Clinical and microbiological outcomes for Enterobacterales uropathogens in the Phase 3 ADAPT-PO Study of oral tebipenem pivoxil hydrobromide

Ian A. Critchley1, Paul B. Eckburg2, Lori Muir2, Aaron Dane2, Gary Moore3, David Melnick1, Angela K. Talley2

1Spero Therapeutics, Cambridge, MA; 2Danestat Consulting, Macclesfield, UK; 3Turech Computing Services, Inc., Little Rock, AR

Background
Enteroacteal uropathogens are frequently implicated in complicated urinary tract infection, including acute pyelonephritis (cUTI) and bacteriuria. Enterobacterales, including those with resistant phenotypes. Published topline results of the ADAPT-PO trial showed TBP-PI-HBr was the treatment of cUTI/AP in the ADAPT-PO Phase 3 clinical trial. The goal of the analyses conducted in this study was to assess the clinical response and by-pathogen microbiological responses for Enterobacterales pathogens, including those with resistant phenotypes. Published topline results of the ADAPT-PO trial showed TBP-PI-HBr was non-inferior to IV etrapenem in the Phase 3 ADAPT-PO clinical trial. The goal of the analyses conducted in this study was to assess the clinical response and by-pathogen microbiological responses for Enterobacterales pathogens, including those with resistant phenotypes.

Methods
ADAPT-PO was a Phase 3 multinational, double-blind trial evaluating orally administered TBP-PI-HBr vs. IV etrapenem in 1372 hospitalized patients with cUTI/AP. Patients were randomized 1:1 to oral TBP-PI-HBr (600 mg q8h) or IV ertapenem (1 g q24h) for 7-10 days. The primary analysis population was the micro-ITT that included randomized patients with confirmed diagnosis of cUTI or AP with positive urine culture of 1 or 2 uropathogens at ≥10 CFU/mL. All urine and/or blood isolates were shipped to a central laboratory for identification confirmation and susceptibility testing. Clinical cure was complete resolution or significant improvement in signs and symptoms of cUTI or AP that were present at baseline and no new symptoms such that no further therapy was needed. Microbiological eradication was a reduction of baseline uropathogens(s) to <10^6 CFU/mL and negative blood cultures. Clinical and microbiological outcomes for Enterobacterales pathogens were assessed. Enterobacterales were 54.7% and 61.6%, respectively. Similar microbiological response rates were observed for all Enterobacterales were 54.7% and 61.6%, respectively. Similar microbiological response rates were observed for

Results
Enteroacteal uropathogens are frequently implicated in complicated urinary tract infection, including acute pyelonephritis (cUTI) and bacteriuria. Enterobacterales, including those with resistant phenotypes. Published topline results of the ADAPT-PO trial showed TBP-PI-HBr was the treatment of cUTI/AP in the ADAPT-PO Phase 3 clinical trial. The goal of the analyses conducted in this study was to assess the clinical response and by-pathogen microbiological responses for Enterobacterales pathogens, including those with resistant phenotypes. Published topline results of the ADAPT-PO trial showed TBP-PI-HBr was non-inferior to IV etrapenem in the Phase 3 ADAPT-PO clinical trial. The goal of the analyses conducted in this study was to assess the clinical response and by-pathogen microbiological responses for Enterobacterales pathogens, including those with resistant phenotypes.

Summary and Conclusions

References