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Health Check: Actinogen shares plunge on Alzheimer's trial miss

Tim Boreham 4 min read • Nov 19, 2026 1:16pm

- **Actinogen's phase IIb/III Alzheimer's trial has missed its primary endpoint**
- **HOWEVER, the study showed a "significant and sustained" benefit in a subset of older patients**
- **The company intends to forge ahead with a development partner**

In the wake of multiple advanced drug clinical trial flops, biotech investors had hoped that Actinogen Medical's (ASX:ACW) much-anticipated Alzheimer's study results would show a clear-cut success.

But as with life, nothing is so simple.

Dubbed Xanamia, the 247-patient, pivotal phase IIb/III study missed its primary endpoint of being statistically superior to the placebo group.

The study also missed the secondary endpoints of improved cognition and daily living activities.

Investors vented their ire by sending Actinogen shares down as much as 4.2 cents, or 88%.

But Actinogen's drug candidate Xanamem showed a much better effect in an older cohort with a median age of 75. These patients comprised half the total study group.

This patient grouping was "predefined", which meant the company didn't go data mining after the fact in a Procrustean attempt to make the data suit its purposes.

Early results from an open-label extension (OLE) study also showed disease stabilisation over 24 weeks. This readout covered the first 29 of 168 OLE patients.

Missed it by that much…

Actinogen said Xanamem was "numerically but not statistically" superior to placebo, for the primary endpoint of delayed disease progression.

This was measured by the 18-point Clinical Dementia Rating Scale – Sum of the Boxes (CDR-SB).

The study showed an overall mean benefit of 0.10 points compared with placebo, at 36 weeks.

This equated to a 'p' – probability – value of 0.65, which means there was a 65% chance the benefit was a fluke.

However, the older cohort showed a zero-disease progression rate of 40%, compared with 22% for placebo.

The 'p' value for this measure was an un-flukey 0.02. The study also showed a 30% rate of disease slowing in this cohort, although the result did not meet the threshold for statistical significance (p=0.22).

A difficult disease

Actinogen CEO Dr Steven Gourlay said while the company would have preferred a "clear win" across the overall patient population, "there have been very few of those ever in Alzheimer's disease."

Gourlay said Alzheimer's trials were notoriously difficult.

"Eli Lilly and Roche and others have thrown tens of billions of dollars at amyloid antibody immune therapies to produce a 30% disease slowing.

"We're seeing exactly that same effect in older patients, where the science says that makes sense for our drug."

Gourlay said it wasn't surprising the older cohort reacted better. That’s because Xanamem targets the enzyme 11-beta HSD1, “which is well known to increase in its expression in the brain with age".

As measured by two biomarkers, neuroinflammation also is more common in older people.

Business as usual?

Investors evidently are deeply concerned that the trial results mean that Actinogen faces a longer path to commercialisation - if there is one at all.

But for Gourlay, little has changed with the company’s commercialisation plans.

“We had always planned a period of a couple of months of discussions with potential global partners,” he said.

“The next phase is a much larger Alzheimer's trial, done across multiple geographies."

Actinogen expects to enrol around 700 patients. But with around $20 million in the bank, the company needs a partner.

Not surprisingly, the company will enrol only the older patients, who account for about 70% of Alzheimer’s patients generally.

“We still need to fully explore where the age cut-off might be to optimise the inclusion criteria for that trial,” Gourlay said.

“For example, is 75 the right age cut-off or do people between 70 and 75 also benefit? We're still working on all of that.

“We will also get good additional data from the open label trial.”

In the short term, investor attention turns to the OLE read-out of the first 100 patients, at 24 weeks. This is due in the March quarter.

An OLE means all patients are on the active drug, with no placebo comparator. The data is unblinded, so all the parties can see how the patients are faring over time.

Immutep airs more positive data

Meanwhile, cancer cell therapy play **Immutep (ASX:IMM)** is doing its best to redeem itself from its phase III lung cancer flop last March.

Immutep shares fell 87% – a similar swoon to Actinogen stock – after the company said it would discontinue the trial, known as TACTI-004.

The company today highlighted positive data for another indication, resectable soft tissue sarcoma (STS), using the same lead compound called 'efti'.

Efti stands for eftilagimod alfa (efti), a soluble LAG-3 protein that bolsters the immune system.

As aired in a conference abstract, phase II data for STS showed 12-month disease-free survival of 81.1%.

The investigator-led study used efti in combo with Keytruda and radiotherapy, before surgery on patients with high-risk resectable STS.

In an investor update yesterday, Immutep CEO Marc Voigt said the company has undertaken a root cause analysis of why the lung cancer trial failed.

"The discontinuation of TACTI-004 was deeply disappointing for patients, investigators and shareholders," he said.

He said the ongoing analysis had "already informed a more focused path forward for efti."

The company expects to share the findings at its AGM on November 27.

A possible factor under investigation in the lung cancer trial failure was the "structural differences" between efti batches of 2000 litres – as used in the study – and earlier batches of 200 litres (as used in earlier trials).

For the nerds among us, the differences relate to the glycan structures attached to the fusion protein.

"We consider these differences potentially relevant given the markedly different immune activation profile observed in TACTI-004 compared to previous studies and the unexpected outcome of the trial," Voigt said.

"We have contracted the manufacture of a new 200 litre batch of efti and considered which clinical development opportunities are most compelling."

Originally published as Health Check: Actinogen shares plunge on Alzheimer's trial miss

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