RNS Number: 5168I

Hemogenyx Pharmaceuticals PLC

14 May 2025

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Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Amendment to Clinical Protocol for HG-CT-1 to Include Pediatric Patients with R/R AML

Hemogenyx Pharmaceuticals plc (LSE:HEMO) is pleased to announce that it has filed an amendment to the clinical protocol for its ongoing Phase I clinical trial of HG-CT-1 to include pediatric patients with relapsed/refractory acute myeloid leukemia ("R/R AML"). HG-CT-1 is the Company's CAR-T therapy, currently undergoing clinical trials in adults for the treatment of R/R AML.

This amendment, filed with the U.S. Food and Drug Administration (FDA), seeks to expand eligibility for the trial beyond adult patients to include children and adolescents with R/R AML, an aggressive disease with limited treatment options and poor prognosis in the relapsed/refractory setting. The expansion reflects the Company's commitment to broadening the potential impact of HG-CT-1 and addressing a critical unmet medical need in pediatric oncology.

The amendment builds on the Company's progress to date in the adult cohort of the trial, in which the first two patients have already been treated.

Dr. Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented:

"We are pleased to take this important step toward making HG-CT-1 available to pediatric patients who currently have very few therapeutic options. The inclusion of children and adolescents in the trial not only reflects our commitment to addressing urgent medical needs across age groups but also supports the broader potential of HG-CT-1 as a transformative therapy for AML."

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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.

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