A Study to Learn About the Effects of Felzartamab Infusions in Adults With Kidney Transplants Who Have Late Isolated Microvascular Inflammation

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 74 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Key

Inclusion Criteria:

* MVI (MVI ≥2), donor specific antibody (DSA)-negative that is either complement activation (C4d) negative or C4d positive (biopsy-confirmed) without T cell-mediated rejection (TCMR) per central reading, as defined by the Banff 2022 criteria. * Biopsy must be within 3 months (preferably within 1 month) prior to randomization and meet adequate criteria (option a preferred over option b): 1. Adequate: 10 or more non-sclerotic/evaluable glomeruli and two muscular arteries 2. Minimally Adequate: at least 7 non-sclerotic/evaluable glomeruli and one muscular artery * For participants who received any prior treatment for antibody-mediated rejection (AMR), MVI, or TCMR as outlined in Exclusion Criterion 5, the biopsy must be performed at least 6 weeks after completing (or stopping) prior treatment. * Kidney transplant at least 6 months prior to Screening visit (recipients of either living or deceased donors). * DSA: Human leukocyte antigen (HLA) Class I and II antigen-specific DSA-negative (preformed and de novo DSA) as determined by the local laboratory's definition of positivity using single-antigen bead-based assays within 3 months prior to randomization. Key

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Exclusion Criteria:

* Transplant: Blood type (ABO)-incompatible transplant. * History of multiple organ transplants including en bloc and dual kidney transplants. * Presence of HLA donor-specific antibodies. * Acute, rapid decline in renal function, defined as a participant likely to require renal replacement therapy within the next 30 days as determined by the Investigator. * Prior AMR or 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 MVI≥2 and DSA negative status and to determine eligibility: 1. Intravenous or subcutaneous immunoglobulin (IVIg or subcutaneous immunoglobulin \[SCIg\]) or plasma exchange (PLEX). 2. Complement system inhibitors (e.g., eculizumab). 3. Proteasome inhibitors (e.g., bortezomib). 4. The anti-interleukin-6 receptor (anti-IL-6R) tocilizumab. 5. Any B cell-depleting therapy (including anti-CD20 agents \[e.g., rituximab\]) within 3 months prior to randomization. 6. Any other investigational agent within 3 months or 5 half-lives (whichever is longer) of randomization. Note: Other protocol-defined Inclusion/Exclusion criteria may apply.

Conditions & Interventions

Interventions:
DRUG: Felzartamab, DRUG: Placebo
Conditions:
Microvascular Inflammation
Keywords:
Kidney Transplant, Kidney Transplant Rejection

More Information

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