

ASX ANNOUNCEMENT

Actinogen files new patent applications to strengthen and extend IP portfolio

- Actinogen has filed two new patent applications directed to:
 - a method of improving cognition or treating cognitive decline in cognitively healthy subjects
 - a commercial scale-up manufacturing process for Xanamem providing a novel, efficient synthesis methodology enabling direct access to high purity Xanamem
- These patent applications further strengthen Actinogen's IP portfolio, placing it in a stronger position to commercialise and maximise the value of its lead drug, Xanamem

Sydney, 9 November 2020. Actinogen Medical ASX: ACW ('Actinogen', 'ACW' or 'the Company') is pleased to announce it has filed two new patent applications to expand and extend its intellectual property (IP) estate. The applications are for Actinogen's lead drug Xanamem, and potentially extend the patent life of protection around Xanamem until at least 2040.

The first new patent application provides patent protection to a method of improving cognition or treating cognitive decline in cognitively healthy subjects. This patent was conceived as a result of the novel breakthrough outcomes achieved with the Phase I XanaHES trial, which demonstrated that Xanamem produced a statistically significant and meaningful improvement in cognition over placebo in healthy elderly subjects.

The second patent application provides protection to a novel commercial scale-up manufacturing process for Xanamem, which incorporates a novel, efficient synthesis methodology enabling direct access to high purity Xanamem. This patent is a result of a productive collaboration with world-leading expert process chemists at a contract development and manufacturing organisation (CDMO) based in Switzerland. This innovation in Xanamem process development, positions Actinogen to efficiently manufacture Xanamem at commercial scale-up quantities for future clinical trials and commercialisation.

Actinogen's IP estate includes a portfolio of granted or pending patents claiming the composition of matter of its lead drug Xanamem in all major pharmaceutical markets for use in a broad range of neurological and metabolic diseases, including Alzheimer's disease. The Company continues to proactively manage, expand, and extend its robust IP estate with additional patent opportunities and patent extensions to enhance the patent life protection for Xanamem.

Dr Bill Ketelbey, Actinogen CEO and MD, commented:

"Strengthening our IP portfolio and extending the patent life of protection over Xanamem is aligned with our broader commercialisation strategy for Xanamem. The potential to treat cognitively healthy subjects, a population in which XanaHES demonstrated clear efficacy results, as well as treat those at risk of cognitive impairment, is a significant medical and commercial opportunity. Equally, the patented and optimised manufacturing methodology provides an efficient and commercially viable process which provides a substantial new barrier to competition. Actinogen remains focused on maintaining and extending the protection of Xanamem to maximise its commercial potential."

ENDS

Actinogen Medical

Dr. Bill Ketelbey
CEO & Managing Director
P: +61 2 8964 7401
E: bill.ketelbey@actinogen.com.au

Investor Enquiries

Miranda Newnham Vesparum Capital P: +61 3 8582 4800

E: actinogen@vesparum.com



Announcement authorised by the Board of Directors of Actinogen Medical

About Actinogen Medical

Actinogen Medical (ASX:ACW) is an ASX-listed biotechnology company developing novel therapies for neurological, psychiatric and metabolic diseases associated with chronically elevated cortisol. The company is currently developing its lead compound, Xanamem, as a promising new therapy for Alzheimer's disease, Fragile X syndrome, schizophrenia and diabetes. The cognitive dysfunction, behavioural abnormalities, and neuropsychological burden 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's novel mechanism of action works by blocking the production of intracellular cortisol – the stress hormone – through the inhibition of the 11β -HSD1 enzyme in the brain. There is a strong association between persistent stress and the production of excess cortisol that leads to detrimental changes in the brain, affecting memory, cognitive function and behaviour and neuropsychological symptoms. The 11β -HSD1 enzyme is particularly highly concentrated in the hippocampus and frontal cortex, areas of the brain impacted by a number of diseases and disorders, including Alzheimer's disease, Fragile X syndrome, schizophrenia, diabetes and other conditions associated with chronically raised cortisol.

The Company's XanaHES Phase I trial exploring the safety and tolerability of Xanamem 20mg once daily in healthy elderly volunteers, confirmed the drug's safety profile with no treatment-related serious adverse events. Additionally, the trial demonstrated that Xanamem produced a statistically significant improvement in cognition over placebo, which, along with other recently generated data, confirms 11β-HSD1 inhibition by Xanamem as a promising potential treatment for cognitive impairment associated with raised cortisol.

The Company plans to initiate Phase II studies of Xanamem in various disease areas in 2021, including MCI due to Alzheimer's disease, and Fragile X syndrome.

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[™] is a trademark of Actinogen Medical.

Disclaimer

This announcement and attachments may contain certain forward-looking statements that are based on subjective estimates and assumptions and relate to circumstances and events that have not taken place and may not take place. Such forward looking statements involve known and unknown risks, uncertainties, and other factors (such as significant business, economic and competitive uncertainties and contingencies, and regulatory and clinical development risks and uncertainties) which may cause the actual results or the performance of Actinogen Medical to be materially different from the results or performance expressed or implied by such forward looking statements. Past performance is not a reliable indicator of future performance. There can be no assurance that any forward-looking statements will be realised. Actinogen Medical does not make any representation or give any warranty as to the likelihood of achievement or reasonableness of any forward-looking statements.

Actinogen Medical encourages all current investors to go paperless by registering their details with the designated registry service provider, Link Market Services.