MEDSIR
MEDICA SCIENTIA INNOVATION RESEARCH

Lay Language Summary

WIN-B

Phase IB/II study to evaluate safety and preliminary efficacy of the WEE1 inhibitor Debio 0123 in combination with sacituzumab govitecan (SG) in triple-negative or hormone receptor–positive (HR+)/HER2-negative (HER2–) advanced breast cancer (ABC): The WIN-B study.

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:	Triple-negative or HR+/HER2– advanced breast cancer
PHASE:	PHASE IB/II
MEDICINE(S) STUDIED:	Debio-0123, Sacituzumab govitecan
DATES OF STUDY:	2023- On going
TITLE OF THIS STUDY:	Phase IB/II study to evaluate safety and preliminary efficacy of the WEE1 inhibitor Debio 0123 in combination with sacituzumab govitecan (SG) in triple-negative or hormone receptor–positive (HR+)/HER2-negative (HER2–) advanced breast cancer (ABC): The WIN-B study.
PATIENTS NUMBER:	52
PHARMACEUTICAL PARTNER:	GILEAD and DEBIOPHARM
DATE OF THIS REPORT:	May 5th, 2025
CLINICAL TRIALS.GOV:	NCT06612203

The content for this document was finalized by **Medica Scientia Innovation Research (MEDSIR)** on May 5th, 2025. The information in this summary does not include additional information available after this date.

What was the purpose of this study?

Debio-0123 is a highly selective ATP-competitive brain penetrant Wee 1 inhibitor. In vitro and in vivo, Inhibition of Wee1 by Debio-0123, pushes cells through their cycle before DNA repair, promoting mitotic catastrophe and consequently tumor regression.

On the other hand, Sacituzumab Govitecan is approved world-wide as monotherapy for the treatment of adult patients with metastatic Triple Negative Breast Cancer (TNBC) who have received two or more systemic therapies. In addition, Sacituzumab Govitecan demonstrated prognosis benefits over chemotherapy in the other target population of the WIN-B study: heavily pretreated HR+/HER2- patients. While both treatments work well for many patients at first, after progression, they can become less effective and there is a need for treatment to improve survival in both target populations.

The WIN-B study is evaluating a new treatment combination (Debio-0123 + Sacituzumab Govitecan) in patients with pretreated metastatic ER+/HER2- and TNBC, with the goal of helping them manage their cancer more effectively.

What did researchers want to find out?

First, in Phase Ib, researchers want to find the best dose of the experimental drug called Debio 0123 when used in combination with the already approved Sacituzumab Govitecan, so that it's strong enough to work but still safe for patients.

Then, in Phase II, they want to see how well this treatment combination actually works. Specifically, they will screen the number of patients which tumors shrinks or disappears after getting the treatment. They will also study how long the treatment keeps the cancer from getting worse, how long patients live overall, as well as the safety profile.

When and where did the studies take place?

This study began recruiting participants in September 2024. The enrollment will take place in three countries, including Spain, the United Kingdom, and the United States.

Who took part of this study?

The WIN-B study i is an international, multicenter, open-label, single-arm phase Ib/II trial designed to test a new treatment approach -Debio0123 + Sacituzumab Govitecan- in previously treated patients with TNBC or HR+/HER2- breast cancer in terms of safety and efficacy.

This study is for adult women with TNBC or HR+/HER2- tumors who have experienced disease progression after 1 or 2 lines of systemic therapy for advanced breast cancer, ECOG performance status of 0-1, with evaluable (for phase Ib) or measurable (for phase II) disease as per RECIST v.1.1. Patients will receive study treatment until progression, death, unacceptable toxicity, or study discontinuation.

What were the main medical conclusions?

The WIN-B trial is a phase Ib/II clinical study, that if successful, it has the potential to position Debio-0123 in combination with Sacituzumab Govitecan as standard second line treatment for patients with pretreated metastatic ER+/HER2- and TNBC.

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/win-b-clinical-trial
The full scientific report of this study is available online at:
https://clinicaltrials.gov/

Thank you who took part in the study

If you took part in this study, **Medica Scientia Innovation Research (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. Learn how MEDSIR brings ideas to life: www.medsir.org