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Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

HEMO-CAR-T Process Qualification Run Completed

Hemogenyx Pharmaceuticals plc (LSE: HEMO), which is developing new therapies and treatments for blood diseases, is pleased to announce the successful completion of its Process Qualification ("PQ") run of the end-to-end process for the manufacture of HEMO-CAR-T cells. This PQ run was a part of the Company's plan to address the U.S. Food and Drug Administration ("FDA") concerns that resulted in a Clinical Hold ("CH") of the HEMO-CAR-T Investigational New Drug ("IND") application, as announced [previously](#). The FDA has [accepted](#) the Company's plan.

This PQ run is the only manufacturing run required for the submission of a complete response to the CH of the IND application to the FDA for HEMO-CAR-T. It was the key remaining step prior to applying 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. Following the successful completion of all tests across the PQ run, data will be compiled for inclusion in the complete response submission pack.

Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx, commented:

"We are pleased that we have now completed the necessary PQ run. We are now working hard to re-submit the IND as expeditiously as possible 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.