Background: Patients with cancer, particularly those with hematologic malignancies, are at high risk for microbiologically defined infections caused by carbapenem-resistant Enterobacteriaceae (CRE). This study evaluated M-V treatment (ceftazidime-avibactam [AVB] and metronidazole [M]) in a novel cohort of patients with ongoing malignancy, including hematologic malignancies, as well as immunocompromised patients.

Methods: This was a phase 3, multi-center, randomised, open-label study of adults with complicated urinary tract infections (cUTI), complicated intra-abdominal infection (cIAI), and hospital-acquired/ventilator-associated bacterial pneumonia (HABP/VABP) due to CRE pathogens. A manual review of all patients and the qualifying key terms was then performed. Patients were included if they had a CRE pathogen (mCRE-MITT population). 43/70 (61.4%) had a qualifying CRE pathogen (mCRE-MITT population).

Results: M-V treatment was associated with a significant decrease in Day 28 mortality (absolute risk reduction 44.6%, 95% CI: 14.3% to 91.5%) in patients with cancer treated with CRE pathogens. 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 CRE pathogens.

Conclusions: M-V was well tolerated. 9 (75.0%) of 12 patients in the M-V Safety population met the criteria for study discontinuation due to TEAEs. A significantly higher clinical cure rate at Day 28 was observed in patients with cancer treated with AVB plus M compared to M/V (81.8% vs. 44.4%, 95% CI: 25.0% to 77.8%). A significantly higher microbiologic cure rate at TOC (62.5% vs. 77.8%) was observed in patients with cancer treated with M/V compared to M (95% CI: 25.0% to 77.8%).

References:

<table>
<thead>
<tr>
<th>Baseline Characteristics (n=8)</th>
<th>M-V (n=8)</th>
<th>BAT (n=9)</th>
<th>p-Value</th>
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**Table 1. Baseline characteristics of patients with cancer:**

**Study discontinuation due to TEAEs:**

**Drug-related adverse events:**

**Serious adverse events:**

**Adverse events in oncology, Safety population M-V (n=12):**

**Clinical cure at TOC:**

**Microbiologic cure at TOC:**

**Global eradication:**

**Conclusion:**

- M-V treatment was associated with a significant decrease in Day 28 mortality (absolute risk reduction 44.6%, 95% CI: 14.3% to 91.5%) in patients with cancer treated with CRE pathogens.
- 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 CRE pathogens.

**References:**