Background: IGNITE is a phase A, global, multicenter, double-blind, non-inferiority phase 3 trial conducted to evaluate the efficacy and safety of meropenem or any other carbapenem, or tigecycline for 7 to 14 days. Clinical outcome at the test of cure visit (TOC, 25-31 days after randomization) was the primary efficacy endpoint.

Results: 500 patients were randomized (250 per group). Baseline isolates were cultured from 400 patients, including Escherichia coli (40.5%), Klebsiella pneumoniae (39), Pseudomonas aeruginosa (39), Enterococci spp (31), Streptococci spp (12), Staphylococcus aureus (10), and Bacteroides fragilis (9). Baseline isolate resistance rates were as follows: meropenem-resistant E. coli 26.5%, meropenem-resistant K. pneumoniae 39%, meropenem-resistant P. aeruginosa 39%, meropenem-resistant Enterococci spp 28.4%, and meropenem-resistant S. aureus 30%

Conclusion: the data from this trial demonstrated non-inferiority of eravacycline versus meropenem in the treatment of complicated intra-abdominal infection. The results of this phase 3 study are consistent with the favorable efficacy, safety and tolerability previously observed in published studies comparing eravacycline to meropenem in CAI. These data further suggest that, if approved, eravacycline may provide an additional monotherapy treatment option for patients with polymicrobial CAI and may offer an alternative treatment in cases where Gram-negative resistance is a concern.

References: