



31 March 2025

THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION AS STIPULATED UNDER THE UK VERSION OF THE MARKET ABUSE REGULATION NO 596/2014 WHICH IS PART OF ENGLISH LAW BY VIRTUE OF THE EUROPEAN (WITHDRAWAL) ACT 2018, AS AMENDED. ON PUBLICATION OF THIS ANNOUNCEMENT VIA A REGULATORY INFORMATION SERVICE, THIS INFORMATION IS CONSIDERED TO BE IN THE PUBLIC DOMAIN.

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Tech Transfer Completion and Clinical Trial Progress

Hemogenyx Pharmaceuticals plc (LSE: HEMO), a biopharmaceutical company focused on the development of innovative therapies for the treatment of blood diseases, is pleased to provide the following update on its HG-CT-1 CAR-T cell therapy program for relapsed/refractory acute myeloid leukemia (R/R AML):

Completion of Manufacturing Tech Transfer and FDA Submission

The Company announces that the technology transfer of the manufacturing process for its HG-CT-1 CAR-T cell therapy has been successfully completed to Made Scientific, a contract development and manufacturing organization (CDMO).

A comprehensive comparability data package has been submitted to the U.S. Food and Drug Administration (FDA). The submitted data demonstrate that HG-CT-1 manufactured by Made Scientific is comparable to that produced by Hemogenyx Pharmaceuticals, confirming the robustness and reproducibility of the manufacturing process across sites.

Clinical Trial Progression

Hemogenyx Pharmaceuticals is now ready to initiate recruitment of adult patients for treatment with the second, increased dose level of HG-CT-1 as part of its ongoing Phase 1 clinical trial in R/R AML.

In parallel, the Company will begin recruitment of pediatric patients, who will receive the lowest dose level of HG-CT-1. This marks an important expansion of the clinical program into pediatric populations suffering from R/R AML.

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

"We are pleased to have successfully completed the tech transfer of HG-CT-1 manufacturing and to have demonstrated comparability between internally and externally manufactured product. This is a critical milestone as we advance our clinical program.

With recruitment set to begin at the next dose level in adults and to expand into pediatric patients, we are well-positioned to accelerate the development of HG-CT-1 for patients with relapsed or refractory AML who have limited treatment options.

While the Company's efforts remain primarily focused on the HG-CT-1 clinical trials, it continues to advance its CDX and CBR product candidates where possible and expects to report further progress on these programmes in due course."

UK Market Abuse Regulation (UK 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 .

The Company is a clinical stage biopharmaceutical group developing new medicines and treatments to treat blood and autoimmune 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.