

A Clinical Study of Letermovir (MK-8228) in Children and Adolescents Who Receive a Kidney Transplant (KT) (MK-8228-077)

Status: RECRUITING

Eligibility Criteria

Sex: ALL

Age: Up to 17 years old

Healthy Volunteers: This study is NOT accepting healthy volunteers

Inclusion Criteria:

The main inclusion criteria include but are not limited to the following:

- Is a recipient of a primary or secondary allograft kidney
- Is at least 4 weeks posttransplant and not more than 52 weeks posttransplant at the time of enrollment (Day 1) and is being managed per local standard of care
- Has stable kidney function posttransplant
- Has undetectable CMV deoxyribonucleic acid (DNA) from a plasma or whole blood sample collected within 14 days prior to enrollment
- Must be able to take (as assessed by the investigator) letermovir tablets or oral pellets by mouth, or via gastrostomy or nasogastric tube (oral pellets only)
- Does not have a condition that may interfere with the absorption of oral medication (e.g., vomiting, diarrhea, or a malabsorptive condition) from the day of enrollment (Day 1) until the intensive pharmacokinetics (IPK) sampling is completed
- Weighs ≥ 2.5 and < 40 kg at enrollment (Day 1)

Exclusion Criteria:

The main exclusion criteria include but are not limited to the following:

- Has CMV disease or suspected CMV disease between screening and enrollment
- Is on dialysis or plasmapheresis at the time of enrollment
- Has evidence of CMV viremia at any time from screening until the time of enrollment
- Has Child-Pugh B or C hepatic insufficiency within 14 days before enrollment
- Is a multi-organ transplant recipient (e.g., kidney-pancreas)
- Has any uncontrolled infection on the day of enrollment
- Requires mechanical ventilation, or is hemodynamically unstable, at the time of enrollment
- Has received or is receiving protocol-specified prohibited medications

Conditions & Interventions

Interventions:

DRUG: Letermovir

Conditions:

Cytomegalovirus Prophylaxis

More Information

Description:

Researchers are looking for a way to prevent cytomegalovirus (CMV) in children and adolescents who receive a kidney transplant (KT) and weigh less than 40 kilograms (88.2 pounds). The goals of the study are to: * Learn what happens to letermovir in the body over time * Learn about the safety of letermovir and if participants tolerate it

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Principal Investigator:

Principal Investigator ID:

Phase: PHASE1

IRB Number:

System ID: NCT07199465

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