EDISON

Actinogen Medical

Clinical study update

XanaCIDD study in MDD now underway

Pharma and biotech

Actinogen announced that the first patient was randomised and treated in its XanaCIDD Phase II study in major depressive disorder (MDD) assessing the effects of lead candidate Xanamem on cognitive performance and depression. The study aims to enrol about 160 patients who have persistent depressive symptoms and cognitive impairment (CI) despite taking standard-of-care (SoC) anti-depression therapy. Having demonstrated the ability to improve cognition in two trials (XanaHES and the Phase Ib portion of XanaMIA) in healthy adults, Actinogen is confident that Xanamem can exert similar cognitive improvement effects in MDD patients; this study will also explore whether the drug can have effects on depression as well. Results are expected in late 2023 or early 2024.

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.

The XanaCIDD Phase II Depression study is a six-week proof-of-concept, placebo-controlled, parallel group design trial aiming to enrol c 160 patients with persistent MDD and CI despite taking SoC anti-depressant therapy. Xanamem 10mg daily or placebo will be added to patients' existing anti-depressant therapy and effects on cognition (using the Cogstate Cognitive Test Battery) and depression (using the Montgomery Asberg Depression Rating Scale) will be evaluated.

MDD is a common disorder, with a c 5% prevalence globally. CI is a feature in most MDD patients and commonly persists even when depression symptoms subside. Elevated cortisol levels have been associated with depression and modification of brain cell cortisol levels has been proposed as a strategy to treat both depression and its associated CI. As Xanamem targets excess brain cortisol, and given the benefits shown in healthy adults in XanaHES and the Phase Ib portion of XanaMIA, we believe it is plausible for cognitive benefits to be shown in patients with persistent MDD. If the XanaCIDD study is successful in showing CI improvement, the company may then move to advance it into pivotal studies. Given that no US-approved antidepressant has a CI label, we believe there is a significant opportunity for Xanamem in this market if it can demonstrate an improvement in CI in this population.

Actinogen reported a gross cash position of A$13.0m at 30 September (excluding a A$4.2m R&D tax rebate received on 20 October 2022), and a Q123 operating cash burn rate of A$3.4m. We continue to model the company will raise A$20m in FY23 and A$40m in FY24. As a reminder the Phase IIb portion of the XanaMIA study is expected to start enrolment in H1 CY23 and 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 pTau).

9 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	1,797m
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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