

A Trial of Felzartamab in Kidney Transplant Recipients With Late Antibody-Mediated Rejection (AMR)

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 75 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* Active or chronic active AMR (biopsy-confirmed) without TCMR per central reading, as defined by the Banff 2022 criteria. * Kidney transplant at least 6 months prior to Screening visit (recipients of either living or deceased donors). * Donor-specific antibody (DSA): Human leukocyte antigen (HLA) Class I and/or II antigen-specific DSA-positive (performed and/or de novo DSA) as determined by the local laboratory's definition of positivity using singleantigen bead-based assays within 3 months prior to randomization. Key

Exclusion Criteria:

* Transplant: Blood type (ABO)-incompatible transplant. * History of multiple organ transplants including en bloc and dual kidney transplants. * Acute, rapid decline in renal function, defined as a participant likely to require renal replacement therapy within the subsequent 30 days as determined by the Investigator. * Treatment: Prior AMR/TCMR treatment (with the exception of corticosteroids) within 3 months prior to randomization is excluded as listed below. Participants who received any of these treatments between 3 and 6 months prior to randomization must have both a renal biopsy (IC3) and DSA testing at least 6 weeks after completing (or stopping) treatment in order to confirm continuing AMR and to determine eligibility: 1. Intravenous or subcutaneous immunoglobulin (IVIg or subcutaneous immunoglobulin \[SCIg\]) or PLEX. 2. Complement system inhibitors (e.g., eculizumab). 3. Proteasome inhibitors (e.g., bortezomib). 4. Tocilizumab. e. Any other investigational agent within 3 months or 5 half-lives (whichever is longer) of randomization. Other protocol-defined inclusion/exclusion criteria apply.

Conditions & Interventions

Interventions:

DRUG: Felzartamab, DRUG: Placebo

Conditions:

Antibody-mediated Rejection

Keywords:

AMR, Felzartamab, Kidney Transplant

More Information

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Principal Investigator:

Phase: PHASE3

IRB

Number:

System ID: NCT06685757

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