ForPatients
*by Roche*

Autoimmune Disorder Lupus Nephritis Healthy Volunteers

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

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Recruiting | 1 Countries | YA42816 |

*The source of the below information is the publicly available website ClinicalTrials.gov. It has been summarised and edited into simpler language.*

## *Trial Summary:*

A Study to Evaluate the Effectiveness and Safety of Obinutuzumab in Chinese Participants with Class III or IV Lupus Nephritis

**F. Hoffmann-La Roche Ltd**
Sponsor

**Phase III**
Phase

**YA42816**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| Both | 18 to 75 years (inclusive) | No |

### Background and study aims:

Lupus is a disease in which the body's defense system (immune system) produces proteins called autoantibodies that attack body's own tissues and organs, including the kidneys. Lupus nephritis (LN) occurs when these proteins (autoantibodies) attack and affect structures in kidneys which causes kidney inflammation and may lead to blood in the urine, protein in the urine, high blood pressure, impaired kidney function or even kidney failure. This study is testing a drug called obinutuzumab (also known as Gazyva ® or Gazyvaro ®) which is an approved drug for certain types of blood cancers but is still an experimental drug for LN. An experimental drug means that Health Authorities have not yet approved obinutuzumab for the treatment of LN.

The purpose of this study is to compare the effects, good or bad, of obinutuzumab compared to a medication that looks like a drug but has no active ingredient (placebo) on participants with lupus nephritis.

**Who can participate?**

People with lupus nephritis between the age of 18-75 years

**What does the study involve?**

Participants will need to be a part of the study for about 2 years (including the screening period and the safety follow-up visit). Participants may remain in the study for 5 years or longer to continue receiving treatment or if additional follow-up for safety is needed. The study has following parts:

1. Screening period: Participants will be screened to check if they are eligible to participate in the study. Screening period will take place from 28 days to 1 day before the start of treatment.

2. Treatment period: During this period participants will have to get admitted to the clinic where they will be randomly assigned to three groups to receive obinutuzumab or placebo into the vein (infusion) up to Week 76. The participant and the study doctor will not know which treatment the participant is receiving.

- Group 1a will receive obinutuzumab

- Group 1b will receive obinutuzumab and one single dose of placebo

- Group 2 will receive placebo

After Week 76, participants will continue receiving treatment with obinutuzumab or placebo if the study doctor determines that participant has adequately responded to treatment.

Participants who do not respond adequately to treatment will receive open-label treatment with Obinutuzumab after Week 76. Open label means that the participant and the study doctor know that the participant is receiving obinutuzumab. During this period participants will also receive also receive corticosteroid (prednisone or a similar drug) as well as mycophenolate mofetil (MMF) by mouth in combination with obinutuzumab as standard treatment for LN.

3. Follow Visit: Participants overall health and occurrence of any side effects will be assessed during a follow up visit that may take place for at least 12 months from last dose of obinutuzumab or placebo.

During this study, participants will have 12 visits through Week 76, then subsequent visits approximately every 6 months and any additional visits if necessary for safety.

**What are the possible benefits and risks of participating?**

Participants will not receive any benefit from participating in this study, but the information learned from this study may be useful to treat future patients with LN. Participants may have side effects from the drug or procedures used in this study, and they can be mild to severe, and they can vary from person to person.

Risks Associated with Obinutuzumab:

1. Very common side effects may include decrease in red blood cells (anemia) with symptoms such as tiredness, weakness, shortness of breath, or poor ability to exercise, constipation, physical weakness, lack of energy (asthenia), pain in joints (arthralgia), back pain, cough, difficulty falling asleep (insomnia), baldness, pneumonia, decrease in platelet count, cells that help stop bleeding (thrombocytopenia), decrease in neutrophils, a type of blood cell that fights infections (neutropenia), decrease in leukocytes, a type of white blood cell (leukopenia), diarrhea, fever, cold, sinus infection (sinusitis), and/or infection of the nose and throat (nasopharyngitis), urinary tract infection, itching (pruritus).

2. Common side effects may include fever associated with decrease in neutrophils, (febrile neutropenia), common form of skin cancers (squamous/basal cell skin cancer), trouble urinating (dysuria), sore throat, stuffy or running nose, high level of uric acid in the blood (hyperuricemia), high blood pressure (hypertension), severe infection in the blood (sepsis), low blood potassium (hypokalemia, irregular heart rate (atrial fibrillation), piles (hemorrhoids), indigestion, inflammation of the skin (eczema), and or feeling low or upset (depression).

3. Side effects with unknown frequency may include brain infection (progressive multifocal leukoencephalopathy), greater risk of developing infections due to removal of cells that help the body fight infections (B-cells) by obinutuzumab, worsening of preexisting heart (cardiac) conditions, and/ or abnormal blood clotting (coagulation abnormalities).

Risks associated with study procedure:

1. Kidney tissue sample (biopsy) may cause pain, redness, swelling, excessive bleeding, bruising, or draining at the needle site.

There may be a risk in exposing an unborn child to study drug, and all risks are not known at this time. Women and men must take precautions to avoid exposing an unborn child to study drug. Participants who are pregnant, become pregnant, or are currently breastfeeding, cannot take part in this study.

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**Who is funding the study?**

F. Hoffmann-La Roche Ltd

**Who is the main contact?**

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