RNS Number: 7491Z

Hemogenyx Pharmaceuticals PLC

16 January 2024

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### Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

#### Submission of Complete Response to Clinical Hold for HEMO-CAR-T IND

Hemogenyx Pharmaceuticals plc (LSE: HEMO) announces the submission of a complete response to the previously announced Clinical Hold ("CH") of the Investigational New Drug ("IND") application to the US Food and Drug Administration ("FDA") for HEMO-CAR-T. A complete response is necessary to apply for the lifting of the CH which is needed to obtain consent from the FDA to commence Phase I clinical trials of HEMO-CAR-T.

**Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented:** "We are pleased to have filed a complete response to the FDA addressing their concerns that resulted in a CH of the HEMO-CART IND. We look forward to becoming a clinical stage biopharmaceutical company once consent is received from the FDA."

### 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.

# **Enquiries:**

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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 a platform technology that it uses as an engine for novel product development.

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