ForPatients
by Roche

Lupus Nephritis

A Study to Evaluate the Safety and Efficacy of Obinutuzumab Compared With Placebo in Participants With Lupus Nephritis (LN)

Trial Status	Trial Runs In	Trial Identifier
Completed	12 Countries	NCT02550652 2015-002022-39 WA29748

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 Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Safety and Efficacy of Obinutuzumab in Patients With ISN/RPS 2003 Class III or IV Lupus Nephritis

Trial Summary:

This Phase II study will compare the efficacy and safety of obinutuzumab plus mycophenolate mofetil (MMF)/mycophenolic acid (MPA) with placebo plus MMF/MPA in participants with proliferative LN.

Hoffmann-La Roche Sponsor	**Phase 2** Phase

NCT02550652 2015-002022-39 WA29748
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years & # 75 Years	No

Inclusion Criteria:

- Diagnosis of Systemic Lupus Erythematosus (SLE), according to current American College of Rheumatology (ACR) criteria
- Diagnosis of International Society of Nephrology/Renal Pathology Society (ISN/RPS) 2003 Class III or IV LN as evidenced by renal biopsy performed within 6 months prior to or during screening. Participants may co-exhibit Class V disease in addition to either Class III or Class IV disease
- Proteinuria (urine protein to creatinine ratio) greater than (>) 1.0

- For women who are not postmenopausal (greater than or equal to [>/=] 12 months of non-therapy-induced amenorrhea) or surgically sterile (absence of ovaries and/or uterus): agreement to remain abstinent or use two adequate methods of contraception, including at least one method with a failure rate of less than (<) 1 percent (%) per year, during the treatment period and for at least 18 months after the last dose of study drug
- For men: agreement to remain abstinent or use a condom plus an additional contraceptive method that together result in a failure rate of <1% per year during the treatment period and for at least 12 months after the last dose of study drug and agreement to refrain from donating sperm during this same period

Exclusion Criteria:

- Retinitis, poorly controlled seizure disorder, acute confusional state, myelitis, stroke or stroke syndrome, cerebellar ataxia, or dementia that is currently active and resulting from SLE
- Presence of rapidly progressive glomerulonephritis
- Severe renal impairment as defined by estimated Glomerular Filtration Rate (GFR) <30 milliliters per minute (mL/min) or the need for dialysis or renal transplant
- Greater than 50% of glomeruli with sclerosis on renal biopsy
- Treatment with cyclophosphamide or calcineurin inhibitors within the 3 months prior to randomization
- Unstable disease with thrombocytopenia or at high risk for developing clinically significant bleeding or organ dysfunction requiring therapies such as plasmapheresis or acute blood or platelet transfusions
- History of severe allergic or anaphylactic reactions to monoclonal antibodies or known hypersensitivity to any component of the obinutuzumab infusion
- Significant or uncontrolled medical disease in any organ system not related to SLE or LN, which, in the investigator's opinion, would preclude participant participation
- Concomitant chronic conditions, excluding SLE, (e.g., asthma, Crohn's disease) that required oral or systemic steroid use in the 52 weeks prior to screening
- Previous treatment with an anti-cluster of differentiation (CD20)-targeted therapy within 12 months
- Previous treatment with a biologic B-cell-targeted therapy (other than anti-CD20) within 6 months of randomization
- Known intolerance to MMF or MPA