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17 June 2025

Hemogenyx Pharmaceuticals plc
("Hemogenyx Pharmaceuticals" or the "Company")

Regulatory Clearance to Proceed with Pediatric Expansion of HG-CT-1 Clinical Trial

Hemogenyx Pharmaceuticals plc (LSE: HEMO) is pleased to announce that the 30-day review period by the U.S. Food and Drug Administration (FDA) for the Company's [previously submitted amendment](#) to the clinical protocol of its ongoing Phase I trial of HG-CT-1 has concluded without a clinical hold. As a result, the Company is now cleared to proceed with the next steps required to initiate pediatric enrolment in the trial.

The protocol amendment expands the eligibility criteria for the Phase I trial of HG-CT-1, Hemogenyx's proprietary CAR-T therapy for relapsed/refractory acute myeloid leukemia (R/R AML), to include children and adolescents with this aggressive and hard-to-treat disease.

The Company will now move forward with Institutional Review Board (IRB) submissions and associated site activation procedures to enable the opening of pediatric cohorts.

Dr. Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented: *"Regulatory clearance to proceed with the pediatric expansion of our HG-CT-1 clinical trial is a significant milestone. It reflects continued momentum in our development program and underscores our commitment to delivering innovative therapies to patients across age groups. This expansion broadens the potential impact and value of HG-CT-1 as we continue to advance toward key inflection points in the clinic. Importantly, it also reinforces the value of Company's robust intellectual property portfolio, which underpins our pipeline and supports long-term strategic growth."*

The Company will update the market as further progress is made in pediatric site activation and patient enrolment.

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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.