respectively, 2.1 (IQ 1.4-2.8) mL/kg/min, 0.6 (IQ 0.5-0.7) L/kg and 3.2 (IQ 2.3-4.0) hours. After the initial dose regimen, 5 (42%) patients reached the therapeutic target.

Conclusion. This was an open-label, randomized, single-dose, semi-replicate, 3-sequence, 4-period crossover, BE, and food effect study. Subjects were randomized to one product. AUC_{0-t} and C_{max} were within the 80% to 125% BE limits when administered under fasted conditions. A standard high-fat/high-calorie meal had no meaningful effect on the total plasma exposure of TBP after administration of the registration product, thus, overall exposure based on AUC_{0-t} and C_{max} was comparable under fed and fasted conditions (Figure 2). Five (14%) subjects reported adverse events of mild severity; no relevant ECGs, vital signs or safety laboratory findings were observed.

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1120. Absorption, Metabolism, and Excretion of [14C]-Tebipenem Pivoxil Hydrobromide (TBP-PI-HBr) Following a Single Oral Dose in Healthy Male Subjects
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Session: P-62. PK/PD Studies

Background. Tebipenem pivoxil hydrobromide (TBP-PI-HBr) is an oral prodrug that is converted to tebipenem (TBP), the active moiety, with activity against multi-drug-resistant gram-negative pathogens, including extended-spectrum β-lactamase (ESBL)-producing Enterobacteriales. TBP-PI-HBr is the first oral carbapenem intended for treating complicated urinary tract infections and acute pyelonephritis. This study evaluated the absorption, metabolism, and excretion (AME) of TBP-PI-HBr following a single oral dose of [14C]-TBP-PI-HBr to healthy males and characterized metabolites in plasma, urine, and feces.

Methods. This was a Phase 1, open-label, single-dose study in healthy subjects. Study drug was provided as radiolabeled and non-radiolabeled active pharmaceutical ingredients containing approximately 150 μCi of [14C]-TBP-PI-HBr. On Day 1, each subject received a 600 mg dose of TBP-PI-HBr, administered with 240 mL of water and fasted overnight for at least 10 hours. Blood samples were collected to determine TBP concentrations (whole blood), total radioactivity (whole blood and plasma), and metabolite profiling and identification were determined from plasma, urine, and feces. For mass balance, total radioactivity derived from urine and feces collections were determined. PK parameters were calculated using noncompartmental methods.

Results. Total radioactivity in plasma and whole blood decreased rapidly with geometric mean t_{1/2} values of 6.0 hours and 3.5 hours, respectively and T_{1/2} of 1 hour. The cumulative mean recovery of radioactivity was 38.7% in urine and 44.6% in feces. Most of the administered radioactivity was recovered in the first 144 hours post dose in urine and feces (80.0%). Six of 8 subjects achieved a mass balance recovery ranging from 80.1% to 85.0%. The TBP plasma to total radioactivity ratio of 0.536 indicated that other metabolites contribute to the total radioactivity AUC in plasma. Metabolite profiling and identification results indicated that TBP was the major component in plasma and urine. The inactive ring open metabolite of TBP (LJC 11,562) was also found in plasma (>10%), urine (5.27%), and feces (>10%) as a secondary metabolite.

Conclusion. This study adequately characterized the AME of TBP-PI-HBr in humans.

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1121. Binequivalence of Two Formulations of Oral Tebipenem-Pivoxil Hydrobromide in Healthy Subjects
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Session: P-62. PK/PD Studies

Background. Tebipenem-pivoxil-hydrobromide (TBP-PI-HBr) is a novel oral carbapenem being developed to treat serious bacterial infections including complicated urinary tract infections. Antacids and proton pump inhibitors are known to change gastric pH after administration, which could affect the absorption of oral formulations. This study evaluated the effect of a single dose of aluminum hydroxide/magnesium hydroxide/simethicone and omeprazole on the pharmacokinetics of Tebipenem Pivoxil Hydrobromide (TBP-PI-HBr) in Healthy Adult Subjects
Vinu K. Gupta, Ph.D.;1 Gina Patel, Ph.D;2 Leanne Gasink, MD;1 Flonzi Bajraktari, MSc;1 Yang Lei, Ph.D;1 Akash Jain, Ph.D;3 Praveen Srivastava, MS, BS;1 Angela Talley, MD;1 Spero Therapeutics, Inc., Cambridge, Massachusetts;2 Patel Kwan Consultancy LLC, Madison, Wisconsin;3 Spero Therapeutics, Cambridge, Massachusetts
Session: P-62. PK/PD Studies

Background. Tebipenem pivoxil hydrobromide (TBP-PI-HBr) is an oral prodrug that is converted to tebipenem (TBP), the active moiety being developed for treating complicated urinary tract infections. Antacids and proton pump inhibitors are known to change gastric pH after administration, which could affect the absorption of oral formulations. This study evaluated the effect of a single dose of aluminum hydroxide/magnesium hydroxide/simethicone and the effect of multiple doses of omeprazole on the PK of TBP, following a single dose of TBP-PI-HBr.

Methods. This was an open-label, 3-period, fixed sequence drug-drug interaction study. On Day 1, Period 1, subjects received a single oral dose of TBP-PI-HBr
600 mg (2 x 300 mg tablets) at Hour 0. On Day 1, Period 2, subjects received a single oral 20 mL dose of aluminum hydroxide 800 mg/magnesium hydroxide 800 mg/simethicone 80 mg suspension per 10 mL (Maalox® Advanced Maximum Strength oral suspension) with a single oral dose of TBP-PI-HBr 600 mg at Hour 0. In Period 3, on Days 1 through 5, subjects received a single oral dose of omeprazole 40 mg (Protonix®) once daily (QD), at Hour -2. On Day 5, a single oral dose of 600 mg TBP-PI-HBr was administered at Hour 0. Whole blood sampling for TBP PK occurred pre-dose and up to 24 hours post dose. Whole blood samples were assayed for TBP by liquid chromatography-tandem mass spectrometry.

