29 October 2025

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

DSMB Clearance to Proceed to the Next Dose Level of HG-CT-1 in Adult Patients, Opening Pediatric Recruitment, and Grant of Restricted Share Units to Hemogenyx Team

Hemogenyx Pharmaceuticals plc (LSE: HEMO) is pleased to announce that the independent Data Safety Monitoring Board ("DSMB") overseeing the Company's ongoing Phase I clinical trial of HG-CT-1, its proprietary Chimeric Antigen Receptor T-cell (CAR-T) therapy for the treatment of relapsed or refractory acute myeloid leukemia ("R/R AML") in adults, has reviewed safety data from the first three patients treated at the initial dose level and has recommended continuation of the trial with escalation to the next dose level.

The DSMB's positive recommendation follows the successful completion of initial safety assessments for all three patients treated at the lowest dose, with no dose-limiting toxicities observed. The trial will now proceed to the next planned dose cohort in accordance with the FDA-approved clinical protocol.

Importantly, clearance to proceed to the next adult dose also enables the initiation of pediatric patient recruitment for the Phase I clinical trial at the lowest dose of HG-CT-1, the same dose level already used in the first cohort of adults. This expansion reflects the Company's ongoing commitment to extending the potential benefits of HG-CT-1 to children and adolescents suffering from this aggressive and difficult to treat form of leukemia.

The Phase I study of HG-CT-1 is a dose-escalation trial designed to evaluate the safety, tolerability, and preliminary efficacy of the Company's proprietary CAR-T therapy in adult and pediatric patients with R/R AML. In addition to safety, the trial includes secondary endpoints such as assessment of AML-specific responses, progression-free survival, duration of response, and overall survival.

The DSMB's clearance to proceed represents a key de-risking milestone in the clinical development of HG-CT-1. It reinforces the favorable safety profile observed to date and signals continued regulatory and operational momentum. For investors, this milestone marks a potential value-inflection point as the Company advances into higher dose cohorts where enhanced efficacy signals are anticipated, paving the way toward broader clinical validation and future pivotal studies.

As a reward for the Hemogenyx team's outstanding contribution to the HG-CT-1 program and their dedication to advancing this groundbreaking therapy, the Company has granted a total of 6,000 Restricted Share Units ("RSUs") to key team members under its existing equity incentive arrangements. These RSUs align the team's interests with those of shareholders and recognize their ongoing efforts in driving Company's clinical and operational success.

Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented:
"We are very pleased to have received DSMB clearance to advance HG-CT-1 to the next dose level. This important milestone marks continued progress in our clinical development program and further validates the safety profile of our CAR-T therapy.
I would also like to express my deep appreciation to the entire Hemogenyx Pharmaceutical team, whose dedication, scientific rigor, and perseverance have made this achievement possible. Their commitment to excellence continues to drive our success and to move this potentially life-saving therapy closer to patients in need.
We remain encouraged by the early clinical findings and are committed to advancing HG-CT-1 through its dose-escalation phase to unlock its full therapeutic potential for patients with relapsed or refractory AML."

Further updates will be provided as the trial progresses.

Market Abuse Regulation (MAR) Disclosure

Certain information contained in this announcement would have been inside information for the purposes of Article 7 of Regulation No 596/2014 (as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018) until the release of this announcement.

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About Hemogenyx Pharmaceuticals plc

Hemogenyx Pharmaceuticals is a publicly traded company (LSE: HEMO) headquartered in London, with its US operating subsidiaries, Hemogenyx Pharmaceuticals LLC and Immugenyx LLC, located in New York City at its state-of-the-art research facility.

The Company is a clinical stage biopharmaceutical group developing new medicines and treatments to treat blood and autoimmune diseases. Hemogenyx Pharmaceuticals is developing several distinct and complementary product candidates, as well as platform technologies that it uses as engines for novel product development.