Safety, Tolerability, Efficacy and Pharmacokinetics of Imipenem/Cilastatin/Relebactam (MK-7655A) in Pediatric Participants With Gram-negative Bacterial Infection (MK-7655A-021)

Status: Recruiting

Eligibility Criteria

Age: Up to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Requires hospitalization and treatment with IV antibacterial therapy for confirmed or suspected gram-negative bacterial infection (in the absence of meningitis), and is expected to require hospitalization through completion of IV study intervention, with at least 1 of the following primary infection types: HABP or VABP; cIAI; or cUTI.

• For Age Cohorts 4 and 5, participant is at least 37 weeks postmenstrual age at the time of signing the informed consent.

• If female, must not be pregnant or breastfeeding, and at least 1 of the following conditions must apply: must not be a woman of childbearing potential (WOCBP); OR, if a WOCBP, must agree to follow contraceptive guidance during the intervention period and for at least 24 hours after the last dose of study intervention.

• Has sufficient intravascular access to receive study drug through an existing peripheral or central line.

Exclusion Criteria:

• Is expected to survive less than 72 hours.

• Has a concurrent infection that would interfere with evaluation of response to the study antibacterials (IMI/REL or Active Control), including any of the following: endocarditis; osteomyelitis; meningitis; prosthetic joint infection; active pulmonary tuberculosis; disseminated fungal infection; concomitant infection at the time of randomization that requires non-study systemic antibacterial therapy in addition to IV study treatment or oral step-down therapy.

• Has HABP/VABP caused by an obstructive process, including lung cancer (or other malignancy metastatic to the lungs resulting in pulmonary obstruction) or other known obstruction.

• Has a cUTI, with any of the following: complete obstruction of any portion of the urinary tract (ie, requiring a permanent indwelling urinary catheter or instrumentation); documented ileal loop reflux; suspected or confirmed perinephric or intrarenal abscess; suspected or confirmed prostatitis, urethritis, or epididymitis; trauma to pelvis/urinary tract; presence of indwelling urinary catheter which cannot be removed at study entry.

• Has any of the following medical conditions at screening: history of a seizure disorder (requiring ongoing treatment with anti-convulsive therapy or prior treatment with anti-convulsive therapy within the last 3 years); cystic fibrosis; history of serious allergy, hypersensitivity (eg, anaphylaxis), or any serious reaction to IMI, or to any carbapenem, cephalosporin, penicillin, or other β-lactam agent, or to other β-lactamase inhibitors (eg, tazobactam, sulbactam, clavulanic acid, avibactam).

• Has a history or current evidence of any condition, therapy, laboratory abnormality, or other circumstance that might expose the participant to risk by participating in the study, confound study results, or interfere with the participant's participation for the full duration of the study.

• If less than 3 months of age, has received more than 72 hours of empiric antibacterial treatment until meningitis has been ruled out prior to initiation of IV study intervention.

• If 3 months of age or older, has received potentially therapeutic antibacterial therapy (eg, with gram-negative activity), including bladder infusions with topical urinary antiseptics or antibacterial agents, for a duration of more than 24 hours during the 48 hours preceding the first dose of study intervention.

• Is anticipated to be treated with any of the following medications: valproic acid or divalproex sodium (or has used valproic acid or divalproex sodium in the 2 weeks prior to screening) through 24 hours after completion of the final dose of IV study intervention for participants who receive IMI/REL or carbapenem; concomitant IV, oral, or inhaled antimicrobial agents with gram-negative activity, in addition to those designated in the study intervention groups, during the course of all (IV/oral) study intervention; planned receipt of suppressive/prophylactic antibiotics with gram-negative activity after completion of study intervention.

• Is currently participating in or has participated in an interventional clinical study with an investigational compound or device within 30 days prior to screening.

• Has enrolled previously in the current study and been discontinued, or has received REL for any other reason.

• Has an estimated creatinine clearance (based on the Cockcroft-Gault equation, for participants ≥12 years of age) or estimated glomerular filtration rate (eGFR, based on the modified Schwartz equation, for participants <12 years of age) below that specified for the appropriate age range; or requires peritoneal dialysis, hemodialysis, or hemofiltration.

• Has alanine aminotransferase (ALT) or aspartate aminotransferase (AST) ≥5 × upper limit of normal (ULN) at the time of screening. NOTE: Patients with acute hepatic failure or acute decompensation of chronic hepatic failure should also be excluded.

• Is a user of recreational or illicit drugs or has had a recent history of drug or alcohol abuse or dependence.

• Is or has an immediate family member (eg, spouse, parent/legal guardian, sibling, or child) who is investigational site or Sponsor staff directly involved with this study.

Conditions & Interventions

Interventions:
Drug: IMI/REL, Drug: Active Control
Conditions:
Suspected or Documented Gram-negative Bacterial Infection

More Information

Contact(s): Toll Free Number - Trialsites@merck.com
Principal Investigator:
Phase: Phase 2/Phase 3
IRB
Number:
System ID: NCT03969901
