PRESS RELEASE

MEDSIR & DEBIOPHARM INITIATE CLINICAL COLLABORATION TO EXPLORE POTENTIAL SYNERGY OF DEBIO 0123 & SACITUZUMAB GOVITECAN IN ADVANCED BREAST CANCER

The WIN-B is a Phase Ib/II investigator-sponsored trial (IST) that will evaluate the safety and preliminary efficacy of the Debiopharm's potent WEE1 inhibitor Debio 0123 in combination with Gilead's antibody-drug conjugate (ADC) Sacituzumab Govitecan (Trodelvy®) in triple-negative and HR+/HER2- advanced breast cancer.

Lausanne, Switzerland & Barcelona, Spain – May 28th, 2024 – 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, today announced that it has entered a clinical collaboration with MEDSIR (www.medsir.org), a Spanish and US-based, international and innovative research organization in clinical oncology. The study will evaluate the safety and efficacy of Debio 0123 (Debiopharm's investigational, potential best-in-class WEE1 inhibitor) together with sacituzumab govitecan (*Trodelvy*®; an antibody-drug conjugate [ADC] owned and commercialized by Gilead Sciences, Inc. [Gilead]). Sites for this Phase 1b/2 investigator-initiated trial in patients with previously treated advanced breast cancer will be opened in Europe, UK, and the USA.

"*We are thrilled about the launch of this study exploring the combination of our WEE1 inhibitor with Trodelvy and are looking forward to seeing the potential benefits in breast cancer patients*" said **Esteban Rodrigo Imedio, Executive Medical Director, Oncology, Debiopharm**.

Hormone receptor-positive (HR+)/HER2- is the most common type of breast cancer and it accounts for 70% of all breast cancers. 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 30%. As patients with HR+/HER2- metastatic breast cancer become resistant to endocrine-based therapy, their primary treatment option is limited to single-agent chemotherapy. For patients treated with single-agent chemotherapy, the prognosis remains poor [1]. Despite having a more favorable outcome than other breast cancer subtypes like HER2-positive and triple-negative breast cancers (TNBC), relapse still occurs and there remains a high unmet medical need for this patient population [2-3]. 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, the relapse rate as well as the mortality rate in the 5 years after diagnosis is significantly higher [4-5].

"*It's great to see companies like Debiopharm that are open to investigating novel combination strategies to support breast cancer patients. I look forward to seeing potential benefits for patients*" **Dr. Tim Robinson, Principal Investigator, University of Bristol**.

Sacituzumab govitecan is a Trop-2-directed ADC currently approved globally for patients with 2L metastatic TNBC and pre-treated HR+/HER2- metastatic breast cancer The clinical trial will enroll patients with HR[+]/HER2[-] metastatic breast cancer and metastatic TNBC, and will be sponsored by MEDSIR, and fully funded by Debiopharm. Gilead will provide supply of sacituzumab govitecan.

“We are honored to develop this Investigator Sponsor Trial (IST) in collaboration with Debiopharm and Gilead to explore new approaches to breast cancer treatment. Together, we're committed to advancing patient care and fostering important partnerships in the oncology field. I believe our work with Debio 0123 and sacituzumab govitecan holds great promise for patients” said **Dr. Javier Cortés, MEDSIR Senior Scientific Lead.**

The foundations for this clinical trial were set by the promising preclinical data suggesting an existing synergy between Debiopharm’s Debio 0123 and Gilead’s sacituzumab govitecan. These results were disclosed at the American Association for Cancer Research (AACR) annual meeting 2024 under the title “*Anti-tumor activity of Debio 0123 in combination with sacituzumab govitecan in preclinical models of breast cancer”* [6].

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

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