



Pitney Pharmaceuticals
Pty Limited



PharmAust canine phase 2b cancer trial expands to New Zealand

- Phase 2b bridging studies expansion to New Zealand in preparation for Phase 3 trial
- New Zealand recruitment anticipated to commence in December 2021

15 November 2021 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, has signed agreements with Veterinary Specialists Auckland and Intuit Regulatory to expand its canine Phase 2b lymphoma studies into New Zealand, in preparation for its Phase 3 trial anticipated to commence in May 2022.

PharmAust has signed an agreement with Dr Mike Coleman DVM and Dr Tommy Fluen DVM, both fellows of the Australian and New Zealand College of Veterinary Scientists and both registered specialists in small animal internal medicine. They both work at Veterinary Specialists Auckland and can accept dog lymphoma referrals in New Zealand's North Island. Regulatory and ethical compliance is overseen by Dr Julia McNab PhD of Intuit Regulatory who has specialist expertise in Phase 3 design and registration.

Dr Tommy Fluen stated, "We look forward to working with PharmAust and trial Principal Investigator Dr Kim Agnew to test the hypothesis that monepantel will provide a well-tolerated oral therapy for canines with lymphoma, which is superior to steroids alone and without the costs and risks of chemotherapy."

Principal Investigator Dr Kim Agnew stated, "It is always very beneficial for any product development building towards a Phase 3 study to expand knowledge in new market settings so having the NZ team combine with our team is very good for the PharmAust program."

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "PharmAust is delighted to work with Dr Coleman, Dr Fluen and Dr McNab to establish a clinical trial site in New Zealand. Establishing trial procedures, structures and systems with these groups and receiving their feedback will provide great value to PharmAust in preparing for Phase 3 and potentially later with product roll-out."

This announcement is authorised by the Board

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About PharmAust (PAA):

PharmAust Limited is listed on the Australian Securities Exchange (code: PAA) and the Frankfurt Stock Exchange (code: ECQ). PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company that generated \$2.2 million in revenue in FY 2021.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a pathway having key influences in cancer growth and neurodegenerative diseases. MPL has been evaluated in Phase 1 clinical trials in humans and Phase 2 clinical trials in dogs. MPL treatment was well-tolerated in humans, demonstrating preliminary evidence of anticancer activity. MPL demonstrated objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as well as neurodegenerative disease as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.

VSA

VSA is a group of people that have dedicated their lives to the care of sick animals. VSA's goal is to provide exceptional care to all our patients and their families. To provide every cat, dog and small animal that enters their hospitals the very best treatment available and a better way of life.

VSA does this by working closely with the general practice vets of New Zealand, providing an extension to their practice – utilising state-of-the-art equipment, progressive techniques, clinical expertise and exceptional care.

VSA has two established hospitals in Auckland, one at Sylvia Park and another at Mt Albert with six surgeons, three imaging specialists and three internal medicine specialists. For more information, please visit: <https://www.vsahospital.co.nz/>

Intuit Regulatory

Intuit Regulatory provides animal health and veterinary medicines regulatory consultancy in New Zealand. We can support all stages of product development and registration, and have expertise in veterinary pharmaceuticals, vaccines, nutritional and other animal health products. Dr McNab has 17 years of experience in the animal health regulatory industry including work with Zoetis, Frontera and Bristol Myers Squibb.