ForPatients
by Roche

Neoplasm Metastasis Cancer

An Extension Study of trastuzumab emtansine administered as a single agent or in combination with other anti-cancer therapies in patients previously enrolled in a Genentech and /or F. Hoffmann-La Roche Ltd. – sponsored trastuzumab emtansine study

A Safety Extension Study of Trastuzumab Emtansine in Participants Previously Treated With Trastuzumab Emtansine Alone or in Combination With Other Anti-Cancer Therapy in One of the Parent Studies

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	35 Countries	NCT00781612 BO25430, 2023 TDM4529g

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 global, multicenter, open-label safety extension study. Participants receiving single-agent trastuzumab emtansine or trastuzumab emtansine administered in combination with other anti-cancer therapies in a Genentech / Roche-sponsored parent study who are active and receiving benefit at the closure of parent study are eligible for continued treatment in this study.

Genentech, Inc.
Sponsor

Phase 2
Phase

NCT00781612 BO25430, 2023 TDM4529g
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is this study needed?

Breast cancer is a health condition where cancer cells form in the breast. Breast cancer can sometimes be diagnosed as ‘metastatic’. Metastatic cancer is cancer that has spread to other parts of the body. Some cancers have more human epidermal growth factor

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receptor 2 (HER2) than normal. HER2 is a protein involved in normal cell growth. When cancers are ´HER2-positive', the extra HER2 causes cancer cells to grow more quickly. Better treatments are needed for HER2-positive breast cancers that have spread to other parts of the body.

This study is testing a medicine called trastuzumab emtansine on its own and combined with other anti-cancer medicines (atezolizumab, pertuzumab, docetaxel and paclitaxel).

Trastuzumab emtansine on its own is approved in some countries by health authorities like the U.S. Food and Drug Administration and European Medicines Agency. This is for HER2-positive breast cancer that has been treated with trastuzumab and another type of anti-cancer medicine called a taxane. Atezolizumab is approved in some countries for treating a type of breast cancer called 'triple negative breast cancer' that has spread. It is not approved for treating HER2-positive breast cancer. Pertuzumab in combination with trastuzumab is approved in some countries for treating HER2-positive breast cancer that has spread. Pertuzumab combined with trastuzumab and either docetaxel or paclitaxel are also approved in some countries to treat HER2-positive breast cancer. This includes cases with or without spread.

Trastuzumab emtansine combined with other anti-cancer medicines are experimental treatments. This means health authorities have not approved these combinations for the treatment of HER2-positive breast cancer. This study aims to continue to assess the safety of trastuzumab emtansine. It will be studied on its own and combined with other anti-cancer medicines. The study will include people with HER2-positive breast cancer that has spread. Participants must have benefited from trastuzumab emtansine or trastuzumab treatment in a Genentech and/or F. Hoffmann-La Roche Ltd–sponsored study (called a parent study).

2. Who can take part in the study?

People of 18 years of age or older with HER2-positive breast cancer that has spread can take part in the study. But only if they have completed treatment in a parent study within the last 6 weeks. They must be expected to benefit from being given trastuzumab emtansine or from continuing their study treatment. They must also not be able to access their study treatment elsewhere.

People may not be able to take part in this study if their cancer got worse during the parent study. People who had unwanted effects from study medicines that were serious or caused them to stop treatment also cannot take part. People who are pregnant, or currently breastfeeding cannot take part in the study.

3. How does this study work?

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Participants will be screened to check if they are able to participate in the study. The screening period will take place from 1 day to 1 month before the start of treatment.

Everyone who joins this study will continue to receive the same study treatment they were given during the parent study. Treatment will be once a week or once every 3 weeks instead if participants agree. If a participants' cancer got worse when being given trastuzumab and docetaxel in the parent study, they may be given trastuzumab emtansine instead. If participants no longer benefit from trastuzumab and docetaxel during this study, they may get trastuzumab emtansine. This includes those who have unacceptable unwanted effects. Study treatment will be given as often as it was given during the parent study.

This is an open-label study. This means everyone involved, including the participant and the study doctor, will know the study treatment the participant has been given.

During this study, the study doctor will see participants regularly to see how well the treatment is working and any unwanted effects participants may have. Participants will have a follow-up visit within 1 month of stopping study treatment, during which the study doctor will check on the participant's wellbeing. Participants who can get pregnant will also have 2 follow-up visits 3 and 7 months after stopping study treatment. Total time of participation in the study could be more than 1 month. Participants have the right to stop study treatment and leave the study at any time, if they wish to do so. Participants will not lose access to regular care if they stop study treatment.

4. What are the main results measured in this study?

The main results measured in the study to assess if the medicines have worked are:

- The number of participants who have unwanted effects and serious unwanted effects
- The number of participants who stop study treatment or have a lower dose of study treatment due to unwanted effects

5. Are there any risks or benefits in taking part in this study?

Taking part in the study may or may not make participants feel better. But the information collected in the study can help other people with similar health conditions in the future.

It may not be fully known at the time of the study how safe and how well the study treatment works. The study involves some risks to the participant. But these risks are generally not greater than those related to routine medical care or the natural progression of the health condition. People interested in taking part will be informed about the risks and benefits, as well as any additional procedures or tests they may need to undergo. All details of the study will be described in an informed consent document. This includes information about possible effects and other options of treatment.

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Risks associated with the study medicines Participants may have unwanted effects of the medicines used in this study. These unwanted effects can be mild to severe, even life-threatening, and vary from person to person. During this study, participants will have regular check-ups to see if there are any unwanted effects.

Trastuzumab emtansine, atezolizumab, pertuzumab, trastuzumab, docetaxel and paclitaxel Participants will be told about the known unwanted effects of trastuzumab emtansine, atezolizumab, pertuzumab, trastuzumab, docetaxel and paclitaxel, and possible unwanted effects based on human and laboratory studies or knowledge of similar medicines. Known unwanted effects include difficulty breathing while resting, feeling tired or weak, having a lack of energy, rash, fever, a feeling of coldness that makes the body shiver, cough, difficulty sleeping, throwing up and wanting to throw up.

Trastuzumab emtansine, atezolizumab, pertuzumab, trastuzumab, docetaxel and paclitaxel will be given as a drip into a vein (infusion). Known unwanted effects of drips into a vein include itching, rash, throat pain, reddening of the skin, headache, fever, a feeling of coldness that makes the body shiver, feeling tired or weak, throwing up and wanting to throw up.

The study medicine(s) may be harmful to an unborn baby. Women and men must take precautions to avoid exposing an unborn baby to the study treatment.

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