PharmAust Receives Ethics Approvals to Commence Phase IIb Dog Cancer Trial

- PharmAust to recommence treating pet dogs with B cell lymphoma with monepantel (MPL) tablets with the aim of demonstrating tumour regression at low dose
- NSW and Qld ethics approvals granted for dosing modification
- APVMA approval to use MPL tablets at two additional trial sites
- MPL tablets for these additional sites to arrive December 2020/January 2021
- Trial recommencement anticipated January/February 2021

22 December 2020 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, is pleased to announce receipt of ethics approvals from the New South Wales Department of Primary Industry (DPI) and Queensland Department of Agriculture and Fisheries (DAF) to undertake a Phase IIb clinical trial in pet owners' dogs with cancer using its newly formulated tablet.

This continuation of the original Phase IIa trial is aimed at demonstrating high efficacy at reduced MPL plasma levels as well as alleviating the inappetence observed in the previous trial iteration. The approvals cover recruitment at five sites in Sydney, Perth and Brisbane. Another two sites previously involved in the trial await approvals following reconvening of respective ethics committees after the Christmas period.

As announced on 12 May 2020, PharmAust recently completed studies testing the effects of MPL tablets upon six pet owners' dogs with treatment naïve B cell lymphoma over a 28 day period. MPL tablets were administered daily at a high target dose and the prospectively nominated objective response criteria for demonstrating anticancer activity were met. All pet dogs achieved stable disease of their target cancer lesions. Despite this success, the trial was terminated early because most but not all dogs developed some inappetence. Of note, all pet dogs had a common high MPL target dose, yet some pet dogs on trial achieved relatively low drug blood levels. The pet dog with the lowest drug blood levels achieved an objective anticancer response with a ≥ 60% reduction in cancer burden, with some cancer lesions disappearing.

PharmAust has scrutinised trial data to understand drug blood level variation and importantly has developed a new dosing methodology that aims to achieve the lower drug blood levels that equated with highest anticancer activity. The trial continuation will involve the same duration and readouts, but just the dosing regimen will be modified.

Additional veterinarians participating in the trial are: Dr Catherine Chan at Veterinary Specialist Services in Brisbane and Dr Jessica Finlay at Perth Vet Specialists. Under Australian Pesticide and Veterinary Medicine Association (APVMA) requirements, PharmAust has shipped existing

tablets out of Australia, so these specific veterinarians can request their legal entry here as unregistered drug products. These tablets are scheduled to arrive at Epichem from the US in December 2020/January 2021. Unregistered drug products manufactured overseas cannot be used by non-nominated veterinarians once they are already in Australia

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "PharmAust is pleased to recommence this trial using MPL tablets to treat pet owner's dogs with B cell lymphoma. PharmAust has been testing two independent hypotheses: that MPL tablets could make cancer disappear and that MPL tablets could stop cancer growing. Previously, PharmAust had demonstrated that MPL liquid stops cancer growing. The first set of trial results using the MPL tablets exceeded expectations with the demonstration that MPL tablets can make certain cancer lesions disappear. This continuation into Phase IIb is designed to understand the dosing regimen that will maximise MPL's anticancer activity."

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About PharmAust (PAA):
PAA is a clinical-stage company developing targeted cancer therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development.

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.