ForPatients
*by Roche*

Lupus Nephritis

# A clinical trial to look at how well obinutuzumab works in treating people with lupus nephritis and how safe it is (REGENCY)

A Study To Evaluate The Efficacy And Safety Of Obinutuzumab In Patients With ISN/RPS 2003 Class III Or IV Lupus Nephritis

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Active, not recruiting | 15 Countries | NCT04221477 2019-004034-42 CA41705 |

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

## *Trial Summary:*

This study will evaluate the efficacy, safety, and pharmacokinetics of obinutuzumab compared with placebo in patients with International Society of Nephrology/Renal Pathology Society (ISN/RPS) class III or IV lupus nephritis (LN) when added on to standard-of-care therapy consisting of mycophenolate mofetil (MMF) and corticosteroids.

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| **Hoffmann-La Roche**<br>Sponsor | **Phase 3**<br>Phase |

**NCT04221477 2019-004034-42 CA41705**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | >=18 Years & <= 75 Years | No |

**How does the REGENCY clinical trial work?** This clinical trial is recruiting people who have a type of disease called lupus nephritis. The purpose of this clinical trial is to compare the effects, good or bad, of obinutuzumab against a placebo in patients with lupus nephritis. Patients who take part in this clinical trial will receive either obinutuzumab or a placebo, in addition to standard treatment with mycophenolate mofetil (MMF) and corticosteroids.

**How do I take part in this clinical trial?** To be able to take part in this clinical trial, you must have been diagnosed with class III or IV lupus nephritis that has been previously treated with corticosteroids within the last 6 months. Patients who have severely damaged

kidneys, are being treated with certain medications and/or women who are pregnant or breast feeding will not be able to take part.

If you think this clinical trial may be suitable for you and would like to take part, please talk to your doctor. If your doctor thinks that you might be able to take part in this clinical trial, he/she may refer you to the closest clinical trial doctor. They will give you all the information you need to make your decision about taking part in the clinical trial. You can also find the clinical trial locations on this page.

You will have some further tests to make sure you will be able to take the treatments given in this clinical trial. Some of these tests or procedures may be part of your regular medical care. They may be done even if you do not take part in the clinical trial. If you have had some of the tests recently, they may not need to be done again.

Before starting the clinical trial, you will be told about any risks and benefits of taking part in the trial. You will also be told what other treatments are available so that you may decide if you still want to take part.

While taking part in the clinical trial, both men and women (if you are not currently pregnant but can become pregnant) will need to either take contraceptive medication or not have heterosexual intercourse for safety reasons.

**What treatment will I be given if I join this clinical trial?**

**Part 1** Everyone who joins this clinical trial will enter a screening period to make sure that they are suitable to join the trial. Patients will then be split into 3 groups and given either obinutuzumab (Groups 1 and 2) or a placebo (Group 3). Patients will have an equal chance of receiving obinutuzumab or placebo.

- Group 1: Obinutuzumab, given as an infusion into your vein on Day 1 and Weeks 2, 24, 26, 50 and 52.
- OR Group 2: Obinutuzumab, given as an infusion into your vein on Day 1 and Weeks 2, 24, 26 and 52, with a placebo on Week 50
- OR Group 3: Placebo, given as an infusion into your vein on Day 1 and Weeks 2, 24, 26, 50 and 52.

As well as treatment with obinutuzumab or placebo, all patients will receive standard treatment with mycophenolate mofetil (MMF) and corticosteroids

Part 1 is called a ‘double blind’ study. This means that neither you nor your clinical trial doctor can choose or know the group you are in. However, your clinical trial doctor can find out which group you are in, if your safety is at risk.

This is a ‘placebo-controlled’ clinical trial, which means that one of the groups will be given medicine with no active ingredients (also known as a ‘placebo’). A placebo is used to show that the doctor or the patients do not sway the results of the clinical trial.

**Part 2**

- If doctors decide you have responded ‘well’ to the treatment in Part 1, you can continue to receive your treatment at Week 80 and then every 6 months thereafter. If you continue, your group will still be ‘double blind’, i.e. you and your doctor will not know which treatment you are continuing to receive.
- If doctors decide you have had some improvement (but not quite responded ‘well’), your study doctor will discuss the option to continue treatment with obinutuzumab. You and your doctor will know which treatment you are receiving.
- If you have not had any response, or got worse, your clinical trial doctor will discuss the alternative treatment options available.

**How often will I be seen in follow-up appointments and for how long?** You will be given obinutuzumab or placebo treatments for at least 52 weeks (1 year). During Part 1, you will have an initial baseline visit on Day 1 with the clinical trial doctor followed by 10 visits on Weeks 2, 4, 12, 24, 26, 36, 50, 52, 64 and 76. Along with any scheduled treatment, these hospital visits will include checks to see how you are responding to the treatment and any side effects that you may be having. After Week 76, your clinical trial doctor will assess how you have responded to treatment. If you continue to receive treatment, you will have visits at least every 6 months thereafter. After being given your last dose you will be seen by the study doctor for around 12 months. You are free to stop treatment at any time.

**What happens if I am unable to take part in this clincial trial?** If this clinical trial is not suitable for you, you will not be able to take part. Your doctor will suggest other clinical trials that you may be able to take part in or other treatments that you can be given. You will not lose access to any of your regular care.

For more information about this clinical trial see the For Expert tab on the specific ForPatient page or follow this link to ClinicalTrials.gov

Trial-identifier: NCT04221477