

19 December 2024

Hemogenyx Pharmaceuticals plc

("Hemogenyx Pharmaceuticals" or the "Company")

Ultrafast CAR-T Manufacturing

Collaboration with Kure.ai to develop ultrafast CAR-T manufacturing process for Hemogenyx Pharmaceuticals' AML Treatment

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical company developing innovative therapies for blood malignancies, and Kure.ai ("Kure"), a leader in ultrafast CAR-T manufacturing technology, are pleased to announce a strategic collaboration to advance the production of CAR-T cell therapies for acute myeloid leukemia (AML) and a subset of acute lymphoblastic leukemia (ALL).

This partnership aims to integrate Kure's ultrafast manufacturing (UM) technology with Hemogenyx Pharmaceuticals's proprietary CAR-T therapy, HG-CT-1 (formerly known as HEMO-CAR-T) to enable faster, more efficient production of CAR-T cells, significantly reducing manufacturing timelines while maintaining therapeutic potency.

Key Highlights of the Collaboration

- 1. Clinical Study:**
Hemogenyx Pharmaceuticals will initiate a clinical study to evaluate its CAR-T therapy for AML and KMT2A-rearranged ALL, utilizing Kure's UM process.
- 2. Process Development:**
Both parties will collaborate on developing a customized UM process for Hemogenyx Pharmaceutical's CAR-T therapy, optimizing its application in AML treatment.
- 3. Material and Expertise Sharing:**
Hemogenyx Pharmaceuticals will provide critical materials, including lentiviral vectors, and necessary technical know-how to facilitate process development.
- 4. In Vitro Testing:**
Hemogenyx Pharmaceuticals will conduct *in vitro* testing to assess the potency and vector copy number (VCN) of CAR-T cells manufactured using Kure's ultrafast platform.
- 5. Adaptation of Manufacturing Technology:**
Kure will adapt and refine its ultrafast CAR-T manufacturing process specifically to the Company's CAR-T therapy requirements.
- 6. Licensing Option:**
Upon successful completion of process development, Hemogenyx Pharmaceuticals will have the option to license Kure's UM technology for clinical trial production, with licensing terms to be negotiated.

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

"One of the most significant challenges in CAR-T therapy is the time and cost associated with manufacturing. Our partnership with Kure.ai allows us to explore and integrate a cutting-edge ultrafast manufacturing process that has the potential to revolutionize CAR-T production. This collaboration is an important step toward accelerating patient access to life-saving therapies."

Dr. David Wald, Founder of Kure.ai and Professor at Case Western Reserve University, added:

"We are excited to partner with Hemogenyx Pharmaceuticals to adapt our ultrafast manufacturing platform to their innovative CAR-T therapy. This collaboration not only advances next-generation CAR-T solutions but also demonstrates the real-world clinical utility of our technology in addressing urgent unmet medical needs."

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% for many patients).

than 50% in adults) and is currently treated using chemotherapy, rather than the potentially more benign and effective forms 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 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 a platform technology that it uses as an engine for novel product development.

About Kure.ai

Kure.ai is a clinical stage privately owned biotechnology company specializing in ultrafast CAR-T manufacturing technology. Founded by Dr. David Wald, a professor at Case Western Reserve University, Kure focuses on optimizing CAR-T production timelines while maintaining therapeutic quality and efficacy.

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