



FIRST PARTICIPANTS RECRUITED FOR SECOND PHASE I STUDY OF XANAMEM™

- **First 8 participants recruited following successful Ethics Committee approval and Therapeutic Goods Administration (TGA) acknowledgement of the study**
- **A total of 40 participants are expected to be enrolled in the double-blind, placebo controlled study over three parts**
- **The primary endpoint of the study is to confirm the safety and tolerability of the drug; in addition the study will demonstrate how the body absorbs and metabolises Xanamem™**
- **The follow-on results will help to confirm the distribution of Xanamem in the central nervous system**
- **Results will add to the evidence base, enabling an Investigational New Drug (IND) application to the Food and Drug Administration's (FDA) for a Phase II study of Xanamem™ in the US**
- **Full results are expected by mid-2015**

Sydney, 24 February 2015: Actinogen Limited (Actinogen Medical, ASX: ACW), an Australian biotechnology company focused on the development of novel treatments for Alzheimer's disease and other major age-related neurodegenerative disorders, is pleased to announce that it has recruited first participants for the second Phase I study for its lead drug candidate, Xanamem™. This follows the granting of independent ethics and local governance approvals for the study earlier this month.

Xanamem™ is being developed as a potential new therapy for Alzheimer's disease, a condition with a multi-billion dollar market potential. The cost of Alzheimer's treatment in the US alone was estimated to be US\$250bn last year by the American Alzheimer's Association. This cost is estimated to increase to US\$1 trillion by 2050, outstripping the cost of treating all other diseases.

Xanamem™'s novel mechanism of action sets it apart from existing Alzheimer's treatments. It works by blocking the production of cortisol - the stress hormone - in the hippocampus and frontal cortex, the areas of the brain most affected by Alzheimer's disease. There is growing evidence that chronic stress and elevated cortisol levels lead to changes in the brain affecting memory and to the development of amyloid plaques and neural death – the hallmarks of Alzheimer's disease.

In the second Phase I study, a total of 24 healthy volunteers will be given doses of 10mg, 25mg and 35mg of Xanamem™, in a multiple ascending dose (MAD) with eight participants in each cohort. The primary endpoint of the study is to confirm safety and tolerability of the drug. In addition the study will demonstrate how the body absorbs and metabolises Xanamem™ and the optimal dose for the drug.

The double-blinded, placebo controlled study will be conducted at Linear Clinical Research, a world-class clinical trial facility that is part of the QEII Medical Centre in Perth, Western Australia.

After the 24 participants have successfully completed their assessments the study will evaluate the food effects on the absorption of Xanamem in an additional cohort of twelve participants. The proposed last part of the Phase I study will involve a cohort of four participants to confirm the distribution of Xanamem in the central nervous system.

All these studies will add to the evidence base enabling an Investigational New Drug (IND) application to the Food and Drug Administration's (FDA) for a Phase II study of Xanamem™ in the US.

Full results of the study are expected by mid-2015. A Phase II study in patients is expected to start in 2016.

Linear Clinical Research Principal Investigator, Dr Janakan Krishnarajah said: "Having the first participants recruited in the trial is a very exciting first step in developing Xanamem™ as a novel new approach to treating Alzheimer's disease. It is so important to investigate new approaches to the disease given the huge and growing burden of Alzheimer's on our society and the changing competitive landscape for treatment."

Actinogen Medical Chief Executive Officer, Dr Bill Ketelbey added: "This is a key milestone for Actinogen Medical and our aim to demonstrate that Xanamem™ is a valuable treatment option for Alzheimer's disease. We are excited about the potential of Xanamem™ given its novel mechanism of action and the limitations of current Alzheimer's treatments on the market today."

ENDS

Actinogen Medical

Bill Ketelbey

CEO & Managing Director

P: +61 2 9251 5620

E: bill.ketelbey@actinogen.com.au

 [@BillKetelbey](https://twitter.com/BillKetelbey)

About Actinogen Medical

Actinogen Medical is focused on the treatment of Alzheimer's disease and mild cognitive impairment, a transitional stage of cognitive impairment between normal aging and the more serious condition of Alzheimer's dementia. It is developing a novel drug to treat the condition and other age-related neurodegenerative diseases. The lead candidate drug Xanamem™, blocks the development of cortisol which appears to contribute to cognitive impairment and amyloid plaques. The Company is currently undertaking a second Phase I multiple ascending dose trial in healthy volunteers with results in mid-2015 and plans to undertake a Phase II study in 2016.