

TPOXX[®] – A Smallpox Antiviral

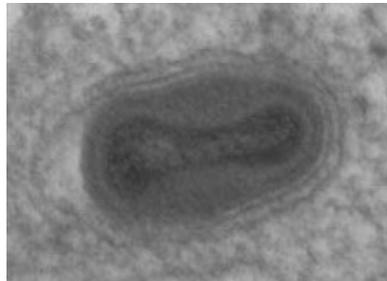
Challenges and achievements of a successful public-private partnership

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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

DTRA/USAMRIID



NIH SBIR1



NIH SBIR2



NIH SBIR2c



DMID/NIH dev



NIH/BARDA dev



BARDA Advanced
Development
& Acquisition



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”