Belumosudil to Block Chronic Lung Allograft Dysfunction (CLAD) in High Risk Lung Transplant Recipients

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 years and over
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Participant and/or parent or guardian must be able to understand the purpose of the study, willing to participate, sign the informed consent, and if applicable assent.
2. Single or bilateral lung transplant recipient age ≥ 12 years
3. A qualifying biopsy obtained 60 to 760 days after lung transplant with evidence of allograft injury histology; a qualifying biopsy must have one or more of the following features alone or in combination: Acute Rejection (AR), Lymphocytic Bronchiolitis (LB), Organizing Pneumonia (OP), or Acute Lung Injury (ALI). The presence of any grade AR (A1 or greater) or LB (B1 or greater) qualifies for inclusion
4. Females of reproductive potential and males with female partners of reproductive potential must agree to use effective contraception during treatment with belumosudil or placebo and for at least 3 months after the last dose. Participants must agree to refrain from donating or cryopreserving sperm, eggs (ova or ovocytes) for the purpose of reproduction during treatment with belumosudil or placebo and for at least 3 months after the last dose.
5. Meeting hematologic laboratory criteria: absolute neutrophil count (ANC) >= 0.5 x 10(9)/L and platelet count >= 50 x 10(9)/L within 30 days of enrollment
6. Meeting all blood chemistry laboratory criteria: aspartate aminotransferase (AST) or alanine transaminase (ALT) < 2x upper limit of normal (ULN), bilirubin < 1.5x ULN unless due to Gilbert's syndrome, estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m2 within 30 days of enrollment
7. Cytomegalovirus (CMV) polymerase chain reaction (PCR) negative or, if detected, <200 IU/ml in the absence of any signs of active infection, within 30 days of enrollment
8. In the absence of contraindications, must have received adult vaccinations or documented immunity as outlined in current National Institute of Allergy and Infectious Diseases (NIAID) Division of Allergy, Immunology, and Transplantation (DAIT) Guidance for Patients in Transplant Trials
9. Intent to receive calcineurin inhibitor (CNI)-based maintenance Immunosuppression (IS) regimen

Exclusion Criteria:

1. Multi-organ transplants involving more than one organ type (e.g., heart-lung)
2. Prior organ transplant or prior bone marrow transplant/hematopoietic stem cell transplantation
3. Greater than 160 days after a qualifying biopsy
4. Active AMR unless resolved and no treatments with prohibited medications for > 90 days prior to enrollment
5. Diagnosed with probable or definite CLAD according to International Society for Heart and Lung Transplantation (ISHLT) guidelines prior to enrollment.
6. Posttransplant treatment with anti-thymocyte globulin within 30 days or alemtuzumab or any other prohibited medication within 90 days prior to enrollment.
7. Epstein-Barr virus (EBV) seronegative recipient who received EBV positive donor lung(s).
8. Treatment with any other investigational pharmacologic agent within 30 days prior to enrollment.
9. Significant active uncontrolled infection which, in the opinion of the investigator, would place the participant at increased risk.
10. Current use of sirolimus or everolimus.
11. Recipient human immunodeficiency virus (HIV) positive.
12. Recipient Hepatitis B surface antigen positive or Hepatitis B core antibody positive.
13. Received lung(s) from a donor with known Hepatitis B virus (HBV) including Hepatitis B core antibody positive donors.
14. Incompletely treated Hepatitis C (absence of ongoing treatment and post-transplant negative HCV PCR)
15. History of clinically significant surgical factors (such as phrenic nerve damage, transplant lung resection, chest wall surgery), or mechanical factors (such as posttransplant airways disease including bronchial dehiscence, stenosis, dilation, or stent placement, pleural disease) that impedes lung function.
16. Past or current medical problems, psychosocial concerns, or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the investigator, may pose undue risk from participation in the study, may interfere with the participant's ability to comply with study requirements, or that may impact the quality or interpretation of the data obtained from the study.
17. Pregnant or breastfeeding

Conditions & Interventions

Interventions:
DRUG: Belumosudil, DRUG: Placebo for Belumosudil
Conditions:
Lung Transplant
Keywords:
Lung Transplant, Belumosudil, CLAD, Acute Rejection, Lymphocytic Bronchiolitis, Organizing Pneumonia, Acute Lung Injury

More Information

Description:
The purpose of this study is to see if taking the study drug, Belumosudil, for 52 weeks in addition to your usual care and medication, will prevent Chronic Lung Allograft Dysfunction (CLAD) in participants who have a lung biopsy that shows evidence of rejection or inflammation to the transplanted lung(s). For this study, biopsies that show evidence of Acute Rejection (AR), Lymphocytic Bronchiolitis (LB), Organizing Pneumonia (OP) or Acute Lung Injury (ALI) are referred to as "Qualifying Biopsies"; patients who had evidence of one or more of these conditions on a recent biopsy are eligible for enrollment in this study. Belumosudil is an investigational drug that blocks a molecule in the body that reduces inflammation and scarring and may play a role in the development and progression of CLAD. Belumosudil is a drug approved by the FDA to treat adults and children 12 years and older with chronic graft-versus-host disease (cGVHD), a condition with some similarities to CLAD. The primary objective it to determine the efficacy of treatment with Belumosudil + maintenance immunosuppression (IS) versus placebo + maintenance IS on preventing the subsequent development of probable or definite CLAD, lung retransplant, or death.

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IRB Number:
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