A Study to Evaluate the Safety and Tolerability of Efgartigimod PH20 SC Given by Prefilled Syringe in Kidney Transplant Recipients With Antibody-Mediated Rejection (AMR)

Status: RECRUITING

Eligibility Criteria

Age: 18 years to 80 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* The participant is within the ages of 18 and 80 years old * The participant had a kidney transplant (living or deceased donor) at least 6 months before the study * The participant has received a diagnosis of active or chronic active antibody-mediated rejection (AMR) with detectable donor-specific antibodies at time of the study * A participant may be allowed into the study if they receive the following medications: 1. Received mycophenolate mofetil for at least 20 weeks before the study 2. Has remained on a stable dose of mycophenolate mofetil and tacrolimus for at least 4 weeks before being allowed to participate in the study 3. Has remained on tacrolimus doses between 5 to 10 ng/mL at least 4 weeks before being allowed to participate in the study 4. Steroid dose was between 0 to 10 mg per day of prednisone (or dose equivalent) for at least 4 weeks before being allowed to participate in the study

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Exclusion Criteria:

* Confirmed T-cell or mixed rejection at time of the study * Recent change in immunosuppressive therapy agents * Any other medical condition that, in the investigator's opinion, would interfere with the results of the study or put the participant at undue risk * Pregnant or lactating state or intention to become pregnant during the study The complete list of criteria can be found in the protocol

Conditions & Interventions

Interventions:
COMBINATION_PRODUCT: Efgartigimod PH20 SC - prefilled syringe, OTHER: Placebo PH20 SC - prefilled syringe
Conditions:
Antibody-mediated Rejection
Keywords:
Active AMR, Chronic active AMR, Late AMR

More Information

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IRB
Number:
System ID: NCT06503731
