ForPatients
by Roche

Chronic Obstructive Pulmonary Disease (COPD)

A clinical trial to look at how safe astegolimab is when given over a long period of time for people with chronic obstructive pulmonary disease by measuring the number and seriousness of side effects

A Study to Evaluate the Long-Term Safety of Astegolimab in Participants With Chronic Obstructive Pulmonary Disease (COPD)

Trial Status	Trial Runs In	Trial Identifier
Recruiting	22 Countries	NCT05878769 2022-502501-15-00 GB43374

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

Trial Summary:

The purpose of this study is to assess the long-term safety and to explore the efficacy of astegolimab in participants with chronic obstructive pulmonary disease (COPD) who have completed the 52-week placebo-controlled treatment period in parent studies GB43311 or GB44332.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT05878769 2022-502501-15-00 GB43374
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=40 Years & <= 90 Years	No

1. Why is the GB43374 clinical trial needed?

Chronic obstructive pulmonary disease (COPD) is a group of conditions that affect the lungs. COPD causes symptoms such as breathlessness and cough. Some people experience episodes when their symptoms flare up (known as ‘COPD exacerbations’). Having COPD exacerbations can affect how the lungs work and is linked to a worsening quality of life. Standard of care treatments for COPD include inhalers of corticosteroids (to reduce inflammation) and bronchodilators (to relax lung muscles and widen airways).

Better treatments are needed to prevent COPD from getting worse, reduce exacerbations and improve overall health-related quality of life.

Astegolimab is a type of drug called a monoclonal antibody that may effectively reduce COPD exacerbations. Astegolimab is an experimental drug, which means health authorities have not approved it for treating COPD. In two previous clinical trials (called 'parent' trials or studies), people with COPD were given astegolimab or placebo (a substance with no active ingredients which looked like astegolimab) as a subcutaneous injection. This clinical trial is called an 'extension' trial or study - people who completed one of the parent trials and agree to join the extension trial will be given astegolimab on a long-term basis. This extension trial aims to test the long-term safety of astegolimab in combination with standard of care COPD treatment.

2. How does the GB43374 clinical trial work?

This clinical trial is recruiting people with COPD. People can take part if they have completed a year of treatment with astegolimab or placebo in one of the two parent trials. People who take part in this clinical trial (participants) will be given the clinical trial treatment astegolimab, as well as their usual COPD medications that their doctor prescribes. Participants will continue to be given astegolimab until they decide to stop being in the trial or until the trial is stopped. Participants will be seen by the trial staff every 2 weeks to be given astegolimab treatment. After the first few treatments, the participant may choose to be given astegolimab at home (or another suitable location) instead of at the trial clinic. Participants may be offered the option and training for themselves or a caregiver to provide the treatment injections or, depending on where the participant is doing the clinical trial, for a mobile nurse (a qualified healthcare provider) to visit them to give astegolimab injections. If the participant chooses to be given astegolimab at home after the first few treatments at the clinic, the clinical trial doctor will see them at least every 3 months. Clinic visits will include checks to see how the participant responds to the treatment and any side effects they may have.

Participants will be seen in the clinic about 2 weeks after the final treatment dose and 3 months later for a follow-up visit. The total time of participation in the clinical trial will be up to 4 years, depending on if astegolimab is approved by health authorities for treating COPD in the participants' country or if the sponsor decides to stop the trial. Participants can stop treatment and leave the clinical trial at any time. The sponsor may stop the trial at any time for various reasons, including safety concerns.

3. What are the main endpoints of the GB43374 clinical trial?

The main clinical trial endpoint (the main result measured in the trial) is the number and seriousness of any side effects. The other endpoints that may be explored include how well the treatment works - by looking at:

- The number of moderate and severe COPD exacerbations while treatment is being given
- Changes in health-related quality of life, respiratory symptoms and the amount of air that participants can forcibly breathe out (called FEV1 - forced expiratory volume in 1 second)

4. Who can take part in this clinical trial?

People can take part in this trial if they have COPD and have completed one of the two parent trials of astegolimab through to Week 52.

People may not be able to take part in this trial if they are taking certain treatments or have a new diagnosis of asthma or a lung disease other than COPD. Women who are pregnant, breastfeeding or planning to become pregnant will not be able to take part in this trial.

5. What treatment will participants be given in this clinical trial?

Everyone who joins this clinical trial will be given astegolimab as two injections under the skin every 2 weeks until they decide to leave the trial, they have unmanageable side effects, or they are required to stop for other reasons (for example, if astegolimab were approved by health authorities for the treatment of COPD in the participants' country). This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the treatment or drug the participant has been given.

6. Are there any risks or benefits in taking part in this clinical trial?

The safety or effectiveness of the experimental treatment or use may not be fully known at the time of the trial. Most trials involve some risks to the participant. However, it may not be greater than the risks related to routine medical care or the natural progression of the health condition. People who would like to participate will be told about any risks and benefits of taking part in the clinical trial, as well as any additional procedures, tests, or assessments they will be asked to undergo. All of these will be described in an informed consent document (a document that provides people with the information they need to decide to volunteer for the clinical trial).

Risks associated with the clinical trial drug

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drug used in this clinical trial. Side effects can be mild to severe, even life-threatening, and vary from person to person. Participants will be closely monitored during the clinical trial; safety assessments will be performed regularly. Participants will be told about the known side effects of astegolimab and possible side effects based on human and laboratory studies or knowledge of similar drugs. Astegolimab will be given as injections under the skin (subcutaneous injections). Participants will be told about known side effects of subcutaneous injections.

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Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial. Still, the information collected may help other people with similar medical conditions and how clinical trials are designed in the future.