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Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Third Patient Treated with HG-CT-1 CAR-T Therapy Successfully Passes Initial Safety Evaluation

Hemogenyx Pharmaceuticals plc is pleased to announce that the third patient has been successfully treated in the ongoing Phase I clinical trial of HG-CT-1, the Company's proprietary Chimeric Antigen Receptor T-cell (CAR-T) therapy for relapsed/refractory acute myeloid leukemia (R/R AML) in adults.

The treatment was well tolerated and met the trial's predefined initial safety criteria. Importantly, early indications of clinical efficacy have been observed. Preliminary assessment shows that original AML cells were not detectable in the patient using standard testing methods. The patient will continue to be monitored in line with the FDA-approved trial protocol to evaluate the achievement of the study's secondary endpoints described below.

Safety data from the first three patients treated at the lowest dose of HG-CT-1 will be submitted to an independent Data Safety Monitoring Board (DSMB) for review. The DSMB will determine whether dose escalation to the next level may proceed.

The Phase I trial is a dose-escalation study designed to evaluate the safety and tolerability of HG-CT-1. In addition to safety, the trial includes several key secondary endpoints:

- Assessing the efficacy of HG-CT-1 based on AML-specific response criteria
- Evaluating overall survival
- Measuring progression-free survival
- Determining duration of response in patients demonstrating clinical benefit

Data related to these secondary endpoints, including efficacy, durability, and overall clinical outcomes, will be collected over time through continued follow-up of the treated patient. These secondary endpoints are critical for assessing the potential clinical impact of HG-CT-1 in a patient population with limited remaining treatment options.

Further updates will be provided as the trial progresses.

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

“The successful treatment of the third patient marks another important milestone for Hemogenyx Pharmaceuticals and for patients battling relapsed or refractory AML. We are encouraged by the favorable safety profile observed to date, together with the early signals of efficacy. These results reinforce the promise of HG-CT-1 as a potential new therapy for one of the most aggressive and intractable forms of leukemia. We remain committed to advancing the clinical development of this therapy to address a critical unmet medical need, while also creating long-term value for our shareholders.”

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.

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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 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.