ForPatients
by Roche

Breast Cancer HER2-Positive Breast Cancer

A clinical trial to compare the combination of atezolizumab plus trastuzumab emtansine versus trastuzumab emtansine in people with HER2-positive breast cancer who still have tumor tissue in the breast(s) and/or lymph nodes in the underarm area after the anti-cancer treatment received before surgery.

A Study Evaluating the Efficacy and Safety of Adjuvant Atezolizumab or Placebo and Trastuzumab Emtansine for Participants With HER2-Positive Breast Cancer at High Risk of Recurrence Following Preoperative Therapy

Trial Status	Trial Runs In	Trial Identifier
Recruiting	32 Countries	NCT04873362 2020-003681-40, 2023-503568-18-00 WO42633

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 is a Phase III, two-arm, randomized, double-blind placebo-controlled study in participants with HER2-positive primary breast cancer who have received preoperative chemotherapy and HER2-directed therapy, including trastuzumab followed by surgery, with a finding of residual invasive disease in the breast and/or axillary lymph nodes.

Hoffmann-La Roche	Phase 3
Sponsor	Phase

NCT04873362 2020-003681-40, 2023-503568-18-00 WO42633
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

How does the Astefania clinical trial work?

This clinical trial is recruiting people who have a particular type of breast cancer called HER2-positive primary breast cancer. HER2, or human epidermal growth factor receptor

2, is a protein that is overproduced by some cancer cells and promotes the growth of this type of cancer.

In order to take part, you must have been treated with anti-cancer therapy before surgery (preoperative therapy), which did not completely eliminate your breast cancer, with the remaining tumor tissue in your breast(s) and/or lymph nodes in your underarm removed during surgery.

Because the preoperative therapy that you received did not completely eliminate your breast cancer, you will receive a different type of treatment after surgery in this clinical trial. The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus trastuzumab emtansine versus a placebo (medicine that contains no active ingredients) plus trastuzumab emtansine in patients with HER2-positive breast cancer, who have previously received anti-cancer treatment followed by surgery. In this clinical trial, you will get either atezolizumab plus trastuzumab emtansine or placebo plus trastuzumab emtansine.

How do I take part in this clinical trial?

To be able to take part in this clinical trial, you must have been diagnosed and previously treated with anti-cancer therapy for HER2-positive breast cancer, after which some tumor tissue was detected in your breast(s) and/or lymph nodes in your underarm area and was removed with surgery.

Your breast cancer must not have spread to another part of the body (known as metastatic, or stage IV) and if you have previously received certain treatments, you may 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 not have heterosexual intercourse or take contraceptive medication for safety reasons.

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

Everyone who joins this clinical trial will be split into 2 treatment groups randomly (like flipping a coin) and receive either:

- Atezolizumab followed by trastuzumab emtansine, both given as an infusion into the vein once every 3 weeks for up to 14 cycles of treatment (experimental group)
- OR placebo followed by trastuzumab emtansine, both given as an infusion into the vein once every 3 weeks for up to 14 cycles of treatment (control group)

You will have an equal chance of being placed in any treatment group.

If you experience side effects as a result of taking trastuzumab emtansine, your doctor may recommend that you stop taking trastuzumab emtansine and switch to a similar drug called trastuzumab. This option is available to you no matter which treatment group you have been placed into.

This is a ‘placebo-controlled’ clinical trial, which means that the control group 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.

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.

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

You will be given the clinical trial treatment atezolizumab plus trastuzumab emtansine OR placebo plus trastuzumab emtansine for up to 14 cycles of treatment (approximately 10 months). You are free to stop this treatment at any time. While being given treatment, you will be seen by the clinical trial doctor for regular checks to see how you are responding to the treatment and any side effects that you may be having.

After your last treatment, you will be contacted by telephone and/or clinic visits every 3 months for the first 2 years, every 6 months for the following 3 years, and annually from year 6 until at least year 10 and up to year 14, depending on when you enter the study.

ForPatients
by Roche

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/NCT04873362

Trial-identifier: NCT04873362