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## Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

### IRB Approval for Phase I Clinical Trial

*Hemogenyx Pharmaceuticals Receives IRB Approval for Phase I Clinical Trial of HEMO-CAR-T (HG-CT-1)*

Hemogenyx Pharmaceuticals plc (LSE: HEMO), a biopharmaceutical company developing innovative therapies and treatments for blood diseases, is pleased to announce that the **Institutional Review Board (IRB)** of the Company's first clinical site has granted approval to initiate a **Phase I clinical trial** of the Company's lead asset, **HEMO-CAR-T** - now given the formal designation **HG-CT-1** - for the treatment of **relapsed/refractory (R/R) acute myeloid leukemia (AML)** in adults.

The **Phase 1 clinical trial** is designed as a **dose escalation study** to assess the **safety of HG-CT-1** in adult patients with R/R AML. Secondary clinical objectives are crucial for evaluating the broader impact of HG-CT-1 and include:

- **Estimating the efficacy** of HG-CT-1 based on standard clinical response criteria for AML.
- **Estimating overall survival (OS)** in evaluable subjects.
- **Estimating progression-free survival (PFS)** in evaluable subjects.
- **Estimating duration of response (DoR)** in evaluable subjects who achieve a clinical response.

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. This IRB approval represents a significant 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: *"We are excited to receive IRB approval to proceed with our Phase I clinical trial of HEMO-CAR-T. This trial is a critical step in the development of our CAR-T therapy for AML patients who have exhausted*

*other treatment options. With this study, we aim to establish the safety profile of HG-CT-1 and gather preliminary efficacy data that could pave the way for future therapeutic development."*

## **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.

## **Market Abuse Regulation (MAR) Disclosure**

Certain information contained in this announcement would have been inside information for the purposes of Article 7 of Regulation No 596/2014 (as it forms part of UK domestic law by virtue of the European Union (Withdrawal) Act 2018) until the release of this announcement. The person responsible for arranging for the release of this announcement on behalf of Hemogenyx Pharmaceuticals plc is Dr Vladislav Sandler, Chief Executive Officer & Co-Founder.

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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.