EDISON

Actinogen Medical

XanaMIA clears hurdle to start US recruitment

Clinical study update

Pharma and biotech

Actinogen has announced that the US FDA has provided the required approvals for it to proceed with US recruitment for its planned six-month, placebo-controlled Phase IIb portion of the XanaMIA study. This study is designed to demonstrate the safety and efficacy of Xanamem in a population of patients with mild cognitive impairment and mild Alzheimer's disease (AD), who at baseline will have been confirmed as biomarker-positive for AD (as determined through elevated blood phosphorylated Tau, or pTau). The study will start enrolment in H1 CY23 and results are expected in late CY24.

Year end	Revenue* (A$m)	PBT** (A$m)	EPS** (A$)	DPS (A$)	P/E (x)	Yield (%)
06/21	2.0	(3.3)	(0.002)	0.0	N/A	N/A
06/22	3.6	(7.9)	(0.005)	0.0	N/A	N/A
06/23e	3.6	(8.7)	(0.005)	0.0	N/A	N/A
06/24e	3.3	(38.7)	(0.022)	0.0	N/A	N/A

Note: *Revenues include tax rebates and financial interest (local GAAP). **PBT and EPS are normalised, excluding amortisation of acquired intangibles and exceptional items.

Actinogen indicates that the FDA agreement follows recent updates of the company's Investigational New Drug dossier to reflect new non-clinical and clinical information to support the trial protocol. We believe the recently reported biomarker data using blood samples from a subset of patients in the prior 185-patient XanADu study in AD patients likely supported Actinogen's dossier. These data showed clinical activity and a relatively large effect size at 12 weeks using the FDA-recognized Clinical Dementia Rating scale – Sum of Boxes (CDR-SB) in biomarker-positive AD patients (as determined through patients who had elevated pTau). Patients with pTau at or above 6.74pg/mL, representing 34 patients (16 on Xanamem 10mg daily, 18 on placebo), showed a 0.6 mean difference (effect size) on CDR-SB (representing a 60% relative reduction in disease progression versus placebo) at 12 weeks between the placebo and treatment arms.

This difference in CDR-SB versus placebo exceeded the level of CDR-SB improvements shown for Aduhelm in its EMERGE study and for lecanemab as shown in the recent Clarity AD study (both at 78 weeks). We note that the XanADu biomarker analysis sample size is relatively small and recognize that there may be limitations in forecasting future trial outcomes based on study analyses determined using retrospective clinical data. Nonetheless, we view these biomarker results as highly encouraging in that they demonstrate the potential for meaningful Xanamem clinical activity in biomarker-confirmed AD patients, if replicated in a prospective trial.

The planned Phase IIb portion of XanaMIA is designed to enrol 330 patients with mild AD and progressive disease, confirmed by an elevated level of pTau-181 protein in the blood. Patients will be randomized to treatment with 5mg, 10mg or placebo once a day, over a six-month period. The study's key efficacy endpoints will be the CDR-SB and the Cogstate computerised test battery of attention and working memory.

23 December 2022

Price	**A$0.112**
Market cap	**A$207m**

Net cash (A$m) at 30 September 2022 (excluding A$4.2m tax rebate received in October 2022)	13.0
Shares in issue	1,806m
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) that 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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