RNS Number : 4304D
Hemogenyx Pharmaceuticals PLC
03 April 2025

3 April 2025

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:**

   A summary of the ongoing clinical study, including its title, design, purpose and objectives, patient population, the total number of planned subjects, and the number enrolled as of the IND anniversary date (*February 6, 2025*). The report confirms the enrollment of the first patient and includes demographic details such as age, sex, and race.

2. **Quality Summary Information:**

   Data obtained from the past year's investigations under the IND related to the stability of the HG-CT-1 drug product and the lentiviral vector used in its manufacturing.

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

   A forward-looking update outlining the plan for continued patient enrollment during the upcoming year of the study.

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 first annual IND report to the FDA is an important milestone that underscores the steady progress we are making in the clinical development of HG-CT-1. For patients facing relapsed or refractory AML, it brings us one step closer to delivering a potentially life-saving therapy. For our investors and partners, it demonstrates our continued execution, scientific rigor, and commitment to transparency. We are advancing with purpose and precision-guided by the urgency of patient need and the confidence of our supporters."

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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.

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