Testing the use of fulvestrant and binimetinib targeted treatment for NF1 mutation in hormone receptor-positive metastatic breast cancer

NRG ONCOLOGY

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Visit the patient webpage for this study:

ABOUT THE TRIAL

This protocol called, EAY191-N2, is part of the ComboMATCH precision medicine initiative for people that have hormone receptor-positive metastatic breast cancer with NF1 mutation. The ComboMATCH registration trial studies show how well treatment that is directed by genetic testing works in treating patients with solid tumors that have spread to nearby tissue or lymph nodes (locally advanced) or have spread to other places in the body (advanced) and have progressed on at least one line of standard systemic therapy or have no standard treatment that has been shown to prolong overall survival.

For patients who have never received the usual drug fulvestrant, EAY191-N2 specifically will be testing if the addition of the drug called binimetinib to fulvestrant can help stabilize your breast cancer and help you live longer. For patients who have received fulvestrant before, EAY191-N2 will be testing if the addition of binimetinib can shrink your breast cancer within 4 months of starting the new treatment.

ABOUT NRG ONCOLOGY

As one of the five research groups in the National Cancer Institute's (NCI) National Clinical Trials Network (NCTN), NRG Oncology carries out clinical trials on gender-specific malignancies, including gynecologic, breast, and prostate cancers, and on localized or locally advanced cancers of all types. NRG Oncology's extensive research organization includes investigators, medical oncologists, radiation oncologists, surgeons, physicists, pathologists, and statisticians. The NRG Oncology includes more than 1,300 research sites worldwide, primarily in the United States and Canada. NRG Oncology is a non-profit research organization, funded mainly through grants from the NCI. To contact NRG Oncology, call 267-519-6630 or email info@nrgoncology.org

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Frequently Asked Questions

What is a clinical trial?
Clinical trials are research studies that look to find better ways to prevent, diagnose, or treat disease.

Who can join this study?
People who have breast cancer that is hormone receptor-positive and has spread (metastasized) outside your breast, and your cancer has a change in the gene called the 'NF1 gene'. Your doctor can determine if you meet these requirements.

Am I required to be in this study?
No. Taking part in this study is voluntary. You are free to choose to participate or not to participate. If you choose to participate in this study, you are able to leave the study at any time. If you decide not to take part in this study, your doctor will discuss other treatment options with you.

What are the possible treatments?
If you decide to take part in this study, you will either get the study drugs fulvestrant and binimetinib or fulvestrant alone if you never received fulvestrant (fulvestrant-naïve) in the past. You will get the study drugs fulvestrant and binimetinib if you have previously received fulvestrant (fulvestrant-exposed). Treatment will continue until your disease gets worse, or the side effects become too severe, or you decide to stop the therapy.

How long will I be in this study?
After you have completed fulvestrant and binimetinib or fulvestrant alone, your doctor and study team will continue to watch you for side effects, until your disease gets worse, or the side effects become too severe. They will check you every 6 months for up to 5 years. This will be done at a visit to your study doctor. You will be in this study for up to 5 years from the time you join the study.

Are there side effects?
There may be. Both fulvestrant and binimetinib may cause side effects. Your doctor will review all of the potential side effects with you. You are encouraged to tell your doctor about any side effects you have during the study so that they may be treated and so that potential adjustments to the study drugs may be made.

MORE INFORMATION

Visit the National Cancer Institute website at https://www.cancer.gov for more information about studies or general information about cancer.

You may also call: 1-(800)-4-CANCER (1-800-422-6237).