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In a major development, [Sydney-based company Actinogen Medical](#) has made a breakthrough in Alzheimer's treatment with the development of Xanamem after making an agreement with the US Food and Drug Administration (FDA).

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The agreement, which provides clarity on a future US marketing application for Xanamem, is being viewed as a major win and strengthens the Australian biotech's position in discussions with potential development and marketing partners.



Bring it on, this would be wonderful, some hope at last against this dreadful disease.
Dr Steve Gourlay is the CEO of Actinogen Medical.

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Key outcomes of the agreement include the confirmation of regulatory starting materials for the commercial manufacturing of the Alzheimer’s pill as well as the FDA’s endorsement of a single 10 mg dose vs placebo design for the pivotal trial.

Dr Steve Gourlay, the CEO and managing director of Actinogen, said Xanamem is the first and only drug to test whether you can slow or halt Alzheimer’s disease by lowering tissue levels of the “stress hormone” cortisol, which has long been associated with brain toxicity.

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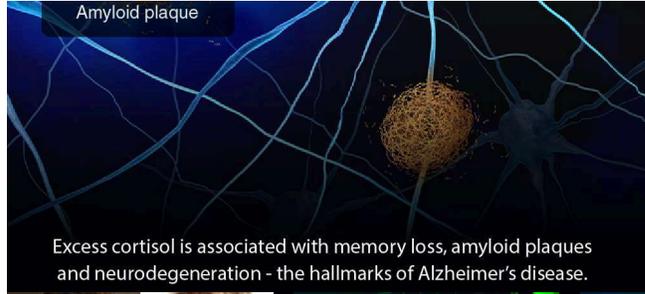
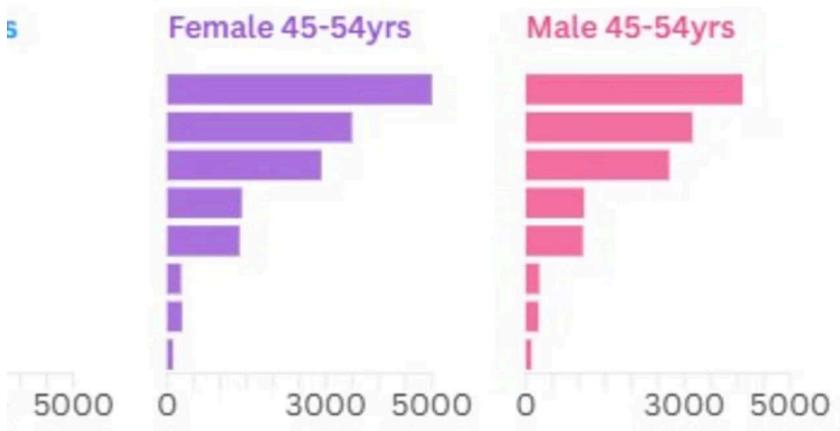
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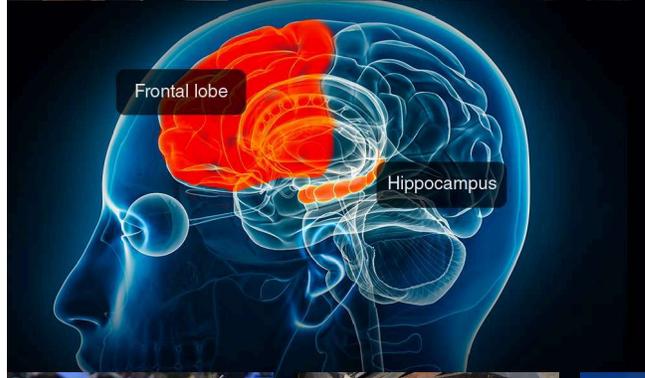


15 minute test to reduce dementia risk

While dementia remains Australia's most feared health condition, a revolutionary 15-minute test now offers hope of reducing your personal risk factors.



Excess cortisol is associated with memory loss, amyloid plaques and neurodegeneration - the hallmarks of Alzheimer's disease.



Parkinson's disease.

Source: Actinogen Medical.

Dr Gourlay said the FDA feedback on the Xanamem program was positive and meant that Actinogen had the option to take Xanamem to market with or without other biopharmaceutical partners.”

“Alzheimer’s disease is the leading cause of death in women in Australia and number 2 for men,” he said.

Business

“The reasonable and measured feedback from the FDA on the final stages of the Xanamem program shows that the FDA is keenly interested in safer and more

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and Xanagem has the potential to be a safer, more effective and more convenient once-a-day pill, which could revolutionise the field."



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The World Health Organisation (WHO) recently granted Actinogen Medical the nonproprietary name 'emestedastat' for Xanagem, and gave it a first-in-class, which Actinogen said was a rare global endorsement that placed Actinogen at the forefront of neurosciences worldwide.

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