Percheron Therapeutics

Positive Phase I readout strengthens outlook

Clinical update

Pharma and biotech

7 October 2025

Percheron Therapeutics has reported final results from the Phase I dose escalation study of HMBD-002, its monoclonal antibody targeting VISTA, a novel immune checkpoint protein. The data confirmed the compound's favourable safety and tolerability profile (maximum tolerated dose not reached with <10% of patients experiencing grade 3 or greater adverse events), with early signs of disease control in advanced solid tumours. The trial was not designed or sufficiently powered to demonstrate efficacy; however, evidence of stable disease (28% of cases) in an otherwise heavily pre-treated patient population (median four to five prior lines of treatment) supports Percheron's move towards Phase II development in CY26. We expect the announcement on the Phase II design and target indications, due in Q4 CY25, as the next big catalyst for the company.

Year end	Revenue (AUDm)	PBT (AUDm)	EPS (AUD)	DPS (AUc)	P/E (x)	Yield (%)
6/24	2.4	(11.7)	(1.33)	0.00	N/A	N/A
6/25e	1.4	(13.4)	(1.31)	0.00	N/A	N/A
6/26e	2.4	(10.5)	(0.97)	0.00	N/A	N/A
6/27e	5.8	(18.9)	(1.73)	0.00	N/A	N/A

Note: PBT and EPS are normalised, excluding amortisation of acquired intangibles, exceptional items and share-based payments.

The Phase Ib study was a multiple-ascending dose trial conducted at six US sites, enrolling 48 patients with heavily pre-treated, metastatic cancers. This included 28 patients on HMBD-002 monotherapy and 20 on HMBD-002 in combination with the market leading PD-1 immune checkpoint inhibitor (ICI) Keytruda (pembrolizumab). Dosing ranged from 20mg to 1,400mg with a standard 3+3 design, administered once weekly for up to 52 weeks.

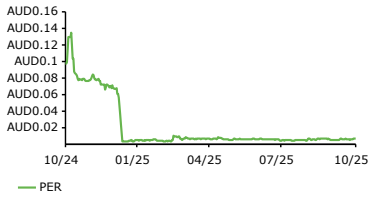
The maximum tolerated dose was not reached (indicative of a potentially broad therapeutic window) with only 7% and 5% of the patients in the monotherapy and combination arms reporting grade 3 or greater adverse events (one case of dose-limiting toxicity; no cases of cytokine release syndrome). We believe this evidences HMBD-002's favourable safety profile, providing key differentiation from the off-target toxicities associated with previous VISTA-targeting antibodies and supporting its combination with other ICIs.

While the Phase I trial was not designed to test HMBD-002's efficacy (no partial or complete responses reported), the preliminary signals of tumour shrinkage (one patient in the combination arm with metastatic triple negative breast cancer saw a 27% shrinkage, approaching a partial response under RECIST criteria) and disease stabilisation in several tumour types (28% of the overall Phase I participants) support the credibility of VISTA as a broad target and validate Percheron's development of the asset. The data need to be viewed in the context of the study participants, who were all in advanced stages of disease activity (median four to five prior lines of treatment), with over 60% having previously been treated with an ICI.

Strategically, these data provide Percheron with an initial platform for value inflection as it transitions into a proof-of-concept Phase II study. Its near-term priorities include defining optimal indications and the Phase II design (more details due Q4 CY25). Successful execution of the Phase II trial could elevate HMBD-002 into the emerging class of next-generation ICIs, addressing tumour resistance mechanisms and expanding the therapeutic potential of immunotherapy.

Price	**AUD0.010**
Market cap	**AUD11m**
	US$0.65/A$
Net cash/(debt) at 30 June 2025	AUD10.2m
Shares in issue	1,087.4m
Code	PER
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



Business description

Percheron Therapeutics is a clinical-stage biotech advancing HMBD-002, a differentiated VISTA-targeting checkpoint inhibitor with potential to address PD-1 resistance across a range of cancer indications. HMBD-002 has completed a Phase I clinical trial in patients with advanced cancer, with favourable safety and tolerability. Phase II trials are expected to commence in 2026.

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