FDA CLEARANCE FOR VANDERBILT HEALTH INVESTIGATOR SPONSORED TRIAL FOR ACUTE MYELOID LEUKAEMIA

- **US FDA has provided approval for Vanderbilt Health to commence the investigator-sponsored clinical trial (IST) evaluating HMBD-002 in combination with venetoclax and azacitidine in acute myeloid leukaemia (AML) and myelodysplastic syndrome (MDS)**

- **FDA clearance represents an important regulatory milestone for HMBD-002 and enables the clinical study to proceed in the United States.**

- **The multi-centre study, led by Vanderbilt Health, is proposed to evaluate HMBD-002 in combination with azacitidine and venetoclax in patients with relapsed or refractory AML or AML / MDS**

- **AML remains a disease with significant unmet medical need, with an estimated 22,720 new cases and 11,500 deaths in the United States in 2026**

- **HMBD-002 clinical trial material has been manufactured and released to support the study**

Melbourne, Australia – 2 November 2026: Percheron Therapeutics Limited (ASX: PER) ('the Company'), an international biotechnology company focused on developing novel therapies for oncology, is pleased to announce that the United States Food and Drug Administration (FDA) has provided approval, allowing the investigator-sponsored trial (IST) of HMBD-002 in combination with venetoclax and azacitidine in patients with Acute Myeloid Leukaemia (AML) and Myelodysplastic Syndrome (MDS) to commence.

Receipt of the Safe to Proceed letter represents an important regulatory milestone for HMBD-002 and clears the US regulatory pathway for the study to advance. As announced 28 August 2026, Vanderbilt Health will lead the design and execution of the investigator-sponsored, multi-centre study, with Percheron providing HMBD-002, technical assistance and financial grant support. Percheron will have full access to the resulting clinical data to inform future clinical development, regulatory interactions and partnering discussions.

Percheron's CEO and MD, Dr Michael Baker, commented:

> *"AML remains a devastating disease for many patients despite significant advances in treatment. With a five-year relative survival rate of approximately 33% there remains a clear need for new therapeutic approaches that can improve outcomes for patients. The Vanderbilt study provides an exciting opportunity to evaluate HMBD-002 in combination with venetoclax and azacitidine, two established AML therapies, and investigate whether targeting VISTA can further*

improve therapeutic outcomes. With HMBD-002 manufactured for the study and the FDA regulatory clearance now received, we are very pleased with the progress towards commencing this important clinical study."

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There is a strong scientific rationale for investigating VISTA (V-domain Ig suppressor of T cell activation) inhibition in myeloid malignancies. VISTA is highly expressed in AML and has been associated with recurrence and resistance to therapy. Experimental VISTA inhibition has also demonstrated preclinical activity in AML models, and AML expression levels are associated with poor prognosis in patients[1].

Significant unmet need in acute myeloid leukaemia

AML is an aggressive malignancy affecting the blood and bone marrow and is the most common form of acute leukaemia in adults. An estimated 22,720 people will be diagnosed with AML in the United States in 2026 and approximately 11,500 people will die from the disease.[2] Despite advances in treatment, long-term outcomes remain poor for many patients. US National Cancer Institute SEER data report a five-year relative survival rate of 33.4% for AML, based on patients diagnosed between 2016 and 2022[3]. These outcomes underscore the continued need for new therapeutic approaches, particularly for patients with high-risk, recurrent or treatment-resistant disease.

Vanderbilt Health Investigator Sponsored Trial

The investigator-sponsored study will be led by Dr Somedeb Ball, Assistant Professor in the Division of Hematology and Oncology at Vanderbilt Health and is proposed to investigate HMBD-002 in combination with azacitidine and venetoclax in up to 20 patients with relapsed or refractory AML or AML / MDS.

The study is aimed at determining the optimal dose of HMBD-002 to use in combination with venetoclax and azacitidine. Percheron expects to provide further updates regarding the study design around the time of commencement.

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[1] Kim et al, 2024. J Clinical Investigation
[2] https://www.cancer.org/cancer/types/acute-myeloid-leukemia/about/key-statistics.html
[3] https://seer.cancer.gov/statfacts/html/amyl.html

About Percheron Therapeutics Limited

Percheron Therapeutics Limited [ASX: PER | US OTC: PERCF] is a publicly listed biotechnology company focused on the development and commercialisation of novel therapies for oncology. The company's lead program is HMBD-002, a monoclonal antibody targeting the immune checkpoint regulator, VISTA. HMBD-002 has completed a phase 1 clinical trial in patients with advanced cancer, showing the drug is generally safe and well tolerated, and Percheron aims to commence further clinical trials in CY2026.

For more information, please contact info@PercheronTx.com.

This announcement has been authorised for release to the Australian Securities Exchange by the Percheron Board of Directors