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Actinogen Medical

Clinical trial update

Phase IIb XanaMIA study opens first study site

Pharma and biotech

Actinogen Medical has opened the first investigational study site for its Phase IIb XanaMIA trial of lead candidate Xanamem in patients with cognitive impairment (CI) associated with mild-to-moderate Alzheimer's disease (AD). The study plans to enrol c 220 patients, who will be randomised to take Xanamem 10mg or placebo once daily for 36 weeks. The trial will concentrate on Australian test sites for the first 100 enrolled patients, and initial efficacy and safety results will be analysed when these patients reach 24 weeks of treatment. The results, expected in H1 CY25, could serve as a significant catalyst if data are positive. Nearer term, the next material milestone will be results, expected in Q2 CY24, from Actinogen's Phase IIa XanaCIDD study in patients with CI and major depressive disorder (MDD). A positive XanaCIDD readout may lead to a share price re-rating, and thereby may potentially accelerate the expansion of XanaMIA to US and global clinical study sites.

Year end	Revenue (A$m)	PBT* (A$m)	EPS* (A$)	DPS (A$)	P/E (x)	Yield (%)
06/22	3.6	(7.9)	(0.005)	0.0	N/A	N/A
06/23	4.9	(9.0)	(0.005)	0.0	N/A	N/A
06/24e	3.9	(23.8)	(0.012)	0.0	N/A	N/A
06/25e	4.8	(60.6)	(0.027)	0.0	N/A	N/A

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

The XanaMIA Phase IIb trial aims to assess Xanamem versus placebo in AD patients with an elevated level of phosphorylated Tau-181 (pTau-181) protein in their blood. With the first study site now activated, patient recruitment is expected to start imminently. The trial will concentrate on Australian sites for the initial c 100 patients to mitigate study costs.

The design of this XanaMIA Phase IIb study is informed by a subset analysis reported in Q4 CY22 in 34 patients with elevated pTau-181 blood levels from the previous 185-patient XanADu trial in mild AD. This subset of patients (16 on Xanamem 10mg daily, 18 on placebo) with biomarker-positive AD (pTau of at least 6.74pg/mL) showed clinical activity and a relatively large effect size at 12 weeks using the FDA-recognised CDR-SB scale.

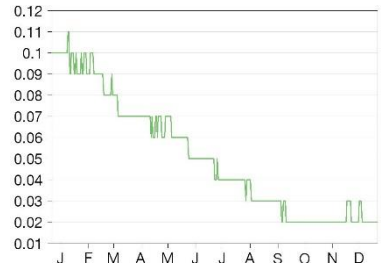
We believe market participants will be keen to observe whether the Phase IIb XanaMIA portion, which prospectively enrols patients with elevated pTau, will confirm the positive efficacy findings shown in the XanADu subset biomarker analysis from the earlier XanADu study. Given the widespread economic and social costs of AD and the limitations of current approved treatments, we believe positive Phase IIb data could introduce the possibility of material out-licensing or value realisation opportunities.

Actinogen expects that Xanamem's inhibition of cortisol formation within the brain can be applicable to CI in other indications besides AD. As such, its ongoing XanaCIDD study, which began in Q422, is assessing the drug in patients with CI and MDD despite standard-of-care antidepressant therapy. With 50% of the targeted recruitment of 160 patients reached in November, Actinogen expects to report study results in Q2 CY24.

22 December 2023

Price	**A$0.023**
Market cap	**A$53m**
Estimated net cash (A$m) at 30 September 2023	13.1
Shares in issue	2,307m
Free float	90%
Code	ACW
Primary exchange	ASX
Secondary exchange	N/A

Share price performance



Business description

Actinogen Medical is an ASX-listed Australian biotech developing its lead asset Xanamem, a specific and selective 11β-HSD1 inhibitor designed to treat cognitive impairment (CI), which occurs in chronic neurodegenerative and neuropsychiatric diseases. Currently, Actinogen is targeting CI in two indications: the early stages of Alzheimer's disease and major depressive disorder.

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