

## **ASX ANNOUNCEMENT**

# Market Update and ACW to Participate in BIO Digital

**Sydney, 4 June 2020. Actinogen Medical ASX: ACW ('ACW' or 'the Company')** provides an update, including its participation in the BIO Digital, clinical trial guidance, and recent publications.

## **Key highlights**

- Dr Bill Ketelbey, CEO and Managing Director, to present at the BIO Digital, held from the 8<sup>th</sup> 12<sup>th</sup>
  June. The conference will be conducted virtually.
- Actinogen to participate in multiple partnering meetings with major pharmaceutical companies during BIO Digital.
- Studies recommence, following lifting of COVID-19 related restrictions.
- Article published in peer-reviewed journal, supporting further clinical development with Xanamem™ for multiple indications.

Dr Bill Ketelbey, said: "We are pleased with the progress being made in a number of clinical and business development activities, while continuing to carefully manage corporate expenses during this time. Our planning for new clinical trials is progressing well, with key discussions with strategic parties ongoing, and we look forward to emerging from this uncertain period in a strong position to initiate several new clinical trials to advance the development of Xanamem."

### **Actinogen participating in BIO Digital**

The BIO International Convention is the world's largest biotech partnering event and attracts over 4,000 biotechnology and pharmaceutical companies from nearly 80 countries, facilitating extensive partnering and networking opportunities across the industry. Due to the COVID 19 pandemic, the BIO International Convention will be held virtually for the first time, as BIO Digital, from 8th to 12th June 2020.

Dr Bill Ketelbey will present Actinogen and the future development plans for Xanamem via a pre-recorded presentation accessible to conference delegates. By means of the conference software partnering platform, Actinogen will also participate in multiple partnering meetings with major pharmaceutical companies interested to receive a first-hand update on the development of Xanamem<sup>™</sup>, and others who have requested meetings in order to learn about Actinogen and Xanamem for the first time. For each of these companies, Actinogen will discuss the clinical development program for Xanamen, including the encouraging efficacy results from the XanaHES clinical trial, the progress of its detailed data analysis, and the multiple clinical trials currently being planned.

## Study guidance: Studies recommence

Prior to the COVID-19 pandemic, Actinogen sponsored a number of pre-clinical studies in the UK and France regarding pharmacokinetic, pharmacodynamic and mechanistic analyses of Xanamem pharmacology, together with standard toxicology studies required by regulators for novel drug development. Now that COVID-19-related restrictions are being lifted, these studies have recommenced. In Australia, the detailed data analysis of the Phase I Target Occupancy study results is progressing well, with 31 of 36 patients treated, and their results collated. We expect the first of the final 5 patients to be enrolled into the study within the

next few weeks, however the available dataset provides significant important insights into Xanamem pharmacology that will help with finalising the design of the next clinical studies.

Planning and start-up activities are progressing for new clinical trials focused on Mild Cognitive Impairment due to Alzheimer's disease and other disease indications, which Actinogen expects to announce in greater detail as soon as possible after the COVID-19 restrictions are lifted. Discussions with key parties continue, and Actinogen continues to review and submit non-dilutive grant applications for a range of opportunities to support the funding of these studies.

## Published review supports further clinical studies with Xanamem™

A comprehensive review<sup>1</sup> of the published scientific literature led by Actinogen collaborator, Dr Sarah Gregory (European Prevention of Alzheimer's Dementia (EPAD) Study Coordinator at University of Edinburgh) was recently accepted for publishing on 20 April 2020, in the peer-reviewed journal Metabolism: Clinical and Experimental. The review, titled "11ß -hydroxysteroid dehydrogenase type 1 inhibitor use in human disease- a systematic review and narrative synthesis", concludes that there are many potential applications in human disease for drugs that inhibit the 11ß-HSD1 enzyme. Adding to this conclusion is independent evidence that this is a growing area of research, and future studies should focus on gaining more understanding into the complex relationship between the 11ß-HSD1 enzyme and disease pathology. This publication supports the ongoing clinical development of Xanamem across multiple indications.

Actinogen continues to progress the drafting of additional Xanamem related journal articles following the recent completion of a number of studies, with the expectation of further publications this year.

#### **ENDS**

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# Announcement authorised by the Board of Directors of Actinogen Medical

## **About Actinogen Medical**

Actinogen Medical (ASX: ACW) is an ASX-listed biotechnology company developing innovative treatments for cognitive impairment associated with chronic neurological, psychiatric and metabolic diseases. The company is currently developing its lead compound Xanamem as a promising new therapy for Alzheimer's disease, and cognitive impairment associated with schizophrenia, diabetes and other disorders associated with cognitive impairment. The cognitive dysfunction associated with these conditions is significantly debilitating for patients, and there is a substantial unmet medical need for new and improved treatments.

### **About Xanamem™**

Xanamem is Actinogen Medical's lead developmental drug candidate. Xanamem's novel mechanism of action sets it apart from other therapies for Alzheimer's disease and other diseases associated with cognitive impairment. It works by blocking the excess production of intracellular cortisol – the stress hormone – through

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<sup>&</sup>lt;sup>1</sup> Gregory, S., Hill, D., Grey, B., Ketelbey, W., Miller, T., Muniz-Terrera, G. and Ritchie, C.W., 2020. 11β-hydroxysteroid dehydrogenase type 1 inhibitor use in human disease-a systematic review and narrative synthesis. Metabolism, p.154246. <a href="https://www.metabolismjournal.com/article/S0026-0495(20)30110-4/pdf">https://www.metabolismjournal.com/article/S0026-0495(20)30110-4/pdf</a>

the inhibition of the  $11\beta$ -HSD1 enzyme in the brain. There is a strong association between persistent stress and the production of excess cortisol that leads to changes in the brain, affecting memory. The  $11\beta$ -HSD1 enzyme is highly concentrated in the hippocampus and frontal cortex, the areas of the brain associated with cognitive impairment in neurological diseases, including Alzheimer's disease and schizophrenia and in metabolic diseases like diabetes.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamem 20mg once daily in healthy elderly volunteers, showed that the drug exhibited a good safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem produced a statistically significant improvement in cognition, which, along with other recently generated data, confirms the underlying mechanism of action of Xanamem.

The Company plans to initiate Phase II studies of Xanamem against various diseases as soon as possible after the current COVID19 health crisis affecting the globe; including in Mild Cognitive Impairment due to Alzheimer's disease.

Xanamem is an investigational product and is not approved for use outside of a clinical trial by the FDA or by any global regulatory authority.

Xanamem<sup>™</sup> is a trademark of Actinogen Medical

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