Reformulation of monepantel into tablet form for upcoming clinical trials

4 September 2018 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage oncology company, is pleased to announce that it has completed its preclinical studies to formulate monepantel (MPL) into a tablet. PharmAust expects the new tablet to be taken into trials for the treatment of both humans and canines with cancer.

PharmAust is now completing several optimisation steps required for the scale up manufacture of the tablets to Good Manufacturing Practice (GMP) standards. Preliminary clinical trials will be completed in the next few weeks to help determine how many tablets canine cancer patients will need to take and how often they should take them.

The data emerging from the canine trials will further inform the required doses for humans and enable confirmation of the non-toxic profile of monepantel.

GMP manufacturing provides the highest possible safety standards of manufacturing and is not a stipulated requirement by the regulatory authorities for these early stage clinical trials. However, manufacturing to GMP standards is significant for accelerating product development and as such, the data collected by PharmAust during these early stage clinical trials will be of value for registration studies by partners as well as informing clinical trials to be set up for humans with cancer.

During Q4 2018, it is expected that the formal Phase I pharmacokinetic study with the new tablets will be undertaken and this will be followed by initiation of the Phase II clinical trial. In the meantime leading up to the Phase I and Phase II trials, PharmAust will report on the effective absorption of MPL in canines from the newly prepared tablets. This work will: (i) determine any food-associated effects upon drug absorption rates into the blood stream and (ii) provide a reference so that GMP manufactures know how compact to make the tablet, thus permitting optimal breakdown rates in the stomach and intestine. This means that the Phase I work will commence with a knowledge base permitting the greatest chance of success and relevance to future Phase II and Phase III trials.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "PharmAust has made significant steps in creating a new monepantel tablet formulation that will be suitable to take into clinical trials in canines with cancer and provide valuable information for the upcoming clinical trials in humans. We wish to thank the PharmAust shareholders for their support during this reformulation program."

Enquiries:

Dr Roger Aston
Executive Chairman and CEO
Tel: 0402 762 204
rogeraston@pharmaust.com

Dr Richard Mollard
Chief Scientific Officer
Tel: 0418 367 855
rmollard@pharmaust.com

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