

Charles E. Geyer, MD

"The CLEOPATRA study demonstrated the addition of pertuzumab to trastuzumab and docetaxel chemotherapy for patients starting treatment for metastatic HER2+ breast cancer improved median survival to almost 5 years with 40% of patients alive 7 years after beginning the therapy. Trastuzumab and pertuzumab were both designed to engage the immune system, and the results of CLEOPATRA were very consistent with a partially effective immune response. The current trial will determine if atezolizumab can make the partial immune response more effective."

-Charles E. Geyer, Jr., MD

Lois E. and Carl A. Davis Centennial Chair in Cancer Research

Deputy Director Houston Methodist Cancer Center



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Paclitaxel, Trastuzumab & Pertuzumab With or Without Atezolizumab For Metastatic HER2+ Breast Cancer

STUDY TITLE: A Randomized, Double-Blind, Phase III Trial of Paclitaxel/Trastuzumab/

Pertuzumab With Atezolizumab or Placebo in First-Line HER2-Positive

Metastatic Breast Cancer

TRIAL NUMBER: NCT03199885

FOCUS: Treatment

TRIAL PHASE: Phase III (Phase 3)

WHAT HAPPENS IN THIS STUDY?

Pertuzumab (Perjeta®) and trastuzumab (Herceptin®) are <u>HER2-targeted therapies</u> used to treat HER2-positive breast cancer. Paclitaxel (Taxol®) and docetaxel (Taxotere®) are chemotherapy drugs routinely used to treat breast cancer. Atezolizumab (Tecentriq®) is a type of immunotherapy called a PD-L1 inhibitor. This study will see if the addition of the <u>immunotherapy</u> drug, atezolizumab (Tecentriq®), to the standard treatment regimen will improve outcomes for people with HER2-positive metastatic breast cancer (MBC). Treatment will include patient/physician choice of paclitaxel or docetaxel, along with trastuzumab and pertuzumab with atezolizumab or a placebo.

This is a randomized trial, meaning that neither the physician nor the participant choose the treatment group. Instead, participants will be assigned by chance to receive either the standard treatment or the standard treatment with atezolizumab.

ARE YOU ELIGIBLE?

This is a study for women or men over age 18 with <u>HER2-positive</u> breast cancer who are starting treatment for MBC (also known as stage IV breast cancer) that has spread to other parts of the body.

The status of this study is subject to change. To see the most current information, visit clinicaltrials.gov.

WHAT WILL THIS MEAN FOR PATIENTS?

This is a promising time in MBC research with many new treatments under study. Findings from clinical trials will determine whether or not these new treatments will become a part of standard care for MBC. This study offers those involved the chance to receive a new combination therapy for HER2-positive metastatic breast cancer. It will help researchers decide if giving atezolizumab with paclitaxel or docetaxel, trastuzumab and pertuzumab works better than treatment without atezolizumab to stop the growth and spread of cancer cells.

WHO DO I CONTACT ABOUT THIS STUDY?

LEAD TRIAL PI AND TRIAL SPONSOR: Charles E. Geyer, MD (PI), NRG Oncology

STUDY LOCATIONS:

This study is offered at multiple sites across the country. See if there is a <u>research site</u> near you or get <u>contact information</u> for a study location.



KOMEN CONNECTION

Clinical trials are key to making progress against breast cancer. People who join clinical trials receive high-quality care, and at the same time contribute to research that could help themselves or others. Susan G. Komen wants to help people with breast cancer find — and participate in — clinical trials. Komen is working with the National Cancer Institute (NCI) to announce some of the clinical trials the NCI supports to test promising cancer treatments and screening methods.

SUSAN G. KOMEN BREAST CARE HELPLINE

For more information about clinical trials, please call our Helpline at 1-877 GO KOMEN (1-877-465-6636) or email at clinicaltrialinfo@komen.org to connect with a trained specialist. Our caring and trained staff provide support and education about clinical trials to help people gain a better understanding of clinical trials.

Disclaimer

This information is being provided for education purposes only and does not contain all information related to this clinical study. The study status and eligibility criteria may change. If you are interested in learning if this study is right for you, please reach out to the study coordinator or your doctor for more information.