ForPatients
by Roche

Cancer

BX44273: A clinical trial to continue to provide cancer treatments to participants who benefitted from them in trials sponsored by Genentech Inc. and/or F. Hoffmann-La Roche Ltd

A clinical trial to continue to provide cancer treatments to participants who benefitted from them in trials sponsored by Genentech Inc. and/or F. Hoffmann-La Roche Ltd

Trial Status	Trial Runs In	Trial Identifier
Recruiting	11 Countries	NCT05862285 2023-504263-16-00 BX44273

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:

An Open-Label, Multicenter Extension Study in Patients Previously Enrolled in a Genentech and/or F. Hoffmann-La Roche Ltd Sponsored Study

Trial Summary:

The purpose of this extension study is to provide continued treatment with Roche investigational medicinal product (IMP[s]) monotherapy or Roche IMP(s) combined with other agent(s) or comparator agent(s) for eligible participants with cancer who are still on study treatment at the time of roll-over from the parent study and who do not have access to the study treatment locally.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT05862285 2023-504263-16-00 BX44273
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

1. Why is the BX44273 clinical trial needed?

People with cancer who benefit from treatment given in a clinical trial (meaning that their cancer shrinks or does not get worse) may continue to be given that treatment if there is no alternative treatment option and it is safe to do so, even if it is not approved by their health authority (such as the Food and Drug Administration, or FDA, in the United States, and the European Medicines Agency). They may also continue to be given the treatment after it is approved if their health insurance or other costs would prevent them from being able to have it.

This clinical trial aims to provide continued clinical trial treatments to people with cancer who take part in Genentech, Inc. and/or F. Hoffmann-La Roche Ltd-sponsored clinical trials (called parent trials) and who do not have access to the treatment locally.

2. How does the BX44273 clinical trial work?

This clinical trial is recruiting people with cancer. People can take part if they were previously treated in a Genentech, Inc. and/or F. Hoffmann-La Roche Ltd-sponsored clinical trial (the parent trial), and their cancer did not progress.

People who take part in this clinical trial (participants) will be given the same clinical trial treatment as in the parent trial for as long as it can help them, or until they have unacceptable side effects or the trial stops. This allows patients who benefit, to continue taking a clinical trial treatment that is otherwise not available to them. The clinical trial doctor will see them regularly. These clinic visits will include checks to see how the participant responds to the treatment and any side effects they may have and will be the same as, or like, the checks that were done in the parent trial. The total time of participation in the clinical trial will depend on how the participant continues to respond to treatment, the local availability of the treatment and if the trial is stopped. Participants can stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the BX44273 clinical trial?

The main clinical trial endpoint (the main result measured in the trial) is the number of participants who continue to take clinical trial treatment. The other clinical trial endpoint is the number and seriousness of any side effects.

4. Who can take part in this clinical trial?

People can take part in this trial if they have cancer and have benefitted from the clinical trial treatment given in the parent trial. People may not be able to take part in this trial if they have stopped the clinical trial treatment in the parent trial for more than a certain amount of time or if they have been given certain other treatments for cancer since treatment in the parent trial stopped. People will also not be able to take part if the clinical trial treatment caused serious side effects that have not gone away or if the clinical trial

treatment becomes available to them through routine healthcare outside of a clinical trial, if they are pregnant or breastfeeding, or are planning to become pregnant during the trial.

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

Everyone who joins this clinical trial will continue to be given the clinical trial treatment they received previously in a Genentech, Inc. and/or F. Hoffmann-La Roche Ltd-sponsored parent clinical trial. The treatment will be given in the same way as in the parent trial (for example, as an injection under the skin, an infusion into the vein, or as a tablet to be swallowed). This is an open-label trial, which means everyone involved, including the participant and the clinical trial doctor, will know the clinical trial treatment 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 drugs

Participants may have side effects (an unwanted effect of a drug or medical treatment) from the drugs 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 clinical trial treatments and possible side effects based on human and laboratory studies or knowledge of similar drugs. Participants will be told about any known side effects of how the treatment will be given – for example, injections under the skin (subcutaneous injections), infusions into a vein (intravenous infusions), or swallowing tablets.

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 in the future.

Inclusion Criteria:

- Eligible for continuing Roche IMP-based therapy at the time of roll-over from the parent study, as per the parent study protocol OR
- Eligible for continuing the comparator agent(s) in a Genentech- or Roche-sponsored study as per the parent study protocol, with no access to commercially available comparator agent
- First dose of study treatment in this extension study will be received within 7 days of the treatment interruption window allowed by the parent study
- Continue to benefit from the Roche IMP-based therapy or comparator at the time of roll-over from the parent study as assessed by the investigator
- Ability to comply with the extension study protocol, per Investigator's judgement

Exclusion Criteria:

- Meet any of the study treatment discontinuation criteria specified in the parent study at the time of enrollment in this extension study
- Study treatment or comparator agent is commercially marketed in the participant's country for the participant-specific disease and is accessible to the participant
- Treatment with any anti-cancer treatment (other than treatment permitted in the parent study) during the time between last treatment in the parent study and the first dose of study treatment in this extension study
- Permanent discontinuation of all study treatment(s) or comparator agent(s) for any reason during the parent study or during the time between last treatment in the parent study and the first dose of study treatment in this extension study (if applicable)
- Ongoing SAE(s) that has not resolved to baseline level or Grade #1 from the parent study or during the time between the last treatment in the parent study and the first dose of study treatment in this extension study
- Concurrent participation in any therapeutic clinical trial (other than the parent study)