOXX Development Challenges

- Developing a drug for a disease that doesn’t exist
- No animal model -----> appropriate animal models
- No GLP animal models up and running
- Surrogate virus in a surrogate animal
- FDA uncertainty on approval pathway
TPOXX Development History

ST-246 → Tecovirimat → TPOXX

ST-246
Discovery

2003

NIH SBIR1

NIH SBIR2

NIH SBIR2c

DMID/NIH dev

NIH/BARDA dev

BARDA Advanced Development & Acquisition

DTRA/USAMRIID

NDA Submitted

NDA Approved
July 13

2018

CDC/FDA
BARDA as a Partner

• Steady committed partner throughout
• Facilitated relationships with other agencies (CDC, FDA, DoD)
• Responsive to unexpected needs
• Responsive to FDA
• Developed essential animal models
• Provided Expertise (SME’s)
Conclusions and Summary

• Establishment of successful private-public working team
  - BARDA, NIH, DOD, CDC, SNS, FDA, WHO
  - Academic Colleagues
  - CROs, CMOs
• Completed delivery of product to the SNS
• NDA filed December 8, 2017
• Approval received July 13, 2018
• New contract awarded September 11, 2018

*It took 15 years and a lot of hard work and innovation to become an “overnight success”*