A Study of Safety and Efficacy of MK-1986 (Tedizolid Phosphate) and Comparator in Participants From Birth to Less Than 12 Years of Age With Acute Bacterial Skin and Skin Structure Infections (MK-1986-018)

Status: Recruiting

Eligibility Criteria

Age: Up to 11 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

• Has a parent/legally acceptable representative who is able to give documented informed consent

• Has ABSSSI, defined as ≥1 of the following: 1) cellulitis/erysipelas, 2) major cutaneous abscess, or 3) wound infection

• Local symptoms of ABSSSI that started within 14 days before study start

• Suspected or documented Gram-positive bacterial infection

• Body weight ≥3.2 kg

Exclusion Criteria:

• Uncomplicated skin and skin structure infection

• ABSSSI due to or associated with disallowed etiology per protocol

• Received antibacterial therapy for treatment of the current episode of ABSSSI except 1) <48 hours of antibacterial therapy with a short-acting antibacterial drug, or 2) response is considered to be failure (no improvement in signs and symptoms) after at least 48 hours of therapy

• Known bacteremia, severe sepsis, or septic shock

• Significant or life-threatening condition, disease, or organ system condition

• Recent history of opportunistic infections where the underlying cause of the infection is still active, or is suspected to be at risk of opportunistic infection with unusual pathogens

• Received or is receiving treatment for active tuberculosis within 1 month of study start

• Known or suspected severe neutropenia

• Human immunodeficiency virus (HIV) positive and has Cluster of Differentiation (CD) 4 cell count <15% (HIV testing is not required for eligibility)

• Renal impairment that requires renal filtration

• Severe hepatic impairment

• Cardiac or electrocardiogram (ECG) finding that would limit participation in the study

• Received an investigational medicinal product (not approved) within 30 days before study start

• Investigational device present or removed within 30 days before study start

• Previously treated with tedizolid phosphate

• Contraindication, including hypersensitivity to tedizolid phosphate, other oxazolidinones, or any component in the formulation

• Contraindication, including hypersensitivity to all available comparator drugs

• Wound infection and history of hypersensitivity to aztreonam adjunctive therapy or metronidazole adjunctive therapy, if adjunctive therapy is required

• Needs oral administration of methotrexate, topotecan, irinotecan, or rosuvastatin, during administration of oral study drug (administration during the follow-up period, ie, after the EOT visit, is allowed, as is administration during treatment with IV drug)

• Female who is pregnant or nursing or is of childbearing potential and not abstinent; or male who is not abstinent

• Use of monoamine oxidase inhibitors, tricyclic antidepressants, buspirone, selective serotonin reuptake inhibitors, or serotonin 5-hydroxytryptamine receptor agonists (triptans)

• Identified as having used illicit drugs (urine drug screening not required for entry)

Conditions & Interventions

Interventions:
Drug: Tedizolid phosphate, Drug: Comparator
Conditions:
Acute Bacterial Skin and Skin Structure Infections

More Information

Contact(s): Toll Free Number - Trialsites@merck.com
Principal Investigator:
Phase: Phase 3
IRB
Number:
System ID: NCT03176134
