



**ANTIMICROBIAL DRUGS ADVISORY COMMITTEE MEETING BRIEFING BOOK
ERRATUM**

Study Drug: Plazomicin

NDA Number: 210303

Sponsor: Achaogen, Inc.
1 Tower Place, Suite 300
South San Francisco, CA 94080

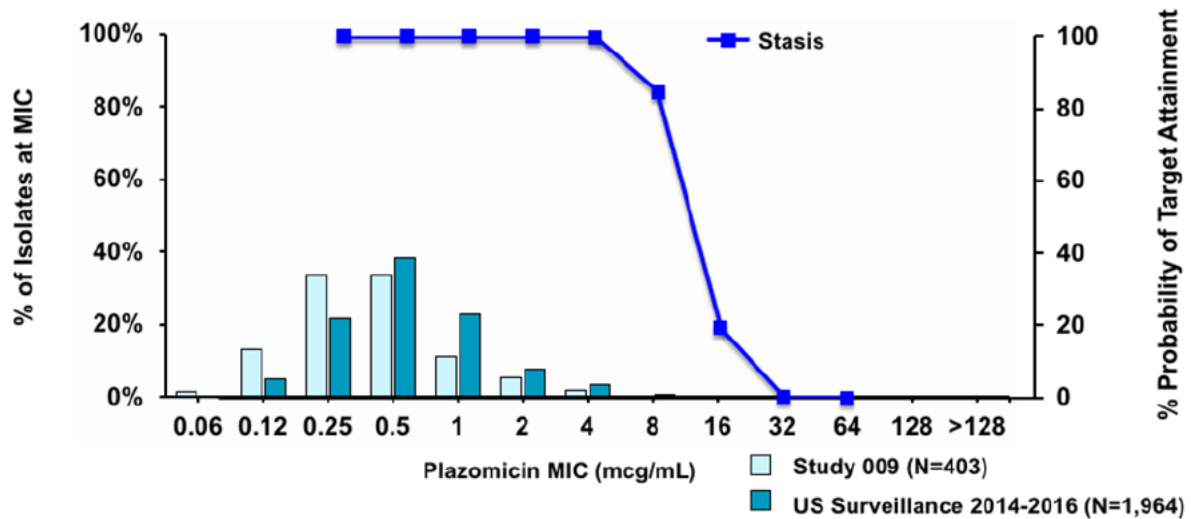
Meeting Date: 2 May 2018

**ADVISORY COMMITTEE BRIEFING MATERIALS:
AVAILABLE FOR PUBLIC RELEASE**

Overview of Erratum

It was discovered that Figure 9 of the Sponsor AMDAC Briefing Book for the plazomicin NDA was not rendered properly when converted to PDF format during publishing. Page 59 with Figure 9 has been rerendered to PDF and should be considered as a replacement to Page 59 in the Briefing Book finalized 30 March 2018.

Figure 8: Probability of Plazomicin Stasis Target Attainment Overlaid on the MIC Distributions of cUTI/AP Baseline Enterobacteriaceae From Study 009 and UTI Enterobacteriaceae from 2014-2016 US Surveillance



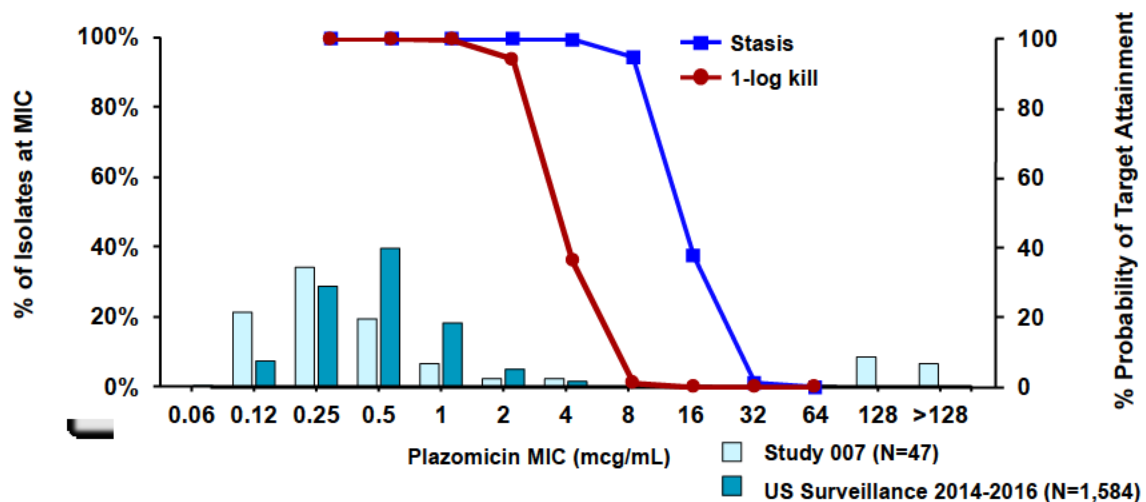
Abbreviations: AP=acute pyelonephritis; BSI=bloodstream infection; cUTI=complicated urinary tract infection; UTI=urinary tract infection; MIC=minimum inhibitory concentration.

Notes: Dark bars—All UTI Enterobacteriaceae isolates from 2014-2016 US Surveillance (N=1964).

Light bars—Baseline Enterobacteriaceae isolates from Study ACHN-490-009 (N=403).

Line with squares—Probability of stasis target attainment.

Figure 9: Probability of Plazomicin 1-log₁₀ Kill Target Attainment Overlaid on the MIC Distributions of BSI Baseline Enterobacteriaceae From Study 007 and BSI Enterobacteriaceae from 2014-2016 US Surveillance



Abbreviations: BSI=bloodstream infection; MIC=minimum inhibitory concentration.

Notes: Dark bars—All BSI Enterobacteriaceae isolates from 2014-2016 US Surveillance (N=1584).

Light bars—Baseline Enterobacteriaceae isolates from Study ACHN-490-007 (N=47).

Line with squares—Probability of stasis target attainment.

Line with circles—Probability of 1-log₁₀ kill target attainment.