A Study of the Drug Letermovir as Prevention of Cytomegalovirus Infection After Stem Cell Transplant in Pediatric Patients

Status: RECRUITING

Eligibility Criteria

Age: 2 years to 18 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* \>= 2 years and \< 18 years at the time of enrollment * Weight must be \>= 18 kg. For patients \< 12 years of age and expected to receive cyclosporine, weight must be \>= 30kg * Planned allogeneic HCT (bone marrow, peripheral blood stem cell, or cord blood transplant) * Patient must be CMV sero-positive (i.e., recipient CMV immunoglobulin G positive) * Patient is eligible for entry only if it is feasible for plasma CMV PCR testing to be sent and resulted within the protocol mandated time period * Reminder: To limit the likelihood of positive plasma CMV PCR post-enrollment and prior to start of study treatment period, it is recommended that patient enrollment proceed after patients start their transplant preparative regimen * Patient must have a performance status corresponding to Lansky/Karnofsky scores \> 50 * Note: Use Lansky for patients =\< 16 years of age and Karnofsky for patients \> 16 years of age. For further reference, see performance status scales scoring under the standard sections for protocols among protocol reference materials provided on the Children's Oncology Group (COG) member website: https://members.childrensoncologygroup.org/prot/reference_materials.asp * Estimated glomerular filtration rate \> 15 mL/min/1.73 m\^2 and not receiving dialysis * Total bilirubin =\< 2.5 mg/dL and serum glutamate-pyruvate transaminase (SPGT) (alanine transaminase \[ALT\]) =\<10 x upper limit of normal (ULN) for age * Note: For the purpose of this study, the ULN for SGPT (ALT) has been set to the value of 45 U/L

Exclusion Criteria:

* Expected inability to tolerate oral formulation (e.g., unable swallow whole tablets) of letermovir * Note: Determination of ability to tolerate the oral formulation will be based on a self-assessment or caregiver assessment; eligible subjects and their caregiver will be shown a life size picture of a tablet (or actual tablet) and confirm ability to swallow whole tablet in order to meet study eligibility * Hypersensitivity to letermovir or any component of the formulation * History of CMV end organ disease within 6 months (180 days) prior to enrollment * Note: CMV end organ disease based on proposed definitions by Ljungman et al. and inclusive of proven, probable or possible disease * Receipt of prior allogeneic HCT within one year of study enrollment * Planned prophylactic administration of other anti-CMV medications or cellular products during the study, including: * High dose acyclovir (defined as doses \>= 1500 mg/m\^2 IV or \>= 3200 mg oral (patients \>= 40 kg) or \>= 2400 mg/m\^2 (patients \< 40 kg) per day) * High dose valacyclovir (defined as doses \>= 3000 mg/day in patients \> 20 kg) * Foscarnet * Ganciclovir * Valganciclovir * CMV-directed cytotoxic T lymphocytes * Planned receipt of the following contraindicated medications during the study treatment period; contraindicated medications must be discontinued at least 14 days prior to Day +1 * Contraindicated medications for all patients: * Pimozide * Ergot alkaloids * Contraindicated medications for patients planned to receive cyclosporine: * Bosentan * Lovastatin * Pitavastatin * Rosuvastatin * Simvastatin * Female patients who are pregnant since fetal toxicities and teratogenic effects have been noted in certain animal reproduction studies with letermovir. A pregnancy test is required for female patients of childbearing potential * Lactating females who plan to breastfeed their infants * Sexually active female patients of reproductive potential who have not agreed to use an effective contraceptive method for the duration of their letermovir treatment and through at least 4 weeks after the last dose of letermovir. * Note: No contraception measures are needed specifically during letermovir treatment for male trial participants who have pregnant or non-pregnant female partner(s) of reproductive potential. Contraception measures may be required for other aspects of the HCT procedure. * All patients and/or their parents or legal guardians must sign a written informed consent * All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

Conditions & Interventions

Interventions:
PROCEDURE: Biospecimen Collection, DRUG: Letermovir
Conditions:
Hematopoietic and Lymphoid Cell Neoplasm, Malignant Solid Neoplasm

More Information

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