**Abstract**

**Background:** IGNITE1 andIGNITE4 were randomized, double-blind, double-dummy, multicenter studies which demonstrated the efficacy and safety of eravacycline (ERV) compared to a carbapenem in subjects with complicated intra-abdominal infections (cIAI). The primary objective of this analysis was to compare the microbiological response at the test-of-cure (TOC) visit for subjects in the 2 treatment groups.

**Methods:** Appropriate aerobic and anaerobic specimens for culture at the time of the initial procedure were collected from the site of infection and directly inoculated into transport media. Blood and intra-abdominal specimens were cultured, and species identified according to local laboratory practice. Pure cultures of isolates were sent to a reference laboratory for susceptibility analysis to ERV and comparators.

**Results:** For subjects with infections caused by Enterobacteriaceae, the overall favorable microbiological response rates for ERV-treated subjects were 86.3% and 91.1% for IGNITE1 and IGNITE4, respectively. The favorable microbiological response rates among pooled ERV-treated subjects are shown in the Table. All isolates were resistant to tetracycline-specific acquired resistance mechanisms (i.e., efflux and ribosomal protection).

**Conclusion:** In IGNITE1 and IGNITE4 studies, high favorable clinical and microbiological responses were observed for ERV. More than 88% of five Enterobacteriaceae spp. and β fragilis, the most common bacteria associated with intra-abdominal infections, were eradicated by ERV. Comparative eradication rates were observed following etampenem and meropenem therapy, further establishing that ERV was at least as effective as carbapenem treatments. These data support in vitro observations that ERV has broad-spectrum activity against common isolates found in intra-abdominal infections.

**Methods**

IGNITE1 andIGNITE4 were phase 3 randomized, double-blind, double-dummy, multicenter, prospective studies designed to assess the efficacy and safety of twice-daily intravenous eravacycline (1 mg/kg every 12 hours) compared to a carbapenem in patients with cIAI. The primary endpoint was clinical response in the micro-ITT population at the TOC visit, which occurred 25 to 31 days after the initial dose of study drug. The difference in clinical cure rates between treatment groups was determined along with the 95% confidence interval. The non-inferiority margins for IGNITE1 and IGNITE4 were 10% and 12.5%, respectively. Favorable microbiological response rates at the TOC visit were determined for each baseline pathogen isolated from blood and/or intra-abdominal specimens in the micro-ITT population.

**Results (cont’d)**

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**Results**

**Conclusion:** In IGNITE1 and IGNITE4, high favorable clinical and microbiological responses were observed for eravacycline as compared to carbapenem therapies. These data support in vitro observations that eravacycline has broad-spectrum activity against common cIAI pathogens, including ESBL positive, carbapenemase-positive, and MDR strains.

**References**


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**Figure 1. IGNITE1 and IGNITE4 Study Design**

**Figure 2. IGNITE1 and IGNITE4 Baseline Pathogen Distribution**

**Table 2. Eravacycline MIC Distributions for Selected Gram-Negative Species in the micro-ITT Population**

**Figure 3. Eradication by MIC value**