**Results.** Twenty subject were enrolled and completed the study. Geometric mean ratios for AUC indicated mean TBP exposure (AUC) was approximately 11% lower and mean C_{max} was 22% lower for TBP-PI-HBr combined with aluminum hydroxide/magnesium hydroxide/simethicone vs. TBP-PI-HBr alone (Figure). Similarly, geometric mean ratios for AUC indicated mean TBP exposure (AUC) was approximately 11% lower and mean C_{max} was 43% lower for TBP-PI-HBr in combination with omeprazole vs. TBP-PI-HBr alone. Because the PK/PD driver for TBP efficacy is AUC dependent, concomitant administration is not expected to impact the efficacy of oral TBP-PI-HBr.

**Conclusion.** Administration of TBP-PI-HBr combined with aluminum hydroxide/magnesium hydroxide/simethicone or omeprazole QD had no meaningful effect on plasma TBP exposure; C_{max} decreased with both agents. Co-administration was generally safe and well tolerated.

**Disclosures.** Vipul K. Gupta, Ph.D., Spero Therapeutics (Employee, Shareholder); Gina Patel, PhD, Spero Therapeutics, Inc. (Consultant); Leanne Gasink, MD, Spero Therapeutics, Inc. (Consultant); Floni Bajraktari, MSc, Spero Therapeutics, Inc. (Employee); Yang Lei, PhD, Spero Therapeutics, Inc. (Employee); Akash Jain, PhD, Spero Therapeutics, Inc. (Employee); Praveen Srivastava, MS, BS, Spero Therapeutics, Inc. (Employee); Angela Talley, MD, Spero Therapeutics, Inc. (Employee).

**Figure 1.** Arithmetic mean plasma TBP concentrations following a 600 mg dose of clinical study drug product (A1 and A2) and registrational drug product (B) – PK population.

**Table 1.** Appropriateness of antibiotic prescribing in the COVID-19 era, by visit type.

| Visit Type                  | Telehealth N (%) | In-person N (%) |
|----------------------------|------------------|-----------------|
| Visits                     | 6,395 (2.0%)     | 310,458 (98.0%)|
| Visits resulting in antibiotics | 594 (9.3%)      | 34,703 (11.2%)  |
| Appropriate                | 67 (11.3%)       | 5,842 (16.8%)   |
| Potentially appropriate    | 410 (69.0%)      | 21,492 (61.9%)  |
| Inappropriate              | 97 (16.3%)       | 7,079 (20.4%)   |

**Conclusion.** Rates and volume of antibiotic prescribing in outpatient pediatric visits have declined in the COVID-19 era, while rates of inappropriate prescribing have increased slightly. Our study suggests use of telehealth for pediatric visits was minimal and led to higher prescribing rates for ‘potentially appropriate’ indications. This could be explained by a lack of clinical certainty in conditions such as otitis media and pharyngitis in virtual visits.

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1124. Evaluation of the Use and Impact of the BioFire FilmArray® Respiratory Panel on Diagnosis and Treatment of Pediatric Respiratory Infections: A Quality Improvement Project

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**Session:** P-63. Pediatric Antimicrobial Stewardship (inpatient/outpatient pediatric focused)

**Background.** The BioFire FilmArray® Respiratory Panel is a respiratory pathogen PCR that is used to detect the presence of 20 different infectious organisms that cause respiratory illness. Young children are prone to viral upper respiratory illness and represent an age group most likely to receive an antibiotic. As rapid diagnostics evolve, utilizing these tools within antimicrobial stewardship programs to improve utilization of antimicrobials is ideal. The purpose of this study was to assess how the BioFire FilmArray® Respiratory Panel is being used in practice and optimize its use in a large, free-standing, academic children’s hospital.

**Methods.** Retrospective chart review evaluating all patients (inpatient and outpatient) that received the BioFire FilmArray® Respiratory Panel from December 1, 2019, to December 10, 2019. Patients were evaluated based on where the panel was administered, results of the panel, results of other cultures, utilization of antibiotics, and overall hospital course. Data was collected from the electronic medical record and entered into a REDCap database and then analyzed descriptively.

**Results.** 151 patients were included with an average age of 2.6 years with 78 (51.7%) being < 1 year of age. 105 (70%) were administered in either the clinic or ED. In the < 1 year group, 29 (37%) received antibiotic therapy; with 20 having positive viral panels and 11 had positive bacterial cultures. In the 2 to <1 year group, 38 (52%) received antibiotic therapy; with 28 having positive viral panels and 9 had positive bacterial cultures. In the outpatient group, 33/105 (31%) were given empiric antibiotics of which 66% had positive viral panels. In the inpatient group, 28/46 (61%) were given empiric antibiotics of which 68% had positive viral panels.

**Conclusion.** The BioFire FilmArray® Respiratory Panel was found to be primarily utilized in the young child and outpatient/ED setting. With approximately 67% of children who received empiric antibiotics having a positive viral panel, and the majority of these not having positive bacterial cultures, work can be done to decrease the initiation of empiric antibiotics or earlier discontinuation. Further studies are needed in order to determine the optimal strategy for using the viral panel to de-escalate and escalate antimicrobial therapy in practice.

**Disclosures.** All Authors: No reported disclosures.