



13 December 2021

## **Hemogenyx Pharmaceuticals plc**

("Hemogenyx Pharmaceuticals" or the "Company")

### **HEMO-CAR-T pre-IND Meeting Request**

Hemogenyx Pharmaceuticals plc (LSE: HEMO), the biopharmaceutical group developing new therapies and treatments for blood diseases, is pleased to announce significant progress in relation to moving its lead product candidate Chimeric Antigen Receptor ("CAR") T-cells ("HEMO-CAR-T") toward clinical trials. The Company has applied for a pre-Investigational New Drug ("PIND") application meeting with the FDA regarding HEMO-CAR-T, the purpose of which is to enable the Company to complete the planning of clinical trials for the product candidate and submission of the Investigational New Drug ("IND") application.

The PIND meeting facilitates the preparation and submission of a complete IND application by giving companies a valuable opportunity to obtain FDA feedback on a drug development programme, the intended design of clinical trials, and other questions including manufacturing, quality, safety and regulatory matters. PIND meetings take place only when a developer is commencing the design of a clinical trial in the US. During the PIND meeting, the FDA may provide recommendations and a preliminary indication of its agreement with key aspects of the manufacturing, quality, safety and the clinical trial programme that can help to shape the IND application. The meeting helps to build a relationship with the FDA, ensures that a submitted complete IND application is not met with objections or possible objections from FDA are minimal, and potentially avoids "clinical holds" (FDA orders to delay or suspend clinical trials once they have begun).

Dr Vladislav Sandler, CEO & Co-Founder of Hemogenyx Pharmaceuticals, commented: *"This is a vital next step on a direct path toward clinical trials for one of our leading product candidates. We are confident that this will help us to hone our IND application and accelerate the development of HEMO-CAR-T which we believe will have a substantial and positive impact on the treatment of AML, significantly improving survival and recovery rates for an acute form of leukemia for which there is currently no effective treatment."*

## 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% in adults) and is currently treated using chemotherapy, rather than the potentially more benign and effective form of therapy being developed by Hemogenyx Pharmaceuticals. The successful development of the 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.

## 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.

For more than 50 years, bone marrow transplantation has been used to save the lives of patients suffering from blood diseases. The risks of toxicity and death that are associated with bone marrow transplantation, however, have meant that the procedure is restricted to use only as a last resort. The Company's technology has the potential to enable many more patients suffering from devastating blood diseases such as leukemia and lymphoma, as well as severe autoimmune diseases such as multiple sclerosis, aplastic anemia and systemic lupus erythematosus (Lupus), to benefit from bone marrow transplantation.