ForPatients
by Roche

Cáncer de mama triple negativoCáncer de mama

A clinical trial to look at how safe and effective atezolizumab plus nab-paclitaxel is for treatment of triple-negative breast cancer (TNBC) that cannot be removed with surgery

A Study of Atezolizumab (Tecentriq) Plus Nab-Paclitaxel or Paclitaxel in the Treatment of Unresectable Locally Advanced or Metastatic Triple#Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Completo	13 Countries	NCT04148911 2019-002488-91 MO39874

La información se obtuvo directamente de sitios web de registros públicos, como ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., y no se ha editado.

Official Title:

An Open-Label, Phase IIIb, Single Arm, Multicenter Safety Study of Atezolizumab (Tecentriq) Plus Nab-Paclitaxel in the Treatment of Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer

Trial Summary:

Study MO39874 is an open-label, Phase IIIb, single arm, global study conducted in participants with unresectable locally advanced or metastatic PD-L1-positive Triple-Negative Breast Cancer (TNBC) who have not received chemotherapy for their unresectable locally advanced or metastatic disease.

Hoffmann-La Roche Sponsor	**Phase 3** Phase

NCT04148911 2019-002488-91 MO39874
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	#18 Years	No

How does the MO39874 clinical trial work?

This clinical trial is recruiting people who have a particular type of breast cancer called ‘triple-negative breast cancer’ or TNBC. In order to take part, patients must have inoperable TNBC that has spread to other parts of the body.

The purpose of this clinical trial is to look at the effects, good or bad, of atezolizumab plus nab-paclitaxel in patients with TNBC. In this clinical trial, you will be treated with atezolizumab plus nab-paclitaxel.

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 inoperable TNBC that has spread to other parts of your body. Doctors must also be able to detect a protein called PD-L1 on the surface of the immune cells that infiltrate your tumour, when looking through a microscope.

You must not have previously received treatment for your inoperable TNBC (radiotherapy is allowed) and you must not be pregnant or breastfeeding. If you have certain other medical conditions or have previously received certain other treatments, you may also 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?

Everyone who joins this clinical trial will be given:

- Atezolizumab as an infusion into your vein on Day 1 and Day 15 of every 28-day (4-week) cycle

AND

- Nab-paclitaxel as an infusion into your vein on Day 1, Day 8 and Day 15 of every 28-day (4-week) cycle

How often will I be seen in follow-up appointments and for how long?
You will be given the clinical trial treatment atezolizumab plus nab-paclitaxel for as long as it can help you. You are free to stop this treatment at any time. During the clinical trial you will have regular visits with your clinical trial doctor so that he/she can see how you are responding to treatment.

After being given treatment, you will still be contacted regularly every three months (either by phone or with a clinic visit) for as long as you agree.

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/NCT04148911

Trial-identifier: NCT04148911

Inclusion Criteria:

- Unresectable locally advanced or metastatic, histologically documented TNBC (negative for HER2 and ER and PgR)
- At least one specimen positive for PD-L1 status as determined by VENTANA PD-L1 SP142 IHC Assay
- No prior chemotherapy, experimental or targeted systemic therapy for unresectable locally advanced or metastatic TNBC
- Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1 or 2
- Life expectancy # 12 weeks
- Measurable disease, as defined by RECIST v1.1
- Adequate haematologic and end-organ function, defined by the following laboratory results obtained within 14 days prior to the initiation of study treatment
- Negative hepatitis B surface antigen (HBsAg) test at screening
- Negative total hepatitis B core antibody (HBcAb) test at screening, or positive HBcAb test followed by a negative hepatitis B virus (HBV) deoxyribonucleic acid (DNA) test at screening
- Negative hepatitis C virus (HCV) antibody test at screening, or positive HCV antibody test followed by a negative HCV ribonucleic acid (RNA) test at screening
- Patients with treated asymptomatic central nervous system (CNS) metastases are eligible, provided that all the following criteria are met: (a) The metastases are limited to the supratentorial region or cerebellum (b) No ongoing requirement for corticosteroids as therapy for CNS disease (c) No stereotactic radiation within 7 days or whole-brain radiation or neurosurgical resection within 2 weeks before the start of study treatment (d) Radiographic demonstration of interim stability between the completion of CNS-directed therapy and the screening imaging study.

