

PharmAust engages Canadian-based specialists to reformulate monepantel

27 June 2017 – Perth, Australia: PharmAust (ASX:PAA) is pleased to announce it has appointed Canadian-based BRI Pharmaceutical Research Inc to reformulate monepantel (MPL) for its clinical trial studies.

BRI will evaluate a range of well validated platforms to determine the optimal formulation for oral delivery of MPL. This work will build-on initial efforts from Juniper who successfully reformulated liquid MPL in the form of Zolvix into capsules. These are now being used in an ongoing phase II clinical trial to treat dogs diagnosed with lymphoma. which recently reported encouraging preliminary data. However, it has also become apparent the current capsule formulation is not suitable for more advanced clinical trials due to the unpalatability of Zolvix even when encapsulated.

To address this, we have selected BRI to prepare a fully optimised MPL formulation that meets the exacting requirements for scaled manufacture, late-stage clinical trials and ultimately registration.

The primary objective is to mask the unpleasant taste of MPL to address the compliance issues encountered with previous formulations. Further aims include increasing the dose of MPL contained in each tablet or capsule to reduce overall pill burden, maximising the amount of drug delivered into the blood stream and ensuring the drug is stable when stored.

BRI is a specialist analytical, bioanalytical and DM/PK contract research organisation (CRO) servicing pharmaceutical and biotechnology companies in discovery, preclinical and clinical programs supporting IND and NDA-enabling studies.

PharmAust's CEO Dr Richard Hopkins said, "We're really excited to be working with BRI who have an impressive track-record in successfully reformulating drugs for clinical development. Within six months we expect to have a reformulated product amenable to scaled manufacture and fully optimised for clinical trials in dogs and humans. Clearly successful delivery of a reformulation product will open-up significant commercial opportunities for the company."

"We're looking forward to keeping the market updated on progress over the coming months" commented Dr Hopkins.

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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. These efforts are supported by PAA's subsidiary, Epichem, a contract synthetic drug manufacturer forecast to generate Aus\$3m in revenues in 2017 at a CAGR of 28%.

PAA's lead drug candidate is Monopantel (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. MPL treatment 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 into Phase 2 clinical trial.