PRESS RELEASE

DEBIOPHARM'S ADC RESEARCH GAINS MOMENTUM WITH LAUNCH OF FIRST-IN-HUMAN TRIAL ASSESSING DEBIO 1562M IN ACUTE MYELOID LEUKEMIA PATIENTS

First patient dosed with Debiopharm's first-in-class CD37 targeted antibody drug conjugate (ADC) in a Phase 1/2, multicenter, open-label trial, for patients with acute myeloid leukemia (AML)

Lausanne, Switzerland – June 16th, 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, today announced that the first patient has been dosed in the first-in-human clinical trial evaluating the safety, tolerability, and antileukemic activity of Debio 1562M monotherapy in patients with relapsed/refractory (R/R) acute myeloid leukemia (AML). This phase 1/2 trial (NCT06969430) will lay the groundwork for further development as it will allow the characterization of the safety and tolerability of the drug, dose optimization, and define the product's activity.

AML remains a significant unmet need in oncology, particularly for older adults who account for the majority of cases. Despite advances in our understanding of AML biology and the introduction of new therapies, outcomes remain dismal for many patients—especially those who are not candidates for intensive treatments such as traditional chemotherapy or stem cell transplantation. While intensive chemotherapy and targeted therapies are available, they have not substantially improved long-term outcomes across all patient populations. The 5-year overall survival (OS) rate remains at just 32%[1], with a median OS as low as 7 months in certain populations.[2] This stark therapeutic gap leaves thousands of patients without viable treatment options each year, highlighting an urgent need for innovative interventions capable of extending survival. Transformative solutions are critical to improving both prognosis and quality of life for this underserved population within the AML treatment landscape.

"It's time for AML research to advance with more precise therapeutic options," **expressed Marianna Muller, Senior Medical Director, Oncology, Debiopharm.** "This study will help us better understand the potential of Debio 1562M and how it could provide an effective new treatment while minimizing tolerability challenges for patients facing this very difficult disease with high unmet medical need."

CD37, a cell-surface antigen, has been shown to be a relevant ADC target in AML due to its broad expression on blasts and leukemic stem cells along with efficient internalization.[3] Research reveals that this increased expression is restricted to malignant cells compared to healthy hematopoietic stem cells and is correlated with poor patient outcomes.[3] **Debio 1562M is a next generation ADC targeting CD37 with 1st-in-class potential. The compound was designed using Debiopharm's Trifecta approach optimizing 3 key components: naratuximab - an anti-CD37 monoclonal antibody, Multilink™ proprietary linker technology, and a microtubule inhibitor as cytotoxic payload.** In pre-clinical studies, Debio 1562M showed anti-leukemic activity across all AML subtypes as well as superior activity vs. the current standard-of-care and targeted therapies in AML models.

Debiopharm has been involved in targeted drug delivery for more than a decade, developing MultiLink™—our unique and versatile proprietary ADC technology suite, key components of which are integrated into this product. We recognize how critical the need is for AML patients and remain dedicated to addressing it through our ADC expertise. As our pre-clinical results have shown promising antitumor activity and tolerability in this hard-to-treat leukemia, we're looking forward to seeing what this clinical stage research with Debio 1562M could reveal," **mentioned Bertrand Ducrey, CEO of Debiopharm.**

Debiopharm's ADC Expertise

We're developing fit-for-purpose antibody-drug conjugates (ADCs) through a tailored "Trifecta" approach: strategic target selection, innovative MultiLink™ linker technology, and smart payload choices. Our ADC portfolio includes first-in-class or best-in-class candidates: Debio 1562M, a CD37-targeted ADC for the treatment of acute myeloid leukemia (AML) and myelodysplastic syndromes (MDS), and Debio 0532, an HER3-targeted ADC for solid tumors, as well as other undisclosed targets. We are actively partnering to access innovative targets, co-develop, or out-license our ADC programs. Key partnerships include options to in-license bispecific antibodies targeting HER2-HER3 and HER3-EGFR. To enable both high drug-to-antibody ratios (DAR) and high stability, our ADCs are designed with our proprietary MultiLink™ linker technology.

We have strong in-house capabilities and in-depth expertise spanning ADC conjugation and optimization, pharmacokinetics/pharmacodynamics (PK/PD), toxicology, translational, pharmaceutical (CMC) and clinical development, and supply chain management. We continue to invest in and explore potential game-changing technologies, such as novel and dual payloads.

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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Sources

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[2] Meyers J, et al. Applied health economics and health policy. 2013 11 (3): 275-286.
[3] Lisa Ivanschitz, AACR 2025 Abstract # 1160