A Study to Evaluate the Safety and Tolerability, Pharmacokinetics, and Antiviral Activity of Maribavir for the Treatment of Cytomegalovirus (CMV) Infection in Children and Adolescents Who Have Received a Hematopoietic Stem Cell Transplant (HSCT) or a Solid Organ Transplant (SOT)

NCT05319353

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	80 participants

Key Eligibility Criteria

Inclusion (13)

- Parent/both parents or legally authorized representative (LAR) must provide signature of informed consent and there must be documentation of assent by the participant, as age appropriate, before completing any study-related procedures.
- Be a male or female child or adolescent \< 18 years of age at the time of consent. For participants in Cohort 3 only (0 to \<6 years) must have a gestational age of at least 39 weeks and a minimum weight of 5 kg.
- Be a recipient of an SOT or an HSCT that is functioning at the time of screening.
- Have a documented CMV infection which may be a first episode of post-transplant CMV viremia (primary or reactivation) or refractory to other anti-CMV treatments, with a CMV DNA screening value of \>= 1365 International Units per milliliter (IU/mL) in whole blood or \>= 455 IU/mL in plasma in 2 consecutive assessments separated by at least 1 day, as determined by local laboratory quantitative polymerase chain reaction (qPCR) or comparable quantitative nucleic acid amplification test (qNAAT) results. Quantitative assays must be standardized to the World Health Organization (WHO) CMV International Standard. Both samples must be taken within 14 days of first dose of study drug, with the second sample obtained within 5 days prior to first dose of study drug. The same laboratory and same sample type (whole blood or plasma) must be used for both assessments. If documented and verified values are available in medical history that fulfill this criterion entirely, they may be used instead.
- Have all the following results as part of screening laboratory assessments:

... and 8 more (see full listing online)

Exclusion (20)

- Have CMV tissue invasive disease involving the central nervous system (CNS) or retina as assessed by the investigator at the time of screening.
- Have uncontrolled other type of infection as assessed by the investigator on the date of enrollment.
- Have a history of clinically relevant alcohol or drug abuse that may interfere with treatment compliance or assessments with the protocol as determined by the investigator.
- Be receiving valganciclovir, ganciclovir, cidofovir, foscarnet, leflunomide, letermovir, or artesunate when study treatment is initiated, or anticipated to require one of these agents during the 8-week treatment period.
- Have a known hypersensitivity to maribavir or to any excipients.

... and 15 more (see full listing online)

Locations (47 total)

University of Nebraska Medical Center -985400 Nebraska Medical Center, Omaha, Nebraska, United States
Cincinnati Children's Hospital Medical Center - PIN, Cincinnati, Ohio, United States
Cook Children's Health Care System, Fort Worth, Texas, United States
... and 44 more locations