Lay Language Summary

ADELA

A randomized, phase 3, double-blind, placebo-controlled trial of elacestrant plus everolimus versus elacestrant in ER+/HER2-advanced breast cancer (aBC) patients with ESR1-mutated tumors progressing on endocrine therapy (ET) plus CDK4/6i

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.
CANCER TYPE:	ER+/HER2- aBC with ESR1-mutated tumors. Breast Cancer
PHASE:	PHASE III
MEDICINE(S) STUDIED:	elacestrant, everolimus
DATES OF STUDY:	Not yet, recruiting
TITLE OF THIS STUDY:	ADELA: A randomized, phase 3, double-blind, placebo-controlled trial of elacestrant plus everolimus versus elacestrant in ER+/HER2-advanced breast cancer (aBC) patients with ESR1-mutated tumors progressing on endocrine therapy (ET) plus CDK4/6i
PATIENTS NUMBER:	240 (planned)
PARTNER:	The MENARINI group
DATE OF THIS REPORT:	October 26th, 2024
CLINICAL TRIALS.GOV:	NCT06382948

The content for this document was finalised by **Medica Scientia Innovation Research (MEDSIR) - Oncoclínicas&Co and the MENARINI group** on the 25th October of 2024. The information in this summary does not include additional information available after this date.

What is the purpose of this study?

Estrogen is a hormone that usually aids in regulating the growth and healthy function of reproductive organs in women. However, it can potentially promote the growth of some breast cancer cells in abnormal situations. In ER[+]/HER2[-] breast cancer, tumor cells have a type of protein called estrogen receptors that allow estrogen to bind and convey growth signals, and low or no levels of another receptor called HER2. Because of this, ER[+]/HER2[-] breast cancer is frequently treated with hormone therapy (ET), which blocks estrogen activity. The current standard therapy for this cancer combines ET with CDK4/6 inhibitors, which disrupt the cancer cells' ability to divide and proliferate.

Unfortunately, many of these patients eventually find that their tumors stop responding to treatment. This often happens due to mutations in a specific gene called ESR1, which affect how the estrogen receptor works, making ET less effective. These mutations are especially common in advanced breast cancers, where the disease has spread to other parts of the body, and they occur in about 40-50% of patients after a long-term treatment with ET. When this happens, the tumor acquires resistance to the previous therapies and becomes harder to treat, highlighting the urgent need for more therapeutic options.

The ADELA study aims to explore a new treatment strategy for patients in this situation to provide help in managing their cancer effectively

What do researchers want to find out?

A previous study called EMERALD found that the medication elacestrant was better at slowing down cancer growth than standard ET when patients have ESR1 mutations. This medication works by binding to the estrogen receptor and breaking it down, reducing its ability to help the cancer grow. In patients who had already been on ET and CDK4/6 inhibitors for 12 months or more, subsequent treatment with elacestrant delayed the progression of their disease for an average of 8.6 months, compared to just 1.9 months with other ET as secondary treatment. Researchers are now also looking into whether combining elacestrant with other medications could enhance its effectiveness. One promising partner is everolimus, a drug that helps stop tumor growth and is typically used when other ETs no longer work.

The ADELA study will test whether the combination of elacestrant with everolimus can lead to better outcomes for ER[+]/HER2[-] patients with ESR1 mutations whose cancer has progressed after receiving standard ET and CDK4/6 inhibitors. The main goal of the study is to evaluate how well the treatment works in terms of delaying cancer progression (progression-free survival, PFS). Secondary goals include measuring how long patients live without their cancer worsening (overall survival, OS), how long the treatment remains effective (duration of response, DoR), how quickly patients respond to the treatment (time-to-response, TTR), how safe the treatment is, and any changes in their quality of life. The study plans to enroll 240 patients.

Countries

Spain, Italy, France, Austria, the Czech Republic, Greece, Germany, the UK, and Brazil.

When and where is the study going to take place?

The study is set to begin recruiting patients in December and aims to complete patients' treatment by 2027. It will involve 66 hospitals across nine countries

Who is taking part of this study?

The ADELA study is an international phase III clinical trial designed to test a new treatment approach -elacestranst + everolimus- in a large group of patients with advanced ER[+]/HER2[-] breast cancer. The study follows a rigorous design, where participants are randomly assigned to one of the different treatment groups, and neither the participants nor the researchers know who is receiving the new treatment (elacestrant + everolimus) or the control treatment (elacestrant + placebo).

This trial is looking for adult women and men with advanced ER[+]/HER2[-] breast cancer and ESR1 mutations. To qualify, patients must have already received ET and CDK4/6 inhibitors for at least six months, experiencing a worsening of the disease afterward. Those treated with CDK4/6 inhibitors after surgery can also participate, as long as their cancer returned or got worse more than a year after starting those inhibitors, but within a year after finishing the treatment. However, individuals cannot participate in this study if they have had chemotherapy for advanced breast cancer or if their cancer has aggressively spread to the brain (known as 'brain metastasis') or to the leptomeninges, which are the thin tissues covering the brain and spinal cord (known as 'leptomeningeal disease')

What are the main social implications?

The ADELA trial is a phase III clinical study, which means that if successful, it could lead to the approval by regulatory agencies of this new treatment regimen of elacestrant plus everolimus, making it accessible to more patients. This could result in significant improvements in patient outcomes, including increased survival rates and a better quality of life.

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/adela-clinical-trial

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

Thank you who took part in the study!

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

ABOUT MENARINI

The Menarini Group is a leading international pharmaceutical and diagnostics company, with a turnover of $4.7 billion and over 17,000 employees. Menarini is focused on therapeutic areas of high unmet needs with products for cardiology, oncology, pneumology, gastroenterology, infectious diseases, diabetology, inflammation, and analgesia. With 18 production sites and 9 Research and Development centers, Menarini's products are available in 140 countries worldwide. For further information, please visit www.menarini.com.