EDISON

Actinogen Medical

Publication of XanADu biomarker analysis

Clinical data publication

Pharma and biotech

Actinogen Medical announced that the prespecified biomarker subset analyses on stored plasma samples (n=72) from its previous Phase IIa XanADu study (n=185) in patients with mild Alzheimer's disease (AD) has been published in the peer-reviewed *Journal of Alzheimer's Disease* (JAD). As reported in Q422, patients with elevated baseline phosphorylated Tau-181 (pTau-181) protein (at least 6.74pg/mL), representing 34 patients (16 on Xanamem 10mg daily, 18 on placebo), showed a 0.6 mean difference (effect size) on the CDR-SB scale at 12 weeks between the placebo and treatment arms, representing a 60% relative reduction in progression. This suggests that Xanamem's potential cognitive or disease-slowing effects may be sensitively detected by the CDR-SB endpoint, which is one of the critical endpoints in the ongoing XanaMIA Phase IIb trial (planned n=220) enrolling participants with cognitive impairment (CI) in mild to moderate AD as confirmed through elevated baseline p-Tau181. Actinogen's next milestone will be results, expected in early Q3 CY24, from its Phase IIa XanaCIDD study of Xanamem in patients with CI and major depressive disorder.

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	7.9	(14.0)	(0.006)	0.0	N/A	N/A
06/25e	7.7	(13.7)	(0.005)	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.

When top-line XanADu results were reported in 2019, blood-based AD biomarker analysis was not available and AD clinical diagnoses were not confirmed by any biomarkers. The JAD publication highlights biomarker data first reported in Q422 whereby XanADu participant plasma samples underwent study analysis in distinct patient subpopulations, and clinical activity and a relatively large effect size using the FDA-recognized CDR-SB scale was determined in biomarker-positive AD patients (who had elevated pTau-181 at baseline).

Newly reported data show that, as we would anticipate, among the biomarker analysis participants (n=72), patients with elevated pTau-181 had much more rapid progression over the 12-week period than patients with lower levels, in four key clinical AD-related endpoints: ADCOMS (p<0.001), CDR-SB (p<0.001), MMSE (p=0.12) and ADAS-Cog14 (p=0.19). Patients with low pTau-181 generally did not worsen during the 12-week trial. Actinogen believes this finding confirms that the original XanADu trial population had a high proportion of non-progressive patients, many of whom may have had an alternate condition instead of AD. The study authors suggest plasma pTau-181 may be suitable for identifying individuals with clinically diagnosed mild AD and who are more likely to progress.

We expect investors will be paying close attention to whether the XanaMIA Phase IIb study, which is prospectively enrolling patients with elevated pTau-181, will confirm the positive efficacy findings shown in the XanADu trial's subset biomarker analysis. Interim results from the first c 100 patients are expected in mid-CY25.

28 June 2024

Price	**A$0.062**
Market cap	**A$166m**
Net cash (A$m) at 31 March 2024 (not including A$8.9m capital raise in Q2 CY24)	6.3
Shares in issue	2,683m
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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