- Patients with a history of autoimmune disease (Appendix 2) are allowed if controlled and on stable treatment (i.e., same treatment, same dose) for the last 12 weeks
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive methods that result in a failure rate of < 1% per year, during the treatment period and for at least 5 months after the last dose of atezolizumab or 6 months after the last dose of nab-paclitaxel/paclitaxel, whichever is later. In addition, women must refrain from donating eggs during the same time period
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm
- Women who are not postmenopausal (# 12 months of non-therapy-induced amenorrhea) or surgically sterile must have a negative serum pregnancy test result within 14 days prior to initiation of study drug

Exclusion Criteria:

Cancer- Specific Exclusion Criteria:

- Spinal cord compression not definitively treated with surgery and/or radiation, or previously diagnosed and treated spinal cord compression without evidence that disease has been clinically stable for > 2 weeks prior to the first dose of study treatment (Cycle 1, Day 1).
- Leptomeningeal carcinomatosis or any symptomatic CNS metastases
- Uncontrolled symptomatic pleural effusion, pericardial effusion, or ascites
- Uncontrolled tumour-related pain
- Uncontrolled hypercalcemia (> 1.5 mmol/L ionized calcium or calcium > 12 mg/dL or corrected serum calcium > ULN) or symptomatic hypercalcemia requiring continued use of bisphosphonate therapy.
- Malignancies other than breast cancer within 5 years prior to the first dose of study treatment (Cycle 1, Day 1), with the exception of those with a negligible risk of metastasis or death and treated with expected curative outcome

General Medical Exclusion Criteria:

- Pregnancy or lactation
- Evidence of significant uncontrolled concomitant disease that could affect compliance with the protocol or interpretation of results, including significant liver disease
- Significant cardiovascular disease such as New York Heart Association (NYHA) cardiac disease (Class II or greater), myocardial infarction within 3 months prior to the first dose of study treatment (Cycle 1, Day 1), unstable arrhythmias, or unstable angina
- Severe infection within 4 weeks prior to the first dose of study treatment (Cycle 1, Day 1), including but not limited to hospitalization for complications of infection, bacteraemia, or severe pneumonia, or any active infection, that in the opinion of the investigator, could impact patient safety.
- Treatment with oral or IV antibiotics within 2 weeks prior to initiation of study treatment (Cycle 1, Day 1)
- Major surgical procedure within 28 days prior to the first dose of study treatment (Cycle 1, Day 1), or anticipation of the need for a major surgical procedure during the course of the study (other than diagnostic procedures)
- Treatment with investigational therapy within 4 weeks prior to Cycle 1, Day 1
- Known hypersensitivity to nab-paclitaxel or any of the excipients, when nab-paclitaxel is used as a backbone taxane
- Known hypersensitivity to paclitaxel or any of the excipients, when paclitaxel is used as a backbone taxane
- Positive human immunodeficiency virus (HIV) test at screening, unless the patient meets all of the following conditions: stable on anti-retroviral therapy, CD4 count #200/mL, undetectable viral load

- Any other disease, metabolic dysfunction, physical examination finding, or clinical laboratory finding that contraindicates the use of an investigational drug, may affect the interpretation of the results, or may render the patient at high risk from treatment complications

Exclusion Criteria Related to Atezolizumab:

- History of severe allergic, anaphylactic, or other hypersensitivity reactions to chimeric or humanized antibodies or fusion proteins
- Known hypersensitivity or allergy to biopharmaceuticals produced in Chinese hamster ovary cells or any component of the atezolizumab formulation
- Prior allogenic stem cell or solid organ transplantation
- History of idiopathic pulmonary fibrosis (including pneumonitis), drug-induced pneumonitis, organizing pneumonia (i.e., bronchiolitis obliterans, cryptogenic organizing pneumonia), or evidence of active pneumonitis on screening chest CT scan
- Current treatment with anti-viral therapy for HBV
- Active tuberculosis
- Receipt of a live, attenuated vaccine within 4 weeks prior to the first dose of study treatment (Cycle 1, Day 1), or anticipation that such a live, attenuated vaccine will be required during atezolizumab treatment or within 5 months following the final dose of atezolizumab
- Prior treatment with CD137 agonists or immune checkpoint blockade therapies (including anti-CTLA4 antibodies), except for anti-PD-1 or anti-PD-L1 antibodies.
- Treatment with systemic immunostimulatory agents (including but not limited to interferons or IL-2) within 4 weeks or five half-lives of the drug (whichever is longer) prior to the first dose of study treatment (Cycle 1, Day 1)
- Only in patients without autoimmune disease: Treatment with systemic corticosteroids or other systemic immunosuppressive medications (including but not limited to prednisone, dexamethasone, cyclophosphamide, azathioprine, methotrexate, thalidomide, and antitumour necrosis factor [TNF] agents) within 2 weeks prior to the first dose of study treatment (Cycle 1, Day 1), or anticipated requirement for systemic immunosuppressive medications during the study