PRESS RELEASE

MEDSIR & DEBIOPHARM ANNOUNCE THE FIRST PATIENT DOSED IN THE WIN-B TRIAL EXPLORING THE COMBINATION OF DEBIO 0123 & GILEAD'S TRODELVY® IN ADVANCED BREAST CANCER

WIN-B (NCT06612203) is a Phase Ib/II, multi-center investigator-initiated trial, evaluating the safety and preliminary efficacy of combining Debiopharm's selective WEE1 inhibitor, Debio 0123 and Gilead's antibody-drug conjugate (ADC) Trodelvy® (sacituzumab govitecan-hziy) in advanced HR+/HER2- and triple-negative breast cancers.

Lausanne, Switzerland & Barcelona, Spain – February 25th, 2025 – Debiopharm (www.debiopharm.com), a privately-owned, Swiss-based biopharmaceutical company aiming to establish tomorrow's standards of care to cure cancer and infectious diseases, and MEDSIR (www.medsir.org), a Spanish and US-based, international and innovative research organization in clinical oncology, today announced that the first patient has been dosed in the WIN-B clinical trial evaluating the safety and efficacy of Debio 0123 plus Trodelvy® in people with hormone receptor positive (HR+), human epidermal growth factor receptor 2-negative (HER2-) and triple-negative advanced or metastatic breast cancers. The WIN-B trial is sponsored by MEDSIR and fully funded by Debiopharm. Gilead Sciences, Inc. (Gilead) is providing supply of Trodelvy.

In late May 2024, Debiopharm and MEDSIR announced a collaboration to evaluate the clinical combination of Debio 0123, an oral, brain-penetrant, highly selective WEE1 kinase inhibitor and Trodelvy, a Trop-2-directed ADC currently approved in more than 50 countries for second-line or later metastatic TNBC patients and in more than 40 countries for certain patients with pre-treated HR+/HER2- metastatic breast cancer. Prior to this clinical collaboration, promising preclinical data results were disclosed at the American Association for Cancer Research (AACR) annual meeting in 2024 under the title, **"***Anti-tumor activity of Debio 0123 in combination with sacituzumab govitecan in preclinical models of breast cancer"* [1].

"*Exploring novel combinations can lead to breakthroughs for cancer patients. We are delighted that this research exploring the combination of our WEE1 inhibitor with Trodelvy is moving forward with the first patient dosed. We are looking forward to seeing the potential benefits of this combination therapy for patients with a critical unmet medical need such as advanced-stage breast cancer,*" said **Esteban Rodrigo Imedio, Executive Medical Director, Oncology, Debiopharm**.

HR+/HER2- is the most common type of breast cancer, accounting for 70% of all cases. It groups estrogen-receptor (ER) and/or progesterone-receptor (PR) expressing cells. Almost one in three cases of early-stage breast cancer eventually become metastatic, and among patients with HR+/HER2- metastatic disease, the five-year relative survival rate is only 30%. Over time, patients with HR+/HER2- metastatic breast cancer can become resistant to endocrine-based therapy, and can ultimately develop resistance to even more recently approved therapies, such as Trodelvy. For patients treated with single-agent chemotherapy, prognosis remains poor [2], underscoring the urgent need for innovative treatment options like those being evaluated in WIN-B. [3-4].

Triple-negative breast cancer (TNBC) is an aggressive type of breast cancer that accounts for 10-15% of all breast cancers. It is called “triple negative” as it does not express ER, PR or HER2 receptors. Because of its aggressive nature, TNBC has a high risk of metastasis either at diagnosis or at time of relapse after initial curative therapy, which explains the poor prognosis many TNBC patients face. Compared to other types of breast cancer, relapse rates as well as the mortality rate five years after diagnosis is significantly higher [5-6].

“This collaboration with Debiopharm and Gilead represents an exciting step forward in developing new treatment options for hard-to-treat breast cancers. Together, we're committed to moving patient care forward through fostering important partnerships in oncology. I believe our work with Debio 0123 and Trodelvy holds great promise for patients with hard-to-treat cancers,” said **Dr. Javier Cortés, MEDSIR Senior Scientific Lead.**

The combination of Debio 0123 and sacituzumab govitecan-hziy is investigational and not approved by any health authority globally. The safety and efficacy of this combination has not been established.

Trodelvy and Gilead are trademarks of Gilead Sciences, Inc., or its related companies.

About Debio 0123
Debio 0123 is a brain-penetrant, highly selective WEE1 kinase inhibitor. WEE1 is a key regulator of the G2/M and S phase checkpoints, activated in response to DNA damage, allowing cells to repair their DNA before resuming their cell cycle. WEE1 inhibition, particularly in combination with DNA damaging agents, induces an overload of DNA breaks. In conjunction with abrogation of other checkpoints such as G1, the compound pushes the cells through cell cycle without DNA repair, promoting mitotic catastrophe and inducing apoptosis of cancer cells. Currently investigated in clinical trials for solid tumors in monotherapy and combination, Debio 0123 is being developed to respond to high unmet needs of patients living with the burden of difficult-to-treat cancers.

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.

Debiopharm's Commitment to Patients
Debiopharm aims to develop innovative therapies that target high unmet medical needs in oncology and bacterial infections. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then hand stewardship to large pharmaceutical commercialization partners to maximize patient access globally.
For more information, please visit www.debiopharm.com
We are on Twitter. Follow us @DebiopharmNews at http://twitter.com/DebiopharmNews.

Debiopharm Contact
Dawn Bonine
Head of Communications
dawn.bonine@debiopharm.com
Tel: +41 (0)21 321 01 11

MEDSIR Contact
Carles Berloso
International PR & Comms
carles.berloso@medsir.org

Tel: +34 677 49 75 23

Sources

[1] Piggott et al., AACR 2024 Abstract #3370

[2] Rugo et al., ASCO 2022 Abstract #LBA1001

[3] American Cancer Society. 2021

[4] McAndrew NP, Finn RS. 2022

[5] Dass SA, Tan KL, Selva Rajan R, Mokhtar NF, Mohd Adzmi ER, Wan Abdul Rahman WF, Tengku Din TADA, Balakrishnan V. 2021

[6] American Cancer Society. 2023