Lay Language Summary

ABIGAIL

ABIGAIL: International, open-label, multicenter, non-inferiority, randomized phase II study of abemaciclib plus endocrine therapy with or without a short course of induction paclitaxel in patients with previously untreated HR-positive/HER2-negative advanced breast cancer with aggressive disease criteria

IMPORTANT:

- The document contains the summary of a clinical trial, and its sole purpose is to communicate the results of it to the general public.
- This document is not intended to promote recruitment or provide medical advice.
- The results reflected in this document may contradict those of other trials.
- It is not recommended to make decisions based on the information collected in this document; it should always be consulted with a medical professional beforehand.

ABOUT THIS SUMMARY

SPONSOR:	MEDICA SCIENTIA INNOVATION RESEARCH S.L.
TUMOR TYPE:	HR-positive/HER2-negative Advanced Breast Cancer
MEDICINE(S) STUDIED:	Abemaciclib Paclitaxel
DATES OF STUDY:	Ongoing from June 2021
TITLE OF THIS STUDY:	ABIGAIL: Randomized phase II study of abemaciclib plus endocrine therapy (ET) with or without a short course of induction paclitaxel in patients (pts) with previously untreated HR-positive/HER2-negative advanced breast cancer (HR+/HER2- ABC) with aggressive disease criteria
DATE OF THIS REPORT:	July 2024
STUDY FUNDER:	LILLY S.A.U
CLINICAL TRIALS.GOV:	NCT04603183

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What was the purpose of this study?

Cancer is a disease in which normal cells grow and divide uncontrollably. When cancer cells leave the original tumor site and invade other areas of the body, we refer to 'advanced breast cancer'. Depending on the distance from the original tumor site, advanced breast cancer can be 'locally advanced' (cancer cells spread to nearby areas), or 'metastatic' (cancer cells invade distant parts of the body, such as bones, liver, or brain).

There are 3 types of advanced breast cancer according to the presence of surface proteins called 'receptors', which control breast cell growth and expansion: (1) Hormone receptor-positive, in which breast cancer cells have receptors for the hormones estrogen or progesterone; (2) HER2-positive, in which breast cancer cells have high quantity of HER2 receptors; and (3) triple-negative, in which breast cancer cells do not present receptors for estrogen, progesterone, and HER2.

The main therapy for patients with hormone receptor-positive/HER2-negative advanced breast cancer is the combination of CDK4/6 inhibitors plus endocrine therapy. CDK4/6 inhibitors are therapies that block the functions of CDK4 and CDK6, which are proteins located inside the cells to help them grow.

Endocrine therapy, also known as hormone therapy, reduces the production of hormones in the body to avoid the growth of cancer cells.

This combinatory treatment does not work properly and the disease worsens when patients have aggressive cancer characteristics, such as visceral disease (that impacts the vital organs of the body, including heart, liver, lungs, or intestines), three or more locations different from the breast where cancer cells spread, and/or breast cancer diagnosed at an advanced stage from the beginning. In this situation, patients usually receive chemotherapy, a type of treatment that kills cancer cells and provides beneficial results. However, chemotherapy can also kill healthy cells, leading to multiple side effects and toxicity.

What did researchers want to find out?

Patients were divided into two groups: Group A received abemaciclib (a type of CDK4/6 inhibitor) plus endocrine therapy, and group B received paclitaxel (a type of chemotherapy) during the first 12 weeks, followed by abemaciclib plus endocrine therapy thereafter. The ABIGAIL study evaluated if treatment from group A produced, at least, the same beneficial results that treatment from group B during the first 12 weeks in hormone receptor-positive/HER2-negative advanced breast cancer with a high risk of worsening. This was assessed by a group of experts who did not know any details about the patients or treatments received to ensure that the evaluation was unbiased.

When and where did the studies take place?

Ongoing from June 2021, in 29 sites from Italy, Portugal, and Spain

What were the results of the study?

80 patients were enrolled in group A and 82 in group B.

Clinical characteristics, such as whether aggressive breast cancer was newly diagnosed and reappeared, how well patients were able to carry out everyday activities, age, or menopausal condition of women, were similar in both groups.

Overall response rate at 12 weeks was notably better in group A, which did not receive chemotherapy, compared to group B (59% vs 40%, respectively). In addition, treatment-related side effects were as expected according to each treatment strategy.

What were the main medical conclusions?

The ABIGAIL study confirmed that abemaciclib plus endocrine therapy achieved higher response rates at 12 weeks compared to chemotherapy in patients with hormone receptor-positive/HER2-negative advanced breast cancer at high risk of worsening.

In addtion, the side effects that occurred were what we expected for each treatment plan.

Altogether, we conclude that chemotherapy could be removed from the treatment strategy due to its toxicity.

Where I can find more information?

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

For more details, please visit:
https://www.medsir.org/abigail-clinical-trial

The full scientific report of this study is available online at:
www.clinicaltrials.gov

Thank you who took part in the study

If you took part in this study, **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co**, as the Sponsor, extends its gratitude for your participation. This overview will outline the findings of the study. If you have any queries regarding the study or its outcomes, please reach out to the doctor or staff at your study location.

About Oncoclínicas & CO

Oncoclínicas - the largest cancer care group in Latin America - has a specialized, innovative model that focuses on the entire oncology care process, combining operational efficiency, humanized service and high specialization, through a medical team made up of more than 2,600 professionals, who mainly specialize in oncology. With the mission of making cancer treatment accessible to everyone in the country, it offers a complete operational system made up of outpatient clinics integrated with highly complex oncology centers. It currently has 134 units in 35 Brazilian cities, providing access to cancer care in all regions where it operates, with the quality standards of the best cancer centers in the world.

Through technology, precision medicine and genomics, Oncoclínicas ensures effective results and facilitates access to oncology treatment and has performed more than 595,000 treatments in the last 12 months alone. It is the exclusive partner in Brazil of the Dana-Farber Cancer Institute, an affiliate of Harvard Medical School and one of the most prestigious cancer research and treatment centers in the world. The Group also owns Boston Lighthouse Innovation, a bioinformatics company based in Cambridge, USA, and holds shares in MEDSIR, a Spanish company dedicated to the development and management of clinical trials for independent cancer research. The company is also developing projects in collaboration with the Weizmann Institute of Science in Israel, one of the world's most prestigious multidisciplinary scientific and research institutions, whose international board includes Bruno Ferrari, founder and CEO of Oncoclínicas.

For further information: www.grupooncoclinicas.com

ABOUT MEDSIR

Founded in 2012, MEDSIR works closely with its partners to drive innovation in oncology research. Based in Spain and the United States, the company manages all aspects of clinical trials, from study design to publication, utilizing a global network of experts and integrated technology to streamline the process. The company offers proof-of-concept support and a strategic approach that helps research partners experience the best of both worlds from industry-based clinical research and investigator-driven trials. To promote independent cancer research worldwide, MEDSIR has a strategic alliance with Oncoclínicas, the leading oncology group in Brazil with the greatest research potential in South America. Learn how MEDSIR brings ideas to life: www.medsir.org