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14 April 2026

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Hemogenyx Pharmaceuticals Files Annual IND Report with FDA for HG-CT-1 CAR-T Therapy for AML

Hemogenyx Pharmaceuticals plc (LSE: HEMO) is pleased to announce that it has submitted its Annual Report to the U.S. Food and Drug Administration (FDA) under the active Investigational New Drug (IND) application for HG-CT-1**,** the Company's proprietary CAR-T cell therapy for the treatment of relapsed or refractory acute myeloid leukemia (R/R AML).

The annual report provides a comprehensive update on the Company's activities under the IND during the first year of the clinical trial of HG-CT-1 and includes the following key elements:

1. **Individual Study Information:**

   The ongoing Phase 1 study is designed to evaluate the safety and preliminary efficacy of HG-CT-1 in adult and pediatric patients with R/R AML. The study plans to enroll up to 36 evaluable subjects (18 adults and 18 pediatric patients), with a primary objective of assessing safety based on dose-limiting toxicities.

   As of the IND anniversary date, three adult patients have been enrolled and treated at the initial lowest dose level (7×10^7 CAR^+ cells).

Across these patients:

- CAR-T cell expansion and persistence were observed in all subjects, with peak levels typically occurring between 14 and 28 days post-infusion
- Reductions in blast burden were observed in peripheral blood and/or bone marrow
- No immune effector cell-associated neurotoxicity syndrome (ICANS) or dose-limiting toxicities (DLTs) were reported
- Adverse events were generally low grade and manageable

These findings remain preliminary due to the limited number of patients and evaluation at a single dose level.

2. **Quality Summary Information:**

   The report includes data from investigations conducted during the reporting period relating to the stability of the HG-CT-1 drug product and its lentiviral vector manufacturing process, supporting continued clinical development.

3. **Update to the General Investigational Plan:**

   The Company plans to continue patient enrollment and dose escalation in the upcoming year to further evaluate the safety profile and potential anti-leukemic activity of HG-CT-1.

This filing marks another important step in the Company's clinical development of HG-CT-1 and reaffirms its commitment to regulatory compliance and transparent communication with stakeholders.

Further updates will be provided as the trial progresses.

Dr. Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented: *"Submitting our second annual IND report to the FDA represents continued progress in the development of HG-CT-1. While early-stage data remain preliminary, we are encouraged by the observed biological activity and manageable safety profile. We are focused on advancing the study through additional dose levels to further evaluate the therapeutic potential of HG-CT-1 for patients with relapsed or refractory 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 disease and to bring the curative power of bone marrow transplantation to a greater number of patients suffering from otherwise incurable life-threatening diseases. Hemogenyx Pharmaceuticals is developing several distinct and complementary product candidates, as well as a platform technology that it uses as an engine for novel product development.