PRESS RELEASE

FOLLOWING ORAL PRESENTATION OF PHASE I DATA AT AACR 2026, DEBIOPHARM ANNOUNCES FDA FAST TRACK DESIGNATION FOR LUNRESERTIB IN COMBINATION WITH ZEDORESERTIB FOR GENOMIC-DEFINED PLATINUM-RESISTANT OVARIAN CANCER

Lausanne, Switzerland – April 20th, 2026 – Debiopharm (www.debiopharm.com), a privately-owned, Swiss-based biopharmaceutical company aiming to establish tomorrow's standard of care to cure cancer and infectious diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to the combination of its PKMYT1 inhibitor, lunresertib (Debio2513), and its WEE1 inhibitor, zedoresertib (Debio 0123).

The designation is for the treatment of adult patients with CCNE1 amplified, or a deleterious mutation in either FBXW7 or PPP2R1A, platinum-resistant/refractory ovarian cancer.

The FDA's Fast Track program is designed to facilitate the development and expedite the review of new drugs intended to treat serious conditions and fill an unmet medical need. Programs granted Fast Track designation benefit from more frequent communication with the FDA and, if relevant criteria are met, may be eligible for Priority Review and Accelerated Approval of a New Drug Application (NDA).

Momentum Following AACR Oral Presentation

This regulatory milestone follows the first clinical data disclosure from the MYTHIC Study (NCT04855656), a Phase I trial evaluating the lunresertib and zedoresertib combination in patients with advanced solid tumors harboring these specific genomic alterations. The data were featured yesterday in an oral presentation at the American Association for Cancer Research (AACR) Annual Meeting by Dr. Timothy A. Yap, Medical Oncologist and Physician-Scientist at The University of Texas MD Anderson Cancer Center, and Principal Investigator of the MYTHIC study.

"The FDA's decision to grant Fast Track designation for this combination therapy validates our synthetic lethality approach to treating high-unmet-need cancers," said ***Esteban Rodrigo Imedio, Executive Medical Director, Oncology, Debiopharm****. "Coming immediately after Dr. Yap's presentation of the MYTHIC data at AACR, this designation highlights the potential of combining lunresertib and zedoresertib to provide a meaningful new clinical option for patients with biomarker-selected ovarian cancer who have exhausted platinum-based therapies."*

Addressing Unmet Need in Ovarian Cancer

Platinum-resistant or refractory ovarian cancer remains one of the most challenging malignancies to treat, with limited effective options for patients whose tumors have developed resistance. By targeting the DNA Damage Response (DDR) pathway through the dual inhibition of PKMYT1 and WEE1, the lunresertib/zedoresertib combination aims to exploit specific genomic vulnerabilities (CCNE1, FBXW7, or PPP2R1A) to induce tumor cell death.

ABOUT DNA DAMAGE REPAIR (DDR)

When cells have damaged DNA, they must undergo a repair process known as DDR to survive. Cancer cells rely heavily on DDR as they divide and grow uncontrollably. Inhibition of DDR, particularly in combination with other anticancer agents, prevents cancer cells from repairing their DNA, ultimately activating a programmed cell death process. DDR inhibitors such as zedoresertib (Debio 0123), Debiopharm's WEE1 inhibitor, are currently being investigated in clinical and preclinical studies.

ABOUT PKMYT1 INHIBITION

Lunresertib (Debio2513) is a first-in-class, oral PKMYT1 inhibitor designed to exploit specific genetic vulnerabilities in solid tumors, such as CCNE1 amplification. By targeting PKMYT1, the drug induces synthetic lethality, preventing cancer cells from repairing DNA damage and forcing them into programmed cell death. As the most advanced PKMYT1 inhibitor in clinical development, lunresertib has shown encouraging proof-of-concept results both as monotherapy and in combination therapies within the ongoing MYTHIC trial.

DEBIOPHARM'S COMMITMENT TO CANCER PATIENTS

Debiopharm develops innovative therapies that target high unmet medical needs in oncology and infectious diseases. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high potential assets and technologies for in-licensing, clinically demonstrate their safety and efficacy, and then select pharmaceutical commercialization partners to maximize patient access globally.

Learn more about the MYTHIC trial: Solid Tumors - Debiopharm - Patients

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