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Hemogenyx Pharmaceuticals PLC
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Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

FDA Consents to Phase I Trials of HEMO-CAR-T

Hemogenyx Pharmaceuticals plc (LSE: HEMO) is pleased to announce that it has been informed by the U.S. Federal Food and Drug Administration ("FDA") that it has lifted the clinical hold on the Investigational New Drug (IND) application for HEMO-CAR-T for the treatment of acute myeloid leukemia ("AML"). The FDA confirmed that the Company had addressed all issues identified in its prior clinical hold letter satisfactorily and consents to the Company proceeding with its Phase I clinical study of HEMO-CAR-T.

Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented: "We are extremely pleased with the FDA's decision to lift the clinical hold. We now look forward to accelerating clinical development of HEMO-CAR-T and to offering patients a potentially life-saving treatment. The removal of the clinical hold was made possible by the hard work and dedication of the entire Hemogenyx Pharmaceuticals team and its Board of Directors and advisors."

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

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