Conclusion. This study demonstrated no increased risk of post-operative infection in patients with a positive urinalysis or urine culture with bacteriuria prior to intervention. There was a high use of broad-spectrum antibiotic as a reflex to positive urinalyses alone highlighting an avenue for improved anti-microbial stewardship. More research is needed to guide clinicians on the role of urines and antibiotics prior to non-urgent urological procedures.

Disclosures. All authors: No reported disclosures.

1477. A Randomized 2 Phase Study of Cefepime with the Novel Extended Spectrum β-Lactamase Inhibitor Enmetazobactam in Hospitalized Adults with Complicated Urinary Tract Infections (cUTI) Including Acute Pyelonephritis (AP)

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Background. Third-generation cephalosporin (3GC)-resistant Enterobacteriaceae has been classified as critical priority pathogens. The novel extended-spectrum β-lactama

Methods. Forty-five patients were enrolled in a randomized, multicenter, double-blinded study of hospitalized adults with cUTI/AP. Patients received dosing regimens of FEP or FEP-EMT IV therapy q8h by 2 hours infusion (table) for 7 to 10 days with a washout period. Efficacy was evaluated in a microbiological-matched ITT (gMITT) population. Safety was monitored in patients who received at least dose 1 of study drug. Clinical cure was a met standard of resolution at cUTI symptoms present at study entry. Plasma and urine PK were determined from all patients.

Results. The drugs were well tolerated in each cohort, with similar % adverse events and no new or unexpected safety concerns (table). Two discontinuations were due to allergic dermatitis. The microbiological- and clinical responses at test-of-cure for the combined FEP-EMT group were 83.3% (20/24) and 95.8% (23/24) compared with responses in the combined FEP group of 73.3% (11/15) and 93.3% (14/15), respectively (table). The most common baseline pathogens were Escherichia coli (66.7%) and Klebsiella pneumoniae (23.1%): 28.2% of isolates produced ESBLs with eradication rates for the combined FEP-EMT group of 85.7% (6/7); and for the combined FEP group of 73.3% (10/14). FEP and EMT PK were best described by a 2-compartment, 1.25 PK model. Both agents exhibited half-lives of 2.3 hours. Creatinine clearance had a significant covariate effect on FEP and EMT, consistent with predominant renal excretion of both agents.

Conclusion. Results from this phase 2 study justify advancement to phase 3 studies to evaluate the safety and efficacy of FEP-EMT in patients with cUTI/AP.

Disclosures. All authors: No reported disclosures.

1478. Efficacy and Safety of a Booster Dose of the MenACWY-TT Vaccine Administered 10 Years After Primary Vaccination with MenACWY-TT or MenACWY-PS

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Background. The quadrivalent meningococcal ACWY polysaccharide tetanus toxoid conjugate vaccine (MenACWY-TT; Nimenrix) is licensed in various countries to prevent disease caused by meningococcal serogroups A, C, W, and Y. In a previous publication, 100% of all subjects had titers ≥1:8 in 100% and 298.0% of subjects (figure); 100% and 296.1% of all subjects had titers ≥1:128. For all serogroups, sBA GMTs at 1 month after the booster dose were higher than before the booster dose. No new safety signals were observed during the booster phase.

Conclusion. Functional antibody responses elicited by MenACWY-TT persisted 10 years after primary vaccination; the booster dose was well tolerated and elicited robust immune responses.

Disclosures. All authors: No reported disclosures.

1479. Clinical Efficacy and Safety Analysis Evaluating Oral Gepotidacin (GSK2140944) From a Phase Ia Study in the Treatment of Uncomplicated Urinary Tract Infections

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Background. Urinary tract infections (UTIs) are very common, with approximately 11% of women >18 years of age experiencing at least 1 episode of acute cystitis per year. Multidrug resistance, typically associated with nosocomial infections, has now emerged at the community level making treatment options for UTIs more difficult. Gepotidacin (GEP), a first-in-class, novel triazaacenaphthylene antibacterial has demonstrated in vitro activity against uropathogens including E. coli and provides high and sustained urine concentrations. It selectively inhibits bacterial DNA replication through a unique mechanism not utilized by any currently approved antibacterial.

Methods. This Phase Ia single-center study was designed primarily to evaluate plasma and urine pharmacokinetics (PK) of gepotidacin in female participants with acute cystitis. Safety data and clinical and microbiological efficacy of gepotidacin were assessed as secondary and exploratory endpoints. All participants received oral gepotidacin 1,500 mg BID for 5 days (total of 10 doses) during clinic confinement. Pretreatment and posttreatment PK collections were performed together with safety, efficacy, microbiological, and exploratory assessments throughout the study.

Results. Summary of Exploratory Endpoints (ITT Population). Clinical Efficacy: All subjects had significant improvement of clinical symptoms (dysuria, frequency, urgency, lower abdominal pain) within 24 to 48 hours of treatment. Most subjects, (20/22; 90.9%) achieved symptom resolution at test of cure (ToC) and follow-up (FU). Microbiological eradication was achieved independent of baseline CFUs (see microbiology abstract). Safety Endpoint: Most common AEs involved the GI tract (diarrhea 18/22 [82%] and nausea 17/22 [77%]). No investigator observation, tolerance to nausea was observed with repeat dosing. No withdrawal due to AE. There were no clinically relevant trends in safety laboratories, ECG, or vital signs.

Conclusion. This first report of efficacy and safety in the treatment of acute cystitis supports further study of the clinical use of GEP in this indication.

Disclosures. All authors: No reported disclosures.

1480. Plasma and Urine Pharmacokinetic Analysis of Gepotidacin (GSK2140944) Following BID Oral Dosing in a Phase Ia Study for Treatment of Uncomplicated Urinary Tract Infections

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Background. In addition to the significance of uncontrolled infection, acute cystitis per year. Multidrug resistance, typically associated with nosocomial infections, has now emerged at the community level making treatment options for UTIs more difficult. Gepotidacin (GEP), a first-in-class, novel triazaacenaphthylene antibacterial has demonstrated in vitro activity against uropathogens including E. coli and provides high and sustained urine concentrations. It selectively inhibits bacterial DNA replication through a unique mechanism not utilized by any currently approved antibacterial.

Methods. This Phase Ia single-center study was designed primarily to evaluate plasma and urine pharmacokinetics (PK) of gepotidacin in female participants with acute cystitis. Safety data and clinical and microbiological efficacy of gepotidacin were assessed as secondary and exploratory endpoints. All participants received oral gepotidacin 1,500 mg BID for 5 days (total of 10 doses) during clinic confinement. Pretreatment and posttreatment PK collections were performed together with safety, efficacy, microbiological, and exploratory assessments throughout the study.

Results. Summary of Exploratory Endpoints (ITT Population). Clinical Efficacy: All subjects had significant improvement of clinical symptoms (dysuria, frequency, urgency, lower abdominal pain) within 24 to 48 hours of treatment. Most subjects, (20/22; 90.9%) achieved symptom resolution at test of cure (ToC) and follow-up (FU). Microbiological eradication was achieved independent of baseline CFUs (see microbiology abstract). Safety Endpoint: Most common AEs involved the GI tract (diarrhea 18/22 [82%] and nausea 17/22 [77%]). No investigator observation, tolerance to nausea was observed with repeat dosing. No withdrawal due to AE. There were no clinically relevant trends in safety laboratories, ECG, or vital signs.

Conclusion. This first report of efficacy and safety in the treatment of acute cystitis supports further study of the clinical use of GEP in this indication.

Disclosures. All authors: No reported disclosures.