

30 October 2024

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Schedule for Phase I Clinical Trial Opening

Hemogenyx Pharmaceuticals Announces Schedule for Opening First Clinical Site for Phase I Trial of HEMO-CAR-T (HG-CT-1)

Hemogenyx Pharmaceuticals plc (LSE: HEMO), a biopharmaceutical company focused on developing breakthrough therapies for blood diseases, is pleased to announce the schedule for the opening of the first clinical site for its lead asset, HEMO-CAR-T, formally designated HG-CT-1, targeting relapsed/refractory (R/R) acute myeloid leukemia (AML) in adults.

The Company has successfully completed the necessary contracts and budgeting preparations to advance HG-CT-1 into clinical testing. Institutional Review Board (IRB) approval at the initial clinical site is anticipated by the second week of November. Following IRB clearance, a Site Initiation Visit (SIV) is expected to take place in the third week of November, marking the official launch of the Phase I clinical trial.

This Phase I trial is designed as a dose-escalation study to evaluate the safety profile of HG-CT-1 in adult patients with R/R AML. Key secondary objectives include assessing the therapy's impact on the following clinical outcomes:

- **Efficacy** of HG-CT-1 based on AML-specific response criteria
- **Overall survival (OS)** rates among participating subjects
- **Progression-free survival (PFS)** in evaluable subjects
- **Duration of response (DoR)** in those who achieve clinical responses

These objectives are pivotal for assessing the overall clinical impact of HG-CT-1 on patients with R/R AML, a population with few remaining therapeutic options. The commencement of this trial will represent a major milestone for Hemogenyx Pharmaceuticals, enabling the Company to advance this promising therapy into clinical testing at one of the world's most prestigious cancer research institutions.

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

"Launching this Phase I clinical trial for HG-CT-1 will mark a critical step forward in our mission to develop transformative therapies for patients battling relapsed and refractory acute myeloid leukemia. For patients who have few remaining treatment options, HG-CT-1 offers a potentially life-saving solution. We are eager to initiate this trial and generate data that will be essential in advancing this therapy toward broader clinical use. This milestone underscores our commitment to innovation and our dedication to addressing the urgent needs of patients with severe blood cancers."

About AML and CAR-T Therapy

AML, the most common type of acute leukemia in adults, has poor survival rates (a five-year survival rate of less than 30% in adults) and is currently treated using chemotherapy, rather than the potentially more benign and effective forms of therapy being developed by Hemogenyx Pharmaceuticals. The successful development of a new therapy for AML would have a major impact on treatment and survival rates for the disease.

CAR-T therapy is a treatment in which a patient's own T-cells, a type of immune cell, are modified to recognize and kill the patient's cancer cells. The procedure involves: isolating T-cells from the patient; modifying the isolated T-cells in a laboratory using a CAR gene construct (which allows the cells to recognize the patient's cancer); amplifying (growing to large numbers) the newly modified cells; and re-introducing the cells back into the patient.

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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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