

23 March 2023

## **Hemogenyx Pharmaceuticals plc**

("Hemogenyx Pharmaceuticals" or the "Company")

## **HEMO-CAR-T Analytical Release Tests Completed**

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical group developing new therapies and treatments for deadly blood diseases, is pleased to announce the successful completion of a full set of analytical tests required to verify the quality of the cells manufactured during three Process Qualification ("PQ") runs of the end-to-end process for HEMO-CAR-T production. Each PQ run is an end-to-end process of the manufacture of HEMO-CAR-T cells. The PQ runs were carried out in the Company's current Good Manufacturing Practice ("cGMP") compliant clean rooms. They were followed by analytical release tests that were conducted both by the Company and a third party to ensure that manufactured HEMO-CAR-T cells comply with a set of required quality attributes. Among these attributes are viability, potency and sterility of the manufactured HEMO-CAR-T cells.

The completion of the full set of analytical tests of all PQ runs is the last manufacturing requirement that is necessary for the submission of an Investigational New Drug ("IND") application to the US Food and Drug Administration ("FDA"), which is now in the course of preparation. The IND is needed to obtain authorization from the FDA to commence Phase I clinical trials of HEMO-CAR-T. All PQ runs as well as analytical tests data will be compiled for inclusion in the IND submission pack.



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