14 September 2023

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Clinical Hold Lift Plan is accepted by FDA

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical group developing new therapies and treatments for blood diseases, announces that the U.S. Food and Drug Administration ("FDA") has accepted the Company's plan to address the FDA's concerns that resulted in a Clinical Hold ("CH") of the HEMO-CAR-T Investigational New Drug ("IND") application.

Further to the announcement on 10 July 2023, Hemogenyx Pharmaceuticals carefully considered the comments provided by the FDA in connection with the CH and responded in August 2023 with a detailed plan, supported by laboratory tests, to address those comments. The Company has now received confirmation from the FDA that the Company's plan satisfactorily addresses the agency's comments.

Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented: *"We are pleased that the FDA has agreed to our plan and preliminary test results to address their concerns regarding our HEMO-CAR-T IND application. We are now working hard to complete the schedule of work set out in the plan and to re-submit the IND as expeditiously as possible in order to move forward with clinical trials of HEMO-CAR-T."*

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.