HMBD-002 PHASE I TRIAL – FINAL DATA SHOWS FAVOURABLE SAFETY PROFILE AND POTENTIAL EFFICACY SIGNALS IN MULTIPLE CANCERS

Melbourne, Australia – 7 October 2025: Percheron Therapeutics Limited (ASX: PER) ('the Company'), an international biotechnology company focused on the development of novel therapies for oncology and rare diseases, is pleased to announce final data from the phase I clinical trial of HMBD-002, a novel therapy under development for multiple forms of cancer.

Key Points

- Phase I clinical trial of HMBD-002 (NCT05082610) was conducted at six centres in the United States, under the oversight of the US FDA via an Investigational New Drug (IND) application.

- The study recruited 48 patients with advanced metastatic cancer, including patients with primary tumours of the pancreas, bowel, breast, lung, and other organs. All patients were heavily pre-treated, having received, on average, between four and five different drug treatments prior to study entry.

- HMBD-002 demonstrated a very favourable safety profile at doses up to 1,400mg per week, both as monotherapy and in combination with Keytruda® (pembrolizumab). Fewer than 10% of patients experienced treatment-related adverse events greater than or equal to grade 3, and there were insufficient dose-limiting toxicities observed to formally establish a maximum tolerated dose (MTD).

- The primary objective of the study was to assess safety and tolerability, and it was not designed or powered to formally quantify the efficacy of HMBD-002. Nevertheless, a number of patients demonstrated an apparent treatment benefit, suggesting potential activity for HMBD-002 in a range of cancer types.

- Percheron expects to further analyse and discuss these results in order to inform a planned phase II efficacy trial in CY2026. The Company also hopes to submit the data for publication in a peer-reviewed scientific journal in CY2026.

"We are delighted to report positive final data from the HMBD-002 phase I study," commented Percheron CEO, Dr James Garner. "These data are very encouraging as we look toward a phase II trial next year. In particular, the data confirms the excellent safety profile of HMBD-002, which has the potential to be best-in-class, and it also provides some tantalising glimpses of potential efficacy. We are immensely grateful to the dedicated clinicians who worked on the study, and to the patients and families who participated."

Investor Webinar

Percheron will hold an online webinar to discuss results of the recently completed phase I human trial of HMBD-002 in patients with advanced cancer.

Date: Tuesday 7 October 2025

Time: 9:00am, AEDT (Melbourne / Sydney / Canberra)
(8:00am, Brisbane / 6:00am, Perth / 8:30am, Adelaide)

Registration Link:
https://us02web.zoom.us/webinar/register/WN_P9C8u0AoRzWGsBLrOmSLHQ

Background

HMBD-002 is an inhibitor of VISTA (v-domain immunoglobulin suppressor of T-cell activation), a novel immuno-oncology target. The drug has shown evidence of activity in a wide range of animal models of cancer. HMBD-002 was developed by Hummingbird Bioscience, a venture-backed biotechnology company based in Singapore, and was licensed to Percheron in June 2025.

Phase I studies are generally designed to assess the safety and tolerability of a medicine in development, and to inform dosing in future studies. In many therapeutic areas, phase I studies are usually carried out in healthy volunteers and provide no indication of potential efficacy. In oncology, they are typically performed in patients with advanced cancer and so can sometimes provide an early signal of potential clinical activity.

Study Design

The HMBD-002 phase I trial was designed as a 'multiple ascending dose' study. An initial cohort of three patients received a very low dose of HMBD-002 and were carefully monitored for safety. Once the safety of that initial dose was established, a second cohort of three patients was administered a higher dose and monitored in a similar fashion. As the safety of each dose level was established, a further cohort of patients were recruited at a higher dose. In the event of any apparent toxicity being seen, that cohort was expanded to better understand the safety signal.

As a consequence of this very common design, the majority of patients in the study received doses of drug that would be expected to be sub-therapeutic. In addition, participating patients were typically those who had exhausted treatment options under existing standard of care and were in the very late stages of their disease.

The study ultimately recruited 28 patients who received HMBD-002 as monotherapy. It then recruited an additional 20 patients who received HMBD-002 together with Keytruda® (pembrolizumab) in order to assess the safety and tolerability of the combination therapy.

Safety

The safety profile of HMBD-002 appeared favourable for a drug intended for use in advanced cancer.

Only 7% of patients in the monotherapy group experienced a treatment-related adverse event (TRAE) greater than grade 3 in severity. Only 5% of patients in the combination group experienced a TRAE greater than grade 3 in severity. No cases of cytokine release syndrome (CRS) were seen. One dose-limiting toxicity was observed: a case of hepatitis which resolved with corticosteroids. Since no cohort generated two dose-limiting toxicities, a maximum tolerated dose (MTD) was not formally determined.

Efficacy Signals

A number of patients demonstrated indications of potential treatment benefit. One 49-year-old female patient with metastatic triple-negative breast cancer exhibited a 27% reduction in tumour size after five weeks of treatment with HMBD-002 in combination with pembrolizumab, which approached the 30% threshold for a partial response under RECIST criteria.

Several patients showed disease stabilisation for a prolonged period, including a 27-year-old male with metastatic dedifferentiated liposarcoma, a 67-year-old female with metastatic triple-negative breast cancer, a 49-year-old male with metastatic non-small-cell lung cancer, and a 59-year-old male with metastatic squamous cell carcinoma of the head and neck. In each case, the patient remained on treatment with stable disease for materially longer than would be anticipated for a patient in their condition.

Next Steps

Percheron aims to submit the full data from the trial, including pharmacokinetic and pharmacodynamic data, for publication in a peer-reviewed scientific journal in CY2026.

The Company intends to share further information regarding a planned phase II clinical trial design in 4Q CY2025, with the intention of commencing recruitment to the trial in CY2026.

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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 and rare diseases. The company's lead program is HMBD-002, a monoclonal antibody targeting the immune checkpoint regulator, VISTA. HMBD-002 has completed a phase I clinical trial in patients with advanced cancer, which has shown the drug to be generally safe and well tolerated, and Percheron aims to commence further clinical trials in CY2026. For further information, please see our website at www.PercheronTx.com, or email info@PercheronTx.com.

This announcement has been authorized for release to the Australian Securities Exchange by the Board of Directors.