ForPatients
by Roche

Linfoma non-HodgkinLinfoma

Studio volto a valutare la sicurezza, la farmacocinetica e l'attività antitumorale preliminare di RO7227166 in associazione a obinutuzumab e in associazione a glofitamab dopo una dose pre-trattamento di obinutuzumab somministrati in partecipanti con linfoma non Hodgkin a cellule B recidivante/refrattario

A Study to Evaluate the Safety, Pharmacokinetics and Preliminary Anti-Tumor Activity of Englumafusp Alfa in Combination With Obinutuzumab and in Combination With Glofitamab Following a Pre-Treatment Dose of Obinutuzumab in Participants With Relapsed/Refractory B-Cell Non-Hodgkin's Lymphoma

Trial Status	Trial Runs In	Trial Identifier
In fase di reclutamento	12 Countries	NCT04077723 2019-000416-28 2022-502616-37-00 BP41072

Le informazioni sono reperite direttamente dai siti web di registri pubblici come ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com ecc. e non sono state modificate.

Official Title:

Studio di fase I in aperto volto a valutare la sicurezza, la farmacocinetica e l'attività antitumorale preliminare di RO7227166 (un ligando 4-1BB bersaglio di CD19) in associazione a obinutuzumab e in associazione a glofitamab dopo una dose pre-trattamento di obinutuzumab somministrati in partecipanti con linfoma non Hodgkin a cellule B recidivante/refrattario

Trial Summary:

Questa sperimentazione consiste in un studio di fase I, in aperto e con incremento progressivo della dose volto a valutare la sicurezza, la tollerabilità e l'efficacia di RO7227166 in partecipanti con linfoma non Hodgkin recidivante/refrattario (NHL r/r). RO7227166 verrà somministrato mediante infusione endovenosa (e.v.) in associazione a obinutuzumab e in associazione a glofitamab. Una dose fissa di obinutuzumab (Gpt; pre-trattamento) verrà somministrata sette giorni prima della prima somministrazione di RO7227166 e sette giorni prima della prima somministrazione di glofitamab. Questo studio *entry-into-human* è suddiviso in una fase con incremento progressivo della dose (Parte I e Parte II) e una fase di espansione della dose (Parte III).

Hoffmann-La Roche	Fase I
Sponsor	Phase

NCT04077723 2019-000416-28 2022-502616-37-00 BP41072

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the BP41072 clinical trial work?

This clinical trial is recruiting people who have a type of disease called B-cell non-Hodgkin's lymphoma. In order to take part, patients must have disease that has returned after successful treatment (relapsed) or that has never responded to treatment (refractory).

The purpose of this clinical trial is to test whether RO7227166 combined with either obinutuzumab or glofitamab is safe at different doses, and to look at its effects (good or bad) on you and your non-Hodgkin's lymphoma.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must be at least 18 years old and have been diagnosed with relapsed or refractory non-Hodgkin's lymphoma according to specific criteria. The clinical trial doctors will also confirm that there are no other suitable treatment options for you before you take part.

You must not be pregnant, breastfeeding or intending to become pregnant during the clinical trial. If you have certain other medical conditions or have previously received certain treatments, you may not be able to take part in this clinical trial.

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 not have heterosexual intercourse or take contraceptive medication for safety reasons.

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

This clinical trial is made up of three parts: Part I, Part II and Part III. Everyone who joins this study will be given a pre-treatment dose of obinutuzumab before they have any other treatment. This dose of obinutuzumab will be given as an infusion into the vein, either in one day (over 4–5 hours) or split over two days, depending on local guidelines.

If you join Part I of the clinical trial, you will be given:

- RO7227166 as an infusion into the vein roughly seven days after your pre-treatment dose of obinutuzumab, followed by RO7227166 and obinutuzumab as infusions into the vein every three weeks for up to a maximum of two years.

If you join Part II or III of the clinical trial, you will be given:

- Glofitamab as an infusion into the vein, between one day and seven days after your obinutuzumab pre-treatment dose, depending on whether it is given over one or two days.
- Additional doses of glofitamab will be given after the first dose – this is called step-up dosing. One week after your last step-up dose of glofitamab, you will be given the first dose of RO7227166 on its own as an infusion into the vein. The next doses of RO7227166 will be given alongside glofitamab, every three weeks for up to a maximum of 18 months.

Both you and your clinical trial doctor will know which treatment you are being given. Different doses will be tested in different participants but you will only take part in one group.

In the early stages of your treatment, you will need to stay at the hospital for some time so that the clinical trial doctors can watch you closely for any side effects:

- If you join Part I of the clinical trial, you will need to stay at the hospital for at least 48 hours after you have your first and second doses of RO7227166 i.e. you may need to stay in hospital overnight for roughly five nights in total during the first two treatment cycles.

- If you join Part II or III of the clinical trial, you will need to stay at the hospital for at least 24 hours after your first and second (and in some patients, third) step-up doses of glofitamab. If clinical trial doctors see any side effects, you will need to stay at the hospital for 36 hours after your next dose of glofitamab. You will also need to stay at the hospital for at least 48 hours after you have your first and second dose of RO7227166 (alone and with glofitamab) i.e. you may need to stay in hospital overnight for roughly seven nights in total during the first two treatment cycles.

How often will I be seen in follow-up appointments and for how long?

You are free to stop the clinical trial treatment at any time.

After being given treatment, you will still be seen regularly by the clinical trial doctor roughly every three months, also with blood tests every four weeks and phone calls every two weeks in the first four months.

During follow-up visits, your clinical trial doctor will check how you have responded to treatment and perform scans to make sure that your cancer has not come back. These visits will stop if your cancer comes back.

If you take part in Part II or III of the clinical trial and you responded well to RO7227166 plus glofitamab, you may be able to restart this treatment if your cancer gets worse while you are being seen in follow-up. To do this, your clinical trial doctor may need to repeat some tests to check the treatment is still right for you.

What happens if I am unable to take part in this clinical 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 https://clinicaltrials.gov/ct2/show/record/NCT04077723

Trial-identifier: NCT04077723

Inclusion Criteria:

Per ulteriori informazioni riguardanti lo studio e i criteri di inclusione, clicca sul seguente codice: NCT04077723

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