PharmAust Receives Pre-Approval for R&D Tax Rebates

- PharmAust receives Australian Government Advance Finding for pre-approval of R&D activities developing monepantel as a treatment for dogs with cancer in Australia
- PharmAust also receives Overseas Finding pre-approval for related off-shore R&D
- Covers three years to 2020/2021 with $1.452 million value of the refundable tax credits for this project

7 October 2019 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, is pleased to announce completion and favourable assessment by the Australian Government's Department of Industry, Innovation and Science regarding its eligibility for pre-approval of R&D tax rebates. The R&D tax rebate amounts to 43.5% on eligible activities.

Tax credits under the R&D Tax Incentive (RDTI) program are only available for research and development conducted in Australia. PharmAust's Phase I and Phase II clinical trials use monepantel as a treatment for canine cancer but much of its research and development cannot be undertaken in Australia due to drug development, manufacturing facilities and canine cancer research services not being available in Australia.

Under these circumstances, PharmAust made an application to the Department of Industry, Innovation and Science (ISA) for Advanced and Overseas Findings seeking: (1) confirmation that the Phase I and II clinical trials in canines constitute research and development activities supported by the RDTI, and (2) the ability to include payments to overseas service providers in current and future applications for the RDTI. Upon review and assessment of the Company's application, the ISA has issued Certificates to PharmAust under sections 28A and 28C of the Industry Research and Development Act, 1986.

The pre-approvals relate specifically to expenses incurred conducting and supporting the clinical trials in Australia testing the effects of monepantel in dogs with cancer. Importantly, the pre-approvals also cover overseas R&D activities supporting these trials. Overseas supporting activities include the reformulation programs and taste tests conducted with BRI in Canada, the scaled tablet manufacturing conducted with Catalent in the USA and the Phase I dog trials in healthy beagles conducted with a major contract research organisation in the USA.

These Findings will enable PharmAust to claim an anticipated R&D expenditure within Australia of $2.215 million and an overseas R&D expenditure of $1.123 million over the specified three-year period. This represents a total refundable tax credits of approximately $1.452 million (at the current rate of 43.5%) over these three years.

To date, PharmAust has manufactured sufficient tablets to conduct its first Phase II trial testing the effects of monepantel in dogs with B Cell Lymphoma. The pre-approval further paves the way for R&D tax rebate eligibility so that PharmAust may, for example, undertake supplementary tablet manufacture to explore long-term effects of the drug for periods of over 12 months as well as widen the scope of treatments to dogs with other types of cancer.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated: "PharmAust is grateful to the Australian Government who provide the Australian pharmaceutical industry with this assistance. Having certainty over the R&D tax rebate for the next three years greatly assists PharmAust accelerate its work. PharmAust is pleased to be developing monepantel as an anti-cancer agent for pet dogs in Australia and also developing monepantel as an Australian export product for overseas markets."

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About PharmAust (PAA):

PAA is a clinical-stage company developing targeted cancer therapeutics for humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. PAA's subsidiary, Epichem, is a successful contract medicinal chemistry company that is forecasting $4.2m revenues in FY2019/20.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a key driver of cancer. MPL has been evaluated in Phase 1 clinical trials in humans and dogs; was well tolerated and produced a significant reduction in key prognostic biomarkers. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as it advances the drug in Phase 2 clinical trials.