Monepantel reformulation project continues to progress

17 October 2017 – Perth, Australia: PharmAust Limited (ASX:PAA) is pleased to report its monepantel (MPL) reformulation project has continued to achieve a number of key milestones.

In July, PharmAust announced the appointment of BRI Pharmaceutical Research to reformulate its lead compound MPL. The key goals are to address the bitter taste and low concentrations of drug delivered by the current formulation. The reformulation initiative also aims to improve its oral bioavailability, that is, the amount of drug absorbed from the small intestine into the body.

BRI is assessing three different formulations:

Micronisation: Uses a milling technique to reduce particle size, which can improve the rate of drug absorption into the body. BRI has successfully milled MPL down to an average particle size of 1µm, which is within the target range. Micronisation can potentially deliver up to 30 times more drug.

Amorphous Solid Dispersion (ASD): Initial studies by BRI have confirmed MPL is amenable to ASD formulation. Latest results suggest this approach could potentially deliver up to 20 times more drug than the current formulation using the same size capsules.

Self-Emulsifying Drug Delivery Systems (SEDDS): An oily emulsion-based formulation that can significantly improve the bioavailability of drugs, such as MPL, which are poorly soluble in water. BRI has shown this approach could potentially deliver six times more drug than the current formulation.

On taste, BRI has not observed unpleasant odours with any of the formulations tested so far. Moreover, taste tests conducted at PharmAust using pure MPL noted only a mild bitterness which BRI expects can be addressed with masking and flavouring agents to improve palatability.

Next steps include continuing further optimisation of each formulation method. BRI expects to begin bioavailability studies in animal models mid-November. Initial studies will use rodent models before moving onto canines in December.

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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 support by PAA's subsidiary, Epichem, a highly successful contract synthetic drug manufacturer which is forecast to generate ~Aus$4m in revenues in the 2018 FY

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. 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.