Meropenem-Vaborbactam (VABOMERE) vs. Best Available Therapy for CRE Infections: TANGO II Randomized, Controlled Phase 3 Study Results

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Background
Meropenem-vaborbactam (M-V) is a new beta-lactam/beta-lactamase inhibitor combination that restores the potency of meropenem in Meropenem-nonproducer carbapenemase (NPC) producing carbapenem-resistant Enterobacteriaceae (CRE). TANGO II is a randomized, double-blind, placebo-controlled study in patients with complicated urinary tract infection (cUTI), acute pyelonephritis (AP), or obstetric infection (endocranial-abdominal isolates) harboring or suspected to harbor a carbapenemase (KPC) -producing carbapenem-resistant Klebsiella pneumoniae, or a carbapenemase (KPC) -producing coliform. M-V demonstrated non-inferiority to Best Available Therapy (BAT) at post-therapy end of treatment (EOT) and trough-once weekly (tow) for key endpoints, including microbiologic cure and clinical cure. A new exploratory analysis of risk-benefit profile was performed to provide a better assessment of the clinical benefits of M-V compared to BAT across infection types.

Methods
• Phase III, multicenter, international, open-label study of adults with infections caused by or suspected to be caused by MER-VAB (i.e., M-V) or BAT (i.e., Meropenem MIC50 in KPC-producing carbapenemase KPC-80%)
• Mean treatment duration was similar for M-V (8.5 days) and BAT (7.4 days).

Results
Of the 72 enrolled patients, 55 (76%) had a gram-negative bacillus baseline (m-MITT) and 43 (59.7%) had a baseline CRE (m-CRE-MITT). Baseline characteristics for the m-CRE-MITT population are shown in Table 1. Meropenem MIC50 in KPC-producing carbapenemase (80%).

Conclusion
M-V was associated with a higher rate of clinical cure at EOT compared to BAT across all CRE-related population. M-V is a promising new option for the treatment of CRE infections.

References