



23 January 2023

RNS Reach – Non-Regulatory

### **Hemogenyx Pharmaceuticals plc**

("Hemogenyx Pharmaceuticals" or the "Company")

### **HEMO-CAR-T Third Process Qualification Run 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 its third Process Qualification ("PQ") run of the end-to-end process for the manufacture of HEMO-CAR-T cells. The process was carried out in the Company's current Good Manufacturing Practice ("cGMP") compliant clean rooms. It is being followed by analytical release tests conducted by the Company required to verify the quality of the manufactured HEMO-CAR-T cells. The HEMO-CAR-T cells will also be tested by a third party to ensure they comply with a set of required quality attributes.

This PQ run is the third of minimum three identical manufacturing runs required for the submission of an Investigational New Drug ("IND") application to the US Food and Drug Administration ("FDA"). The IND is needed to obtain authorization from the FDA to commence Phase I clinical trials of HEMO-CAR-T. Following completion of all tests across all PQ runs, 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.