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Lay Language Summary

PRIMED

Prevention of sacituzumab govitecan-related neutropenia and diarrhea in patients with triple-negative or HR[+]/HER2[-] advanced breast cancer (PRIMED): a phase 2 trial

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+/HER2- and triple negative advanced breast cancer

MEDICINE(S) STUDIED: Sacituzumab govitecan, loperamide, and granulocyte colony-stimulating factors

DATES OF STUDY: February 2023 to September 2023

TITLE OF THIS STUDY: Prevention of sacituzumab govitecan-related neutropenia and diarrhea in patients with triple-negative or HR[+]/HER2[-] advanced breast cancer (PRIMED): a phase 2 trial

DATE OF THIS REPORT: May 2024

STUDY FUNDER: Gilead Sciences Inc.

CLINICAL TRIALS.GOV: NCT05520723

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What was the purpose of this study?

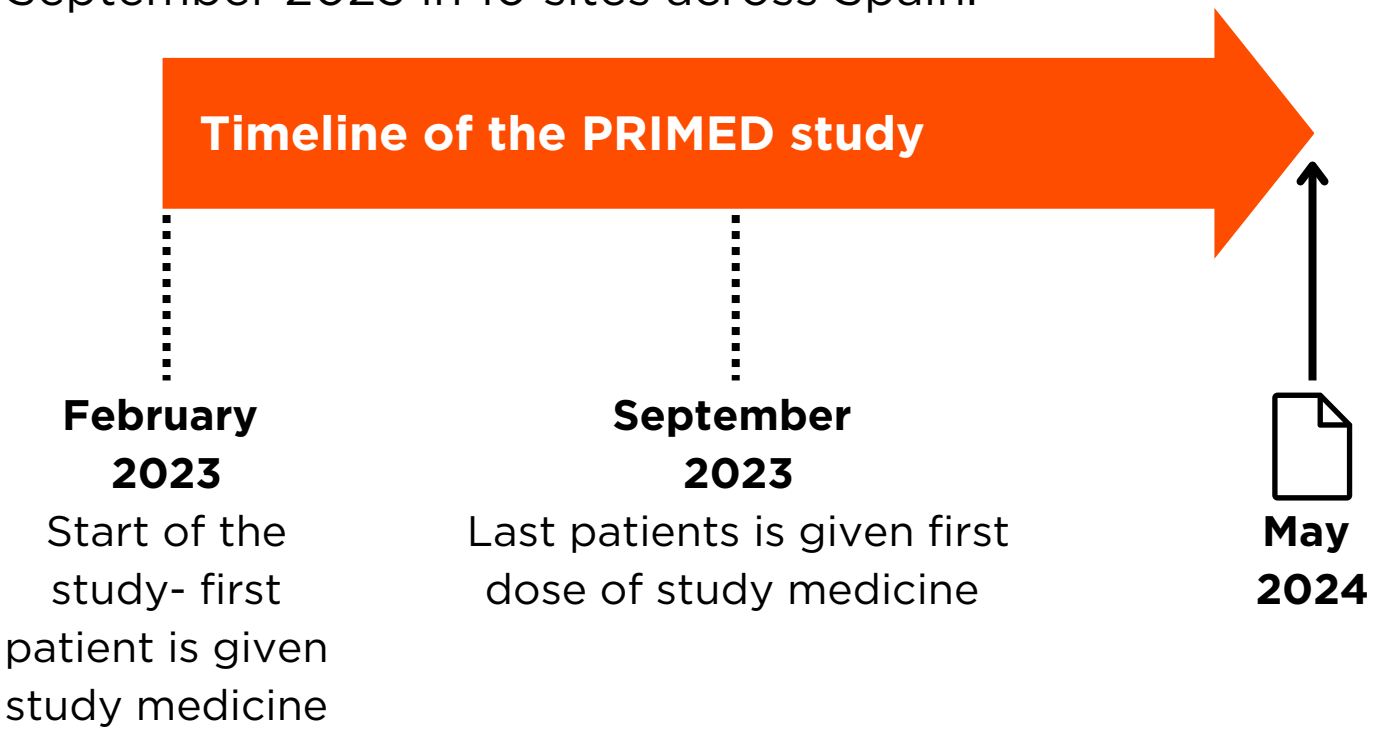
Breast cancer is a disease that is caused by a variety of distinct genetic mutations in the breast tissue and is often defined by the common receptors that are found in breast cancer. HR-positive/HER2-negative breast cancer is a type of breast cancer that has receptors for hormone receptors (estrogen receptor and/or progesterone receptor) but no human epidermal growth factor receptor 2. Patients with triple negative breast cancer lack these three receptors. Additionally, breast cancer is considered advanced when it has spread (metastasized) to other parts of the body. Recently, it has been found that the protein, trophoblast cell surface antigen 2 (Trop-2), is highly expressed in breast cancer, making it a potential target. Two recent clinical trials, ASCENT and TROPiCS-02, found promising results for Sacituzumab govitecan, a Trop-2 targeting drug, in treating patients with pretreated triple negative and HR-positive/HER2-negative advanced breast cancer. However, these trials noted that patients experienced high rates of diarrhea and neutropenia (low white blood cell counts) while taking Sacituzumab govitecan. Therefore, PRIMED was to designed to determine if there was a way to prevent neutropenia and diarrhea in order to keep patients on treatment.

What did researchers want to find out?

The PRIMED clinical trial was designed to determine if giving granulocyte colony stimulating factors and loperamide during the first two treatment cycles could improve the tolerability of sacitizumab govitecan. Granulocyte colony stimulating factor and loperamide are drugs that are commonly used to treat neutropenia and diarrhea, respectively. However, they are usually administered after these side effects occur. In PRIMED, researchers wanted to test whether given them at the start of treatment, before patients experienced any neutropenia or diarrhea, could reduce the incidence of these sides effects. They also wanted to determine how this effected the need for dose reductions, treatment interruptions, and permanent discontinuations.

When and where did the studies take place?

The study enrolled 50 patients between February 2023 and September 2023 in 10 sites across Spain.



What were the results of the study?

The PRIMED study determined that giving loperamide during the first two treatment cycles resulted in a clinically relevant reduction in the incidence and severity of sacituzumab govitecan-related neutropenia and diarrhea. The incidence of any grade neutropenia was 28.0%, compared to 63.2% and 70.1% in ASCENT and TROPiCS02, respectively. The incidence of any grade diarrhea was 34.0%, compared to 59.3% and 56.7% in ASCENT and TROPiCS02, respectively. The side effects were similar to the known safety profile of sacituzumab govitecan, with the exception of constipation which occurred in 26 patients (52.0%). Additionally, PRIMED had less dose reductions, treatment interruptions, and permanent discontinuations compared to ASCENT and TROPiCS02.

What were the main medical conclusions?

PRIMED demonstrated that adding granulocyte colony-stimulating growth factors and loperamide during the first two treatment cycles reduced cases of neutropenia and diarrhea and could help lower the need for dose reductions, treatment interruptions, and permanent discontinuations.

What were the main social conclusions?

The PRIMED study demonstrated that administering drugs to treat the common side effects of neutropenia and diarrhea before they occured resulted in less cases and could be a potential solution to help keep patients on treatment.

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:
www.medsir.org/primed-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