



**ASPR**

# The Plazomicin Project:

## A Partnership Results in BARDA's 36<sup>th</sup> FDA Approval

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# An Eight-Year Partnership

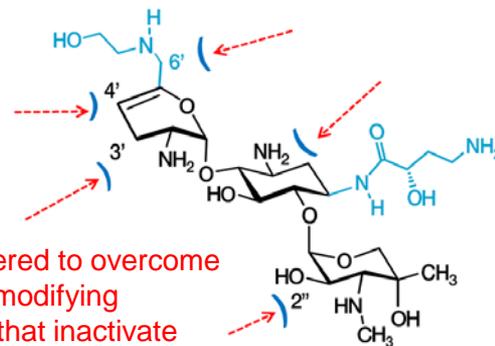


## ACHAOGEN

- Contract award: August 30, 2010
- First contract for the BARDA antibacterials portfolio
- Total BARDA cost-share: \$124.4 M
- Total Achaogen cost-share: \$48.9 M

**Candidate:** Plazomicin is a novel antibiotic designed to overcome multidrug resistance

- Aminoglycoside class (bactericidal)
- Activity against key biothreat agents
- Overcomes critical resistance mechanisms



Uniquely engineered to overcome aminoglycoside-modifying enzymes (AME) that inactivate existing aminoglycosides

# Adapting to Evolving Needs



## CARE study:

- Unmet need (“urgent” pathogen)
- Challenging study population
- Indications: pneumonia, bloodstream infections



## Introduce EPIC study:

- Established pathway to NDA
- Robust anticipated enrollment
- Indication: complicated UTIs



**Challenge:**  
slow enrollment  
in CARE study

**Solution:** BARDA and Achaogen agree to cost-share Phase 3 EPIC Study to expedite pathway to approval

# Helping Partners Meet Their Targets

- Partnership includes BARDA review of regulatory submissions prior to FDA submission

**Challenge:** ambitious target date for NDA submission

**Solution:** Develop review schedule based on both partners needs

- Rolling review, targeted reviewers
- Proactive forecasting of upcoming reviews and review periods
- Schedule adjustments based on anticipated reviewer bandwidth

NDA Document Review Forecasting			
NAME	REVIEW REQUEST	bd	REVIEW DEADLINE
plazo vs amikacin in treating mouse thigh & lung infections	8/24/2017	8	9/7/2017
Module 3 (all 3.2P sections)**	8/25/2017	16	9/15/2017
INFORM*: INCREMENT Report on colistin outcomes	8/28/2017	1	8/29/2017
INFORM*: 2.7.4 appendix Audiology Report	8/28/2017	1	8/29/2017
TDMAIgo: Team and Cross-functional Review	8/29/2017	5	9/5/2017
Module 3 (all 3.2S sections except 3.2.s26)**	8/30/2017	13	9/15/2017
Plazomicin dose selection report for patients with serious CRE Am2	9/7/2017	6	9/15/2017
2.7.2: Cross-Functional Review	9/14/2017	5	9/20/2017
2.4: Cross-Functional Review	9/14/2017	5	9/20/2017
2.6.1: Cross-functional Review	9/15/2017	5	9/21/2017
Module 3 (3.2s26)**	9/15/2017	13	10/3/2017
1.14.1: BARDA Review of full USPI	9/25/2017	5	9/29/2017
2.5: Cross-Functional Review	10/3/2017	3	10/5/2017

# ZEMDRI is FDA Approved



- FDA approved ZEMDRI (plazomicin) for the treatment of complicated UTIs on June 25\*.
- BARDA's 36<sup>th</sup> FDA Approval (2<sup>nd</sup> for Antibacterials Program)

*"Today's milestone was made possible by... BARDA, who contributed significant funding for the development of ZEMDRI. This marks an important step in our commitment to fighting MDR bacteria and we are excited to launch ZEMDRI, a much needed once-daily antibiotic."*

– Blake Wise, CEO, Achaogen

\*see label for full prescribing information