ForPatients
by Roche

Renal FailureChronic Renal FailureChronic Kidney Disease

A Study of Obinutuzumab to Evaluate Safety and Tolerability in Hypersensitized Adult Participants With End Stage Renal Disease Awaiting Transplantation

Trial Status	Trial Runs In	Trial Identifier
Completed	1 Country	NCT02586051 WT29749

The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.

Official Title:

A Phase Ib, Single- and Multiple-Dose, Open-Label Study of The Safety, Pharmacokinetics and Pharmacodynamics of Obinutuzumab in Adults With End-Stage Renal Disease and Hypersensitization Awaiting Renal Transplantation

Trial Summary:

This is a Phase Ib, open-label study of single and repeat doses of obinutuzumab administered as intravenous (IV) infusion in adults with end stage renal disease (ESRD). Participants will be enrolled into two cohorts receiving either one (Cohort 1) or two or more (Cohort 2) obinutuzumab infusions. Both cohorts will receive standard pretreatments to reduce the risk of infusion-related reactions (IRRs). Desensitization Period: In Cohort 1, participants will receive single dose obinutuzumab IV infusion on Day 1. Following review of Cohort 1 aggregated safety data up to 4 weeks post dose for the last participant of Cohort 1, Cohort 2 will be allowed to proceed. In Cohort 2, participants will receive obinutuzumab IV infusion on Days 1 and 15. Transplantation Period: Participants who qualify for transplantation and receive a compatible kidney offer after inclusion in Cohort 1 or Cohort 2 will receive two additional infusions (one at the time of transplantation and second at Week 24 post-transplantation) of obinutuzumab. Assessment of the safety and tolerability of the obinutuzumab regimen will be conducted at Week 24 of the desensitization phase and at Week 28 post-transplantation. All participants will be monitored for a minimum of 12 months following the last obinutuzumab infusion.

Hoffmann-La Roche	Phase 1
Sponsor	Phase

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Trial Identifiers

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Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	**#18 Years & # 65 Years**	**No**

Inclusion Criteria:

- ESRD with a history of sensitizing events
- United network for organ sharing (UNOS) listed for a deceased donor kidney transplantation
- Estimated high likelihood of receiving an offer in the coming 12-18 months from screening as evidenced by: present on at least one match run for a deceased donor kidney during the past year, or calculated panel reactive antibody (cPRA) greater than or equal to (#) 98 percent (based on revisions to allocation policy introduced in 2014)
- Female participants of childbearing potential: agreement to remain abstinent or use two adequate methods of contraception during the treatment period and for at least 18 months after the last dose of study drug
- Male participants: agreement to remain abstinent or use contraceptive measures and agreement to refrain from donating sperm during the treatment period and for at least 12 months after the last dose of study drug

Exclusion Criteria:

- Incomplete recovery from recent major surgery or less than (<) 12 weeks since major surgery prior to baseline and participants planned surgery within 24 weeks of baseline except for kidney transplantation
- Pregnant or lactating women
- Positive serum human chorionic gonadotropin (hCG) measured at screening unless considered not clinically significant based on best medical judgement and if reassessment after #48 hours shows a less than a 2-fold rise from previous level
- Primary or secondary immunodeficiency disease
- Seropositivity for hepatitis B surface antigen (HBsAg) or hepatitis B core antibody (HBcAb) or seropositivity for Hepatitis C
- History of active or latent tuberculosis (TB) or suspicion of active TB
- Known active infection of any kind or any major episode of infection requiring hospitalization or treatment with IV anti-infective agents within 4 weeks of baseline or completion of oral anti-infective agents within 2 weeks prior to baseline
- Currently active alcohol or drug abuse or history of alcohol or drug abuse
- Participants with a history of prior kidney transplantation(s) after 6 participants with prior kidney transplants will be enrolled in the study
- Participants on peritoneal dialysis with a history of peritoneal infection at any time during the 12 weeks from prior to screening
- Participants on peritoneal dialysis with a positive culture or high cell count numbers on peritoneal fluid indicative of confirmed or suspected infection at the time of screening.
- Participants for synchronous organ transplant
- Recipients of any live attenuated vaccine(s) within 1 month of the screening visit
- Abnormal screening laboratory results
- Participants with a history of major cardiovascular or pulmonary disease
- Use of investigational agents within 12 weeks or five half-lives of randomization
- Use of an anti-CD20 therapy within the past 12 months
- Known contraindications to obinutuzumab

- History of severe allergic or anaphylactic reactions to monoclonal antibodies or components of obinutuzumab infusion