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Lay Language Summary

LUZERN trial

Niraparib Plus Aromatase Inhibitors for Luminal-like(HER2-,ER+) and gBRCA or HDR+ Metastatic Breast Cancer (LUZERN)

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.

MEDICINE(S) STUDIED: HR+/HER2- advanced breast cancer with a germline BRCA mutation or germline BRCA wild-type with HRD

DATES OF STUDY: 2020 June to 2022 November

TITLE OF THIS STUDY: Niraparib Plus Aromatase Inhibitors for Luminal-like(HER2-,ER+) and gBRCA or HDR+ Metastatic Breast Cancer (LUZERN)

DATE OF THIS REPORT: April 2024

PHARMACEUTIC PARTNERS: GSK

The content for this document was finalised by **MEDSIR** on the 23nd of April of 2024. The information in this summary does not include additional information available after this date.

What was the purpose of this study?

BRCA proteins are involved in DNA repair, helping to fix damaged cells and preventing the uncontrolled growth of tumor cells. It is estimated that 1 in every 500 women in the United States has a BRCA mutation and women with BRCA mutations have a 45–85% likelihood of developing breast cancer. Defects in the DNA repair pathways can lead to breast cancer. Two common DNA repair defects include germline (inherited) BRCA mutations (gBRCAm) or having a germline normal BRCA (wild-type BRCA, gBRCAwt) but with homologous recombination deficiency (HRD).

HRD refers to a cellular condition where the repair of damaged DNA is impaired due to the malfunctioning of proteins, which could be either BRCA or other proteins. Because this researchers exploring ways to target this pathway as a treatment option. For example, PARP is a protein that helped damaged cells repair themselves, and inhibiting it, especially in patients with BRCA deficiencies, can lead to tumor cell death.

The purpose of the LUZERN study was to evaluate the combination of niraparib, a PARP inhibitor, in combination with aromatase inhibitors for patients with HR-positive/HER2-negative advanced breast cancer that has either a gBRCAm or gBRCAwt with HRD.

What did researchers want to find out?

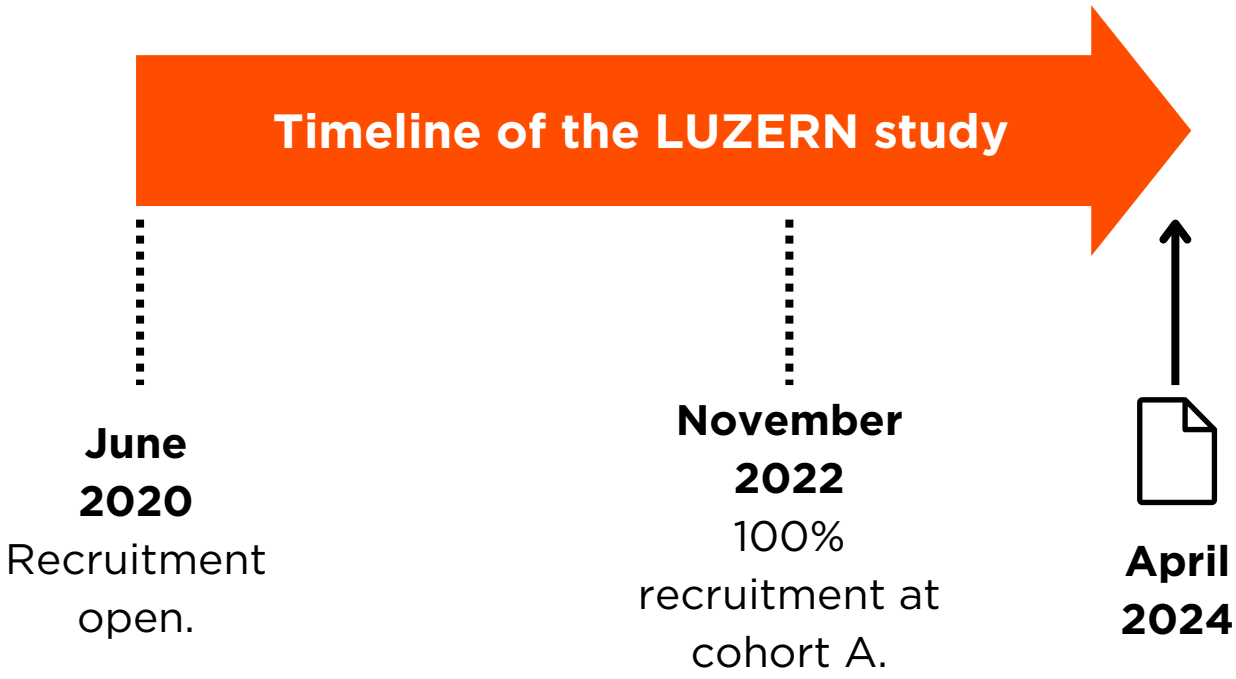
The researchers wanted to find out if combining niraparib and aromatase inhibitors would be an effective treatment for patients with HR-positive/HER2-negative advanced breast cancer with BRCA deficiencies.

Specifically, the primary goal of the study was to determine how many patients had what is known as a clinical benefit. A clinical benefit is defined as the number of patients that have a complete response, partial response, or stable disease for 24 weeks or longer.

Additional goals included assessing the progression-free survival (the time in which the breast cancer doesn't get worse), the overall survival (the time until death of any cause), time to response, duration of response, maximum tumor shrinkage, overall response rate (complete and partial responses), and the side effects.

When and where did the studies take place?

This study enrolled patients from seven medical institutions across Spain between June 15, 2020 to November 17, 2022.



What were the results of the study?

The study demonstrated the combination of niraparib plus aromatase inhibitors may be an effective treatment with manageable side effects for patients that have aromatase-inhibitor resistant HR-positive/HER2-negative advanced breast cancer and a mutation in their BRCA gene. The clinical benefit rate was 50%, with a median progression-free survival of 6.9 months and a median overall survival of 18.1 months. The most common treatment related side effects were fatigue, nausea, and abnormally low white blood cell counts. The results of the LUZERN study warrant further research on this combination.

What were the main medical conclusions?

The combination of PARP inhibitors and aromatase inhibitors demonstrated clinical efficacy and warrants further evaluation in patients with aromatase inhibitor resistant HR-positive/HER2-negative advanced breast cancer harboring a BRCA mutation.

Where I can find more information about the study?

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.

Thank you to the people who took part in the study

If you took part in this study, **MEDSIR**, 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 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.