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Actinogen Medical

Clinical trial updates

First patient dosed in Phase IIb XanaMIA study

Pharma and biotech

Actinogen Medical announced that the first randomised patient in its Phase IIb XanaMIA trial of lead candidate Xanamem received their first treatment on Friday 12 April. This study is designed to enrol c 220 patients with cognitive impairment (CI) associated with biomarker-positive mild-to-moderate Alzheimer's disease (AD), as confirmed through an elevated level of phosphorylated Tau-181 (pTau-181) protein in their blood at baseline. The study has commenced at 13 Australian sites and will concentrate on domestic sites for the first c 100 patients, and initial efficacy and safety results will be analysed when these patients reach 24 weeks of treatment. These results are now expected in mid-CY25 (vs prior guidance of H1 CY25) and Actinogen expects to expand the trial to US study sites following this interim readout. In the near term, the next material milestone for the company will be results, now expected in early Q3 CY24 (vs Q2 CY24 previously), from its Phase IIa XanaCIDD study in patients with CI and major depressive disorder (MDD).

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	(8.9)	(0.005)	0.0	N/A	N/A
06/24e	7.7	(15.8)	(0.008)	0.0	N/A	N/A
06/25e	20.3	(37.9)	(0.016)	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 blood pTau-181 protein, with patients randomised to take Xanamem 10mg or placebo once daily for 36 weeks. With the first patient now treated, the company has refined its projection for interim analysis to mid-CY25 (vs H1 CY25 previously), and it expects to report final results in H1 CY26 (in line with our existing estimate of CY26). The design of this 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 expect investors will be paying close attention to whether the XanaMIA Phase IIb study, which prospectively enrols patients with elevated pTau, will confirm the positive efficacy findings shown in the XanADu trial's subset biomarker analysis.

Xanamem's inhibition of cortisol formation within the brain may be applicable to CI in other indications besides AD. As such, the ongoing XanaCIDD study is assessing the drug in patients with CI and MDD despite standard-of-care antidepressant therapy. With more than 90% of the targeted recruitment of 160 patients reached in April, Actinogen expects to report study results in early Q3 CY24 (vs prior Q2 CY24 guidance). Altogether, these announced timeline revisions (for XanaCIDD top-line results and the interim XanaMIA Phase IIb data) are minor, and we continue to estimate potential Xanamem commercialisation in AD and MDD indications in CY29 and CY28, respectively.

16 April 2024

Price	**A$0.029**
Market cap	**A$68m**
Estimated net cash (A$m) at 31 December 2023	11.5
Shares in issue	2,332m
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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