

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

NCT06476132

Status	RECRUITING
Phase	Phase 2
Sponsor	National Institute of Allergy and Infectious Diseases (NIAID)
Enrollment	234 participants

Key Eligibility Criteria

Inclusion (9)

- 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.
 - Single or bilateral lung transplant recipient age \geq 12 years
 - A qualifying biopsy obtained 60 to 550 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
 - 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 oocytes) for the purpose of reproduction during treatment with belumosudil or placebo and for at least 3 months after the last dose.
 - Meeting hematologic laboratory criteria: absolute neutrophil count (ANC) $\geq 0.5 \times 10^9/L$ and platelet count $\geq 50 \times 10^9/L$ within 30 days of enrollment
- ... and 4 more (see full listing online)

Exclusion (17)

- Multi-organ transplants involving more than one organ type (e.g., heart-lung)
 - Prior organ transplant or prior bone marrow transplant/hematopoietic stem cell transplantation
 - Greater than 120 days after a qualifying biopsy
 - Clinical AMR prior to enrollment. Subclinical AMR is permitted if 90 days or greater prior to enrollment.
 - Diagnosed with probable or definite CLAD according to International Society for Heart and Lung Transplantation (ISHLT) guidelines prior to enrollment.
- ... and 12 more (see full listing online)

Locations (10 total)

University of California, Los Angeles (Site #: 71123), Los Angeles, California, United States
Johns Hopkins (Site #: 71119), Baltimore, Maryland, United States
University of Minnesota (Site 71151), Minneapolis, Minnesota, United States
... and 7 more locations

<https://clinicaltrials.gov/study/NCT06476132>

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