Lay Language Summary

PRIMED

Efficacy analysis and updated safety from the phase 2 PRIMED study of prophylactic granulocyte-colony stimulating factor (G-CSF) and loperamide for patients (pts) with HER2-negative advanced breast cancer (ABC) treated with sacituzumab govitecan (SG)

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:	HER2-negative Advanced Breast Cancer
PHASE:	PHASE II
MEDICINE(S) STUDIED:	sacituzumab govitecan (SG), granulocyte-colony stimulating factor and loperamide
DATES OF STUDY:	February 2023 - September 2023
TITLE OF THIS STUDY:	PRIMED: Efficacy analysis and updated safety from the phase 2 PRIMED study of prophylactic granulocyte-colony stimulating factor (G-CSF) and loperamide for patients (pts) with HER2-negative advanced breast cancer (ABC) treated with sacituzumab govitecan (SG)
PATIENTS NUMBER:	50
PHARMACEUTICAL PARTNER:	Gilead Sciences
DATE OF THIS REPORT:	Ocotber 26th, 2024
CLINICAL TRIALS.GOV:	NCT05520723

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

What was the purpose of this study?

Breast cancer is often classified by the common receptors that are found on cancer cells. HER2-negative tumors lack the human epidermal growth factor receptor 2 (HER2). Within the HER2-negative tumors, there is HR-positive/HER2-negative breast cancer, which has the hormone receptors (HR) estrogen and/or progesterone, and triple-negative breast cancer, which lacks all three receptors -estrogen, progesterone, and HER2. Additionally, breast cancer is considered advanced when it has spread (metastasized) beyond the breast to other parts of the body.

Recently, a new class of drugs, known as Antibody-Drug Conjugates (ADCs), have been showing promise in cancer treatment. ADCs are made up of an antibody that targets a specific protein found on tumor cells coupled with a toxic drug that kills tumor cells. In this way, the specific targeting of cancer cells allows for a precise delivery of the drugs directly to them, potentially reducing toxicity in healthy cells.

Sacituzumab govitecan (SG), a Trop-2 targeting ADC, has demonstrated promising results in treating patients with advanced triple negative and HR-positive/HER2-negative breast cancer that has already been treated. However, the ASCENT and TROPiCS-02 trials noted that patients receiving SG often experienced high rates of diarrhea and neutropenia (a low count of white blood cells).

Because of this, the PRIMED study was designed to find ways to prevent these side effects, helping patients stay on treatment longer.

What do researchers want to find out?

The PRIMED clinical trial aimed to determine if giving two medications -granulocyte colony stimulating factor (G-CSF) and loperamide- during the first two treatment cycles could make SG treatment easier to tolerate. G-CSF and loperamide are commonly used to treat neutropenia and diarrhea, respectively. However, they are usually administered after these side effects appear.

In PRIMED, researchers tested whether given these medications at the start of treatment, before patients experienced any neutropenia or diarrhea, could reduce their incidence. After the first two cycles, doctors decided whether a patient should continue taking G-CSF or loperamide or not. Previously, results after two cycles showed that this combination was successful at reducing incidences of neutropenia and diarrhea.

A summary of those results can be found here. In these updated results, researchers were looking at the safety of the PRIMED study with a longer follow-up time as well as looking at common efficacy measurements.

When and where did the studies take place?

February 2023 (first patient starts treatment) to September 2023 (last patient starts treatment)

What were the results of the study?

At the time of this analysis, after a median follow up time of 9 months, 9 patients were still on treatment. The median time a patient's disease did not worsen, known as progression free survival, for all patients was 6.2 months (6.4 months in patients with triple-negative breast cancer; 5.8 months in patients with HR-positive/HER2-negative breast cancer). Twenty-eight percent of patients experienced neutropenia and 44% had diarrhea. These rates were lower than those seen in the previous clinical trials (~60-70% neutropenia; ~60% diarrhea). Four patients stopped treatment due to side effects, two of which were related to SG. Other side effects were similar to the known safety profile of SG, except there was an increase in constipation (56%), which was expected given the use of loperamide.

What were the main medical conclusions?

The use of G-CSF and loperamide at the start of treatment with SG resulted in a meaningful reduction of neutropenia and diarrhea, as well as less treatment modifications and discontinuations. The efficacy was in line with previous studies of SG. Therefore, G-CSF and loperamide should be considered as preventative treatment for patients taking SG.

What were the main social conclusions?

The use of G-CSF and loperamide at the start of treatment with SG could be beneficial in helping to prevent cases of neutropenia and diarrhea.

Countries

Spain, Italy, Germany, UK, France, US, Brazil

What does this study imply for OC-MEDSIR?

Demonstrates MEDSIR's commitment to patients by finding solutions that make treatments more tolerable and, ultimately, improve their 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/primed-clinical-trial

The full scientific report of this study is available online at:
https://clinicaltrials.gov/study/NCT05520723

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.

Thank you who took part in the study

ABOUT Oncoclínicas & Co

Oncoclínicas&Co is the largest group dedicated to cancer treatment in Latin America, with a specialized and innovative model focused on the entire oncology care journey, combining operational efficiency, humanized care, and high specialization through a medical team composed of over 2,700 specialist physicians with an emphasis on oncology. With its mission to democratize cancer treatment, it offers a comprehensive system that integrates outpatient clinics with high-complexity cancer centers. The company operates 145 units across 39 Brazilian cities, allowing high-quality access in all regions it serves, aligned with world-class standards.

Focusing on technology, precision medicine, and genomics, Oncoclínicas performed approximately 635,000 treatments in 2023. It is the exclusive partner in Brazil of the Dana Farber Cancer Institute, affiliated with Harvard Medical School, one of the world's leading cancer research and treatments centers. The company also owns Boston Lighthouse Innovation, a bioinformatics firm based in Cambridge, United States, and holds shares in Medsir, a company dedicated to the development and management of clinical trials for independent cancer research, based in Barcelona, Spain. Recently, Oncoclínicas

expanded its operations to Saudi Arabia through a joint venture with the Al Faisaliah Group, bringing its mission to beat cancer to a new continent and providing advanced oncology care on a global scale by combining oncological hyperspecialization with innovative treatment approaches.

The company is part of the IDIVERSA index, launched by B3, highlighting companies committed to gender and racial diversity. For more information, visit: visit 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