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)

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: Up to 17 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- 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:
- Absolute neutrophil count >= 500 per cubic millimeter (/mm^3) (0.5 × 10^9 per liter [/L])
- Platelet count >= 15,000/mm^3 (15 × 10^9/L)
- Hemoglobin >= 8 grams per deciliter (g/dL) (>=80 grams per liter [g/L]).
- Have an estimated glomerular filtration rate (creatinine-based Bedside Schwartz equation) >= 30 milliliters per minute (mL/min) /1.73 meter square (m^2).
- Be a female of nonchildbearing potential. If a female of childbearing potential, have a negative serum human chorionic gonadotropin (hCG) or beta-human chorionic gonadotropin (β-hCG) pregnancy test at screening. Males, or nonpregnant, nonlactating females who are sexually active must agree to comply with the applicable contraceptive requirements of this protocol during the study treatment administration period and for 90 days after the last dose of study treatment.
- Have life expectancy of >= 8 weeks.
- Be willing and have an understanding and ability to fully comply with the study procedures and restrictions defined in the protocol. For younger children, the parent/both parents or LAR must meet this criterion.
- Participants must have a confirmed negative human immunodeficiency virus (HIV) test result within 3 months of first dose of study drug or, if unavailable, be tested by a local laboratory during the screening period.

Exclusion Criteria:

- 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.
- Have severe vomiting, diarrhea, or other severe gastrointestinal (GI) illness within 24 hours prior to the first dose of study treatment or a GI absorption abnormality that would preclude administration of oral medication.
- Require mechanical ventilation or vasopressors for hemodynamic support at baseline (Visit 2/Day 1/Week 0).
- Be pregnant (or expecting to conceive) or nursing.
- Have previously completed, discontinued, or have been withdrawn from this study.
- Have received any investigational agent or device within 30 days before initiation of study treatment (includes CMV specific T-cells) or plan to receive an investigational agent or device during the study.

Previously approved agents under investigation for additional indications are not exclusionary.

- Have previously received maribavir or CMV vaccine at any time.
- Have any clinically significant medical or surgical condition that, in the investigator's opinion, could interfere with interpretation of study results, contraindicate the administration of the study treatment, or compromise the safety or well-being of the participant.
- Have severe liver disease (Child-Pugh score of >= 10).
- Have serum aspartate aminotransferase greater than (>) 5 times upper limit of normal (ULN) at screening, or serum alanine aminotransferase > 5 times ULN at screening, or total bilirubin >= 3.0 times ULN at screening (except for documented Gilbert's syndrome)

aminotransferase >= 5 times ULN at screening, or total bilirubin >= 3.0 times ULN at screening (except for documented Gilbert's syndrome), as analyzed by local laboratory.
- Have positive results for HIV.
- Have active malignancy with the exception of nonmelanoma skin cancer, as determined by the investigator. Participants who experience relapse or progression of their underlying malignancy (for which HSCT or SOT was performed), as determined by the investigator, are not to be enrolled.
- Be undergoing treatment for acute or chronic hepatitis B or hepatitis C.
- Requiring ongoing treatment with or an anticipated need for treatment with a strong cytochrome P450 3A (CYP3A) inducer.
- Have a low body weight where total blood volume (TBV) required during study participation will exceed 1 percent (%) TBV per study visit or 3% TBV over a 4-week period.

Conditions & Interventions

Interventions:
DRUG: Maribavir
Conditions:
Cytomegalovirus (CMV)

More Information

Description:
The main aim of this study is to find out the safety, tolerability and pharmacokinetics (PK) of maribavir for the treatment of CMV infection in children and teenagers after HSCT or SOT and to identify the optimal dose of maribavir using a 200 milligrams (mg) tablet formulation or powder for oral suspension. The participants will be treated with maribavir for 8 weeks. Participants need to visit their doctor during 12-week follow-up period.

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