20181436
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IRB Approved at the
Protocol Level
Dec 21, 2018

Keynote 756

A Clinical Trial for Early Stage Breast Cancer in both adult male and females

In this brochure, you will learn about high Risk **ER+/HER2–** (Estrogen Receptor Positive/ Human Epidermal growth factor receptor Negative) **breast cancer** and a clinical trial for this disease. This clinical trial is trying to find out if a study drug when added to chemotherapy and endocrine therapy can help stop or slow down ER+/HER2– breast cancer.

What is High Risk ER+/HER2– Breast Cancer?

ER+/HER2- breast cancer is the most common form of breast cancer. When diagnosed early and treated appropriately it has a low recurrence rate and good long term survival. However, similar to other breast cancer subtypes, ER+/HER2– breast cancer is a combination of several subtypes including what is considered a high- risk subtype. In order to determine what subtype of breast cancer you have, your doctors look to see whether your disease has certain signs such as tumor size, nodal involvement, histological grade, and certain receptors, or proteins that live in a cell. Your doctor will tell you if you are considered high risk.

What is a clinical trial?

Clinical trials are research studies that can help doctors find out if study drugs (alone or with other treatments) are safe and if they can help prevent, find, or treat diseases or conditions.
This clinical trial may include people with breast cancer that has:

- Just been diagnosed
- A high chance of coming back after it has been removed

Your treatment options

If you have newly diagnosed ER +/HER2- breast cancer, your cancer care team will discuss your treatment options with you and those close to you. Your options will depend on several things:

- The stage of your cancer, which tells you if it has spread, and if so, how far
- Your overall health
- Chance of the cancer coming back
- Side effects you might have from the treatment
- What chance the treatment has of reducing or removing the disease
- How long the treatment might help extend your life
- How much the treatment might help reduce your symptoms

Your care team may offer you one or more of these options:

- Surgery – removes all or part of the cancer
- Chemotherapy – uses medicines meant to kill the cancer cells in your body
- Radiation therapy – uses beams of intense energy meant to kill cancer cells.
- Clinical trials

Deciding to join a clinical trial is something only you, those close to you, and your doctors and nurses can decide together.

All about this clinical trial

Why is this study being done?

This study is trying to find out if a research study drug in combination with chemotherapy and endocrine therapy is safe and works to slow or stop the growth of high risk estrogen receptor positive breast cancer. Researchers don't know if this study drug works to treat this type of cancer.

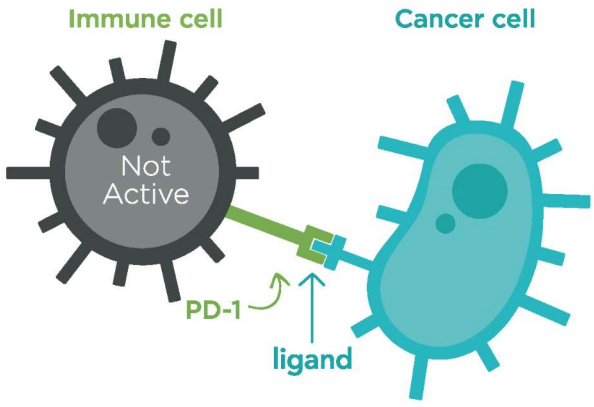
The treatment being studied

The treatment being studied is called pembrolizumab (or MK-3475). It is a type of immunotherapy, which may help the body's immune system attack cancer cells.

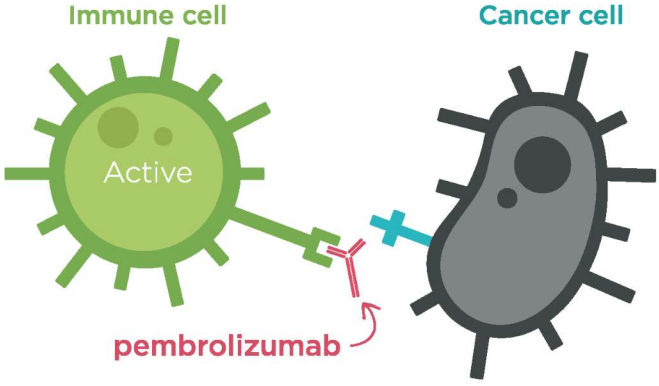
Here's how pembrolizumab (or MK-3475) works:

1. A protein called PD-1 (on some of your immune system cells) sometimes binds with certain molecules called ligands (on some cancer cells)
2. When these 2 bind, it turns off the immune system cell, which means it can't do its work to help protect you and attack cancer cells
3. This is where pembrolizumab comes in - this study drug binds with PD-1 and blocks PD-1 from binding with ligands
4. By blocking PD-1 from binding with ligands, pembrolizumab may help the immune system stay on so it can find and attack cancer cells

Another way to think about the treatment



When PD-1 and ligands bind, it's like turning off the immune cell. This means that the immune cell will not do its work to attack cancer cells.



These clinical trials are studying whether pembrolizumab can block PD-1 and ligands from binding so that the immune system cell stays on and can start working.

Who can join this study?

There are certain rules that you must meet in order to join. Your study team will give you certain tests, which will include testing a sample of your tumor for the protein PD-L1.

You and your study doctor will discuss the other rules to decide if this study is a good option for you, as well as the possible benefits and risks of joining this study.

If I join, what will happen during the study visits?

You will visit the study site on a regular schedule so that your doctors can see how the study drug is working for you. During your study visits, you might get:

- Blood tests
- Physical exams
- Research study drugs
- Imaging scans such as CAT scans or MRIs

If you join the study, your doctor will need to stay in contact with you even after your study visits are over.

This is very important because this clinical trial is studying how well the study drug works over time.

Ask your doctor any questions about what happens in the study visits and how often they will happen

Your questions and notes

To learn more

Talk to your study doctor or contact:

Keynote
Oncology Clinical Trials

MSD
Merck Sharp & Dohme
Corp., NJ USA

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