

PharmAust Progresses Monepantel Tablet Program for Cancer

15th October 2018 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage oncology company, is pleased to announce that it has completed testing of different monepantel (MPL) tablet prototypes in healthy Beagle dogs in collaboration with BRI Biopharmaceutical Research Inc. The data emerging is better than expected and provides a strong basis for PharmAust to build its therapeutic MPL platform. Achieving good palatability and absorption from the new tablet formulation is vital for the next stages as it will be the product with which PharmAust will conduct its Phase II efficacy study to start in Q1 2019.

The levels tested represent those PharmAust has nominated for the first stage of the dose escalation programs for both human and dog anticancer clinical trials. Levels of monepantel in the blood using just one tablet exceeded the levels predicted to achieve anticancer activity. These anticancer activity levels of MPL have been calculated from PharmAust's: (i) *in vitro* work on human cancer cell lines, (ii) *in vivo* work on human cancer cell lines engrafted in mice, and (iii) earlier clinical trials in human patients with cancer. This blood analysis was not performed during PharmAust's earlier reported clinical pilot Phase II study in dogs with B-cell lymphoma due to ethical considerations. However, by extrapolation of the new tablet data, it appears that the monepantel levels in the blood of these healthy Beagle dogs, from a single tablet, exceeded the dose for anticancer activity required in the previous pilot study in dogs with B-cell lymphoma.

PharmAust now has sufficient data to take the best biologically performing and most financially economical tablet to GMP manufacture through a scale up process with cGMP grade monepantel.

During the next stage, these tablets will be used in formal dose escalation studies in healthy Beagle dogs to determine the maximum dose that can be given and with what safety margin. This is a necessary part of the normal drug development process. From previous studies in dogs and sheep, it appears that blood levels for anticancer activity already fall within a very acceptable safety margin, yet this must be formally proven to regulatory authorities before continuing to market.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "These data from the tablet reformulation program are very encouraging. We can now continue on to the next step of formally confirming anticancer activity in target species in clinical trials using a very convenient delivery method and with a tremendous amount of knowledge of how the drug performs in the body".

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About PharmAust (PAA):

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 which generated ~Aus\$3.02m in revenues in the 2018 FY.