



2 June 2023

## **Hemogenyx Pharmaceuticals plc**

("Hemogenyx Pharmaceuticals" or the "Company")

### **Hemogenyx Pharmaceuticals Announces Clinical Hold on IND for HEMO-CAR-T**

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical group developing new therapies and treatments for blood diseases, announces that the Company has received a notice from the U.S. Food and Drug Administration ("FDA") regarding the Investigational New Drug ("IND") application for the Company's product candidate Chimeric Antigen Receptor ("CAR") T-cells ("HEMO-CAR-T") for the treatment of acute myeloid leukemia ("AML") to the effect that HEMO-CAR-T be put on clinical hold pending an FDA letter to be received within 30 days setting out additional information required to be provided by the Company.

Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented: *"We are confident that we will be able to address the FDA's questions and concerns regarding the IND. AML has poor survival rates and we are eager to resolve this hold and continue down the treatment development pathway toward saving lives."*

#### **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 form 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 pre-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 platform technologies that it uses as engines for novel product development.