ForPatients
by Roche

Triple Negative Breast CancerBreast Cancer

A clinical trial to compare atezolizumab plus chemotherapy with chemotherapy alone in people with triple-negative breast cancer (ALEXANDRA/IMpassion030/BIG 16-05/AFT-27).

A Study Comparing Atezolizumab (Anti PD-L1 Antibody) In Combination With Adjuvant Anthracycline/Taxane-Based Chemotherapy Versus Chemotherapy Alone In Patients With Operable Triple-Negative Breast Cancer

Trial Status	Trial Runs In	Trial Identifier
Terminated	31 Countries	NCT03498716 2016-003695-47 WO39391

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:

A Phase III, Multicenter, Randomized, Open-Label Study Comparing Atezolizumab (Anti PD-L1 Antibody) in Combination With Adjuvant Anthracycline/Taxane-Based Chemotherapy Versus Chemotherapy Alone in Patients With Operable Triple Negative Breast Cancer

Trial Summary:

This study will evaluate the efficacy, safety, and pharmacokinetics of adjuvant atezolizumab in combination with paclitaxel, followed by atezolizumab, dose-dense doxorubicin or epirubicin (investigator's choice), and cyclophosphamide, compared with paclitaxel followed by dose-dense doxorubicin or epirubicin (investigator's choice) and cyclophosphamide alone in patients with Stage II-III TNBC (Triple Negative Breast Cancer)

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT03498716 2016-003695-47 WO39391
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 18 Years	No

How does the ALEXANDRA/IMpassion030 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 operable TNBC.

The purpose of this clinical trial is to compare the effects, good or bad, of atezolizumab plus chemotherapy versus chemotherapy alone in patients with TNBC. In this clinical trial, you will get either atezolizumab plus chemotherapy or chemotherapy alone.

How do I take part in this clinical trial?
To be able to take part in this clinical trial, you must have been diagnosed with triple-negative breast cancer or TNBC and you must have had surgery to remove the tumour within the last 2 months.

You must not have previously had any other invasive breast cancers, or any previous treatment for your TNBC. You cannot join the trial if you are pregnant or breastfeeding.

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 confirm you have TNBC and 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 groups randomly (like flipping a coin) and given either:

- atezolizumab given as an infusion into your vein every 2 weeks for 5 months and then every 3 weeks for 7 months, plus chemotherapy given as an infusion into your vein
- OR chemotherapy given as an infusion into your vein

Chemotherapy will be given as a mixture of drugs:

- paclitaxel given as an infusion into your vein every week for the first 3 months

and then:

- cyclophosphamide plus doxorubicin or epirubicin given as an infusion into your vein every 2 weeks for the next 2 months

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

How often will I be seen in follow-up appointments, and for how long?
You will be given the clinical trial treatment atezolizumab and chemotherapy OR chemotherapy alone for a set amount of time (1 year for atezolizumab and 5 months for chemotherapy). You are free to stop this treatment at any time. After being given treatment, you will still be seen regularly by the clinical trial doctor. These visits will include checks to see how you are responding to the treatment and any side effects that you may be having.

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/NCT03498716

Trial-identifier: NCT03498716

Inclusion Criteria:

- Non-metastatic operable Stage II-III breast cancer
- Histologically documented TNBC (Triple Negative Breast Cancer)
- Confirmed tumor PD-L1 evaluation as documented through central testing of a representative tumor tissue specimen
- Adequately excised: Patients must have undergone either breast-conserving surgery or mastectomy/ nipple- or skin-sparing mastectomy
- Adequate hematologic and end-organ function
- For women of childbearing potential: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures
- For men: agreement to remain abstinent (refrain from heterosexual intercourse) or use contraceptive measures and agreement to refrain from donating sperm.
- No more than 8 weeks (56 days) may elapse between definitive breast surgery and randomization.
- Representative formalin-fixed, paraffin embedded (FFPE) tumor specimen from surgical resection in paraffin blocks (preferred) or at least 25 unstained slides.

Exclusion Criteria:

- Prior history of invasive breast cancer
- For the currently diagnosed breast cancer, any previous systemic anti-cancer treatment (e.g., neoadjuvant or adjuvant), including, but not limited to, chemotherapy, anti-HER2 therapy.
- Previous therapy with anthracyclines or taxanes for any malignancy
- Cardiopulmonary dysfunction
- Prior malignancies within 5 years prior to randomization, with the exception of those with a negligible risk of metastasis or death and treated with expected curative outcome
- Active or history of autoimmune disease or immune deficiency
- History of idiopathic pulmonary fibrosis, organizing pneumonia, drug-induced pneumonitis, idiopathic pneumonitis, or evidence of active pneumonitis on screening chest computed tomography (CT) scan
- Urinary outflow obstruction
- Active tuberculosis
- Major surgical procedure other than for diagnosis within 4 weeks prior to initiation of study treatment or anticipation of need for a major surgical procedure during study treatment or within 5 months following the last dose of Atezolizumab (for patients randomized to Atezolizumab)
- Prior allogeneic stem cell or solid organ transplant
- Treatment with systemic immunosuppressive medications within 2 weeks prior to initiation of study treatment or anticipation of need for systemic immunosuppressive medication during the study