ForPatients
by Roche

Triple Negative Breast Cancer Breast Cancer

A clinical trial to compare tobemstomig with pembrolizumab in combination with nab-paclitaxel in people with untreated breast cancer

A Study of Tobemstomig + Nab-Paclitaxel Compared With Pembrolizumab + Nab-Paclitaxel in Participants With Previously Untreated, PD-L1-Positive, Locally-Advanced Unresectable or Metastatic Triple-Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Active, not recruiting	19 Countries	NCT05852691 2022-502457-34-00 CO44194

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 efficacy and safety of a novel immunotherapy candidate, tobemstomig, in combination with nab-paclitaxel, for patients with previously untreated, locally advanced, unresectable or metastatic (Stage IV) programmed death-ligand 1 (PD-L1)-positive triple-negative breast cancer (TNBC).

Hoffmann-La Roche	Phase 2
Sponsor	Phase

NCT05852691 2022-502457-34-00 CO44194
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	>=18 Years	No

1. Why is the CO44194 clinical trial needed?

Breast cancer is a disease in which cancer cells form in the breast tissue. Breast cancer can sometimes be diagnosed as ‘locally advanced unresectable’ or ‘metastatic’. Locally advanced unresectable cancer grows outside of the breast area and is not removable by surgery but has not yet spread to other body parts. Metastatic means the cancer has spread to other parts of the body.

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Triple-negative breast cancer (TNBC) is a type that does not respond to hormonal treatments or treatments that target a protein called HER2 found in other types of breast cancer. Programmed death ligand 1 (PD-L1) is a protein that regulates the body's immune response that can be found in higher-than-normal amounts on some types of cancer cells (known as 'PD-L1-positive cells'). TNBC that is PD-L1 positive is currently treated with chemotherapy (such as nab-paclitaxel) combined with a medicine that helps the body to use its own immune system to fight the cancer (known as 'immunotherapy', such as pembrolizumab) if it is available and approved locally by health authorities for use. These treatments can stop working after time, so better treatments are needed for PD-L1-positive TNBC.

Researchers hope that new drugs, like tobemstomig, used in combination with chemotherapy will provide better outcomes for people with PD-L1-positive TNBC. Tobemstomig is an experimental drug – which means it is not approved to treat PD-L1 positive TNBC.

This clinical trial aims to compare the effects, good or bad of tobemstomig plus nab-paclitaxel with pembrolizumab plus nab-paclitaxel in people with untreated PD-L1-positive TNBC that is locally advanced unresectable or metastatic.

2. How does the CO44194 clinical trial work?

This clinical trial is recruiting people who have untreated PD-L1-positive TNBC that is locally advanced unresectable or metastatic.

People who take part in this clinical trial (participants) will be given the clinical trial treatment tobemstomig plus nab-paclitaxel OR pembrolizumab plus nab-paclitaxel for 2 years or until their cancer symptoms get worse or until the clinical trial treatment becomes intolerable. The clinical trial doctor will see them approximately 10 times each 12 weeks. The 12-week visit schedule will be repeated for up to 2 years for as long as the participant continues to agree to take the clinical trial treatment. These clinic visits will include checks to see how the participant is responding to the treatment and any side effects they may have. Participants who complete 2 years of treatment without their cancer worsening, and whose TNBC worsens after stopping treatment, may be able to continue being given the same clinical trial treatment if the trial has not stopped. However, they cannot have had a different treatment outside of the clinical trial. After the last dose of treatment, participants will be seen 1 month later, then followed up every 3 months at clinic visits, by telephone or through their medical records, for as long as they agree to it. The total time of participation in the clinical trial will depend on how the participants' breast cancer responds to treatment and could be more than 2 and a half years. Participants are free to stop trial treatment and leave the clinical trial at any time.

3. What are the main endpoints of the CO44194 clinical trial?

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The main clinical trial endpoint (the main result that is measured in the trial to see if the treatment has worked) is how much time there is between the start of the trial and participants cancer worsening (known as ‘progression-free survival’).

The other clinical trial endpoints include:

- The number and seriousness of any side effects
- The number of participants whose tumours have got smaller and the amount of time this lasts if disease then progresses (known as ‘objective response rate')
- How long participants live (known as ‘overall survival’)
- How the body processes tobemstomig, and how tobemstomig affects the immune system

4. Who can take part in this clinical trial?

People can take part in this trial if they are aged at least 18 years old and have been diagnosed with PD-L1-positive, metastatic, or locally advanced unresectable TNBC.

People may not be able to take part in this trial if they have received previous treatment for their locally advanced unresectable or metastatic breast cancer (except radiotherapy) or have received certain other treatments before, including pembrolizumab or chemotherapy within 1 year. People with certain other medical conditions, such as heart, lung, autoimmune disease or certain infections, or who are pregnant, or breastfeeding, will not be able to take part.

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

Everyone in this clinical trial will join 1 of 2 groups randomly (like flipping a coin) and be given either:

- Group 1: tobemstomig, given as an infusion into a vein every 3 weeks, and nab-paclitaxel, given as an infusion into a vein 3 times each month (every week for 3 weeks followed by 1 week off)
- Group 2: pembrolizumab, given as an infusion into a vein every 3 weeks, and nab-paclitaxel, given as an infusion into a vein 3 times each month (every week for 3 weeks followed by 1 week off)

Participants will have an equal chance of being placed in either group. This is a double-blinded trial, which means that neither the participant nor the clinical trial doctor can choose or know the group the participant is in, until the trial is over. This approach helps to prevent bias and expectations about what will happen. However, the participant’s clinical trial doctor can find out which group the participant is in, if their safety is at risk.

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

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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 and even life-threatening, and can vary from person to person. Potential participants will be told about the known side effects of tobemstomig, pembrolizumab and nab-paclitaxel, and where relevant, also potential side effects based on human and laboratory studies or knowledge of similar drugs. Tobemstomig, pembrolizumab and nab-paclitaxel will each be given as an infusion into a vein (intravenous). Participants will be told about any known side effects of intravenous infusion.

Potential benefits associated with the clinical trial

Participants' health may or may not improve from participation in the clinical trial, but the information that is collected may help other people who have a similar medical condition in the future.

For more information about this clinical trial see the **For Expert** tab on the specific ForPatients page or follow this link to ClinicalTrials.gov

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