**ABSTRACT**

Patients with a prior diagnosis of malignancy who present with confirmed CRE infections have limited treatment options. Meropenem-vaborbactam (M-V) is a novel cyclic boronic acid beta-lactamase inhibitor/extended-spectrum beta-lactam combination developed for treatment of serious infections caused by CRE. The objective of this study was to evaluate outcomes of patients with cancer treated with M-V versus best available therapy (BAT) in TANGO II, a multicenter, open-label, randomized, blinded noninferiority trial. In patients with a prior diagnosis of malignancy who presented with confirmed CRE infections, treatment with M-V was associated with higher clinical and microbiologic cure rates and a lower incidence of serious adverse events compared with BAT. These results support the use of M-V as a promising treatment option for CRE in this population.

**METHODS**

• The current best available therapy involves treatment with one or more of the following: ceftazidime-avibactam (CAZ-AVI), ceftazidime-avibactam plus an aminoglycoside and/or fluoroquinolone, or a carbapenem alone or in combination with an aminoglycoside.

• Among patients with solid tumors or hematologic malignancy and CRE (cUTI, HABP/VABP, cIAI) infections, treatment with M-V was associated with higher clinical and microbiologic cure rates and a lower incidence of serious adverse events (16.7% vs. 33.3%), compared with BAT (mCRE-MITT population).

• A significantly higher microbiologic cure rate at TOC (62.5%, 95% CI: 14.3% to 91.5%) was observed in patients with cancer treated with M-V versus BAT (mCRE-MITT population). The difference in clinical cure rate at EOT was 73.2% (95% CI: 21.0% to 96.4%) to those treated with BAT (mCRE-MITT population). The difference in clinical cure rate at EOT was 73.2% (95% CI: 21.0% to 96.4%) to those treated with BAT (mCRE-MITT population).

• Patients with underlying malignancies, particularly hematologic malignancies, are at higher risk for mortality due to infections caused by carbapenem-resistant Enterobacteriaceae (CRE). Meropenem-vaborbactam (M-V) is a novel cyclic boronic acid beta-lactamase inhibitor/extended-spectrum beta-lactam combination developed for treatment of serious infections caused by CRE. The objective of this study was to evaluate outcomes of patients with cancer treated with M-V versus best available therapy (BAT) in TANGO II, a multicenter, open-label, randomized, blinded noninferiority trial. In patients with a prior diagnosis of malignancy who presented with confirmed CRE infections, treatment with M-V was associated with higher clinical and microbiologic cure rates and a lower incidence of serious adverse events compared with BAT. These results support the use of M-V as a promising treatment option for CRE in this population.

**RESULTS**

- **Endpoints Among Outcomes in Oncology, mCRE-MITT population**
  - **Clinical cure at EOT**: 7 (87.5%) vs. 1 (14.3%) vs. 8 (53.3%) +73.2 (21.0%, 96.4%)
  - **Outcomes at EOT+7 days**: 5 (62.5%) vs. 0 (0%) vs. 5 (33.3%) +62.5 (14.3%, 91.5%)
  - **Serious adverse events**: 1 (8.3%) vs. 2 (22.2%) vs. 3 (14.3%) 2 days (2 days)
  - **Any 3 (25.0%) vs. 7 (77.8%) vs. 10 (47.6%) 2 days (2 days)
  - **Study discontinuation due to TEAEs**: 1 (8.3%) vs. 4 (44.4%) vs. 5 (23.8%) 2 days (2 days)

**DISCUSSIONS**

1. Alma Mater Studiorum University of Bologna, Bologna, Italy; 2. National and Kapodistrian University of Athens, Medical School, Greece; 3. Accelerate Diagnostics, Los Angeles, CA, USA; 4. Tufts Medical Center, Boston, MA, USA; 5. Weill Cornell Medicine, New York, NY, USA; 6. National and Kapodistrian University of Athens, University Hospital ‘G. Gennimatas’, Athens, Greece; 7. The Medicines Company, San Diego, CA, USA; 8. Well-Grounded Consultants, New York, NY, USA; 9. No sponsor contributions were received from the authors of this manuscript.

**REFERENCES**


