

A Phase 1, Open-label, Single-arm Study to Evaluate the Pharmacokinetics and Safety of Letemovir in Pediatric Kidney Transplant (KT) Recipients Less Than 18 Years of Age and Weighing Less Than 40 Kilograms

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 17 years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- up to 17 years old - recipient of a primary or secondary allograft kidney - at least 4 weeks posttransplant and not more than 52 weeks posttransplant - has stable kidney function since the transplant - able to take letermovir tablets or oral pellets by mouth, or via gastrostomy or nasogastric tube - weighs ≥ 2.5 and < 40 kg at enrollment (5.5 to 88 pounds) - see link to clinicaltrials.gov for complete Inclusion criteria

Exclusion Criteria:

- has CMV disease - on dialysis or plasmapheresis - multi-organ transplant recipient (e.g., kidney-pancreas) - any uncontrolled infection - see link to clinicaltrials.gov for complete Exclusion criteria

Conditions & Interventions

Interventions:

Drug: Letemovir

Conditions:

Children's Health, Infectious Diseases, Kidney, Prostate & Urinary

Keywords:

CMV, cytomegalovirus, kidney transplant

More Information

Description: Letemovir (MK-8228) is a medication that is used to prevent cytomegalovirus (CMV) infection and disease. This trial is testing letermovir in children and adolescents who weigh less than 40 kilograms and have had a kidney transplant. Letemovir is experimental in this trial. Everyone in this trial will get letermovir. The dose a child gets will depend on their weight at the start of the trial. The child, the trial doctor and the trial staff will know your child is getting letermovir and what dose they are getting.

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Phase: PHASE1

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