PharmAust and Catalent Commence GMP Tablet Manufacture for Canine Clinical Anti-Cancer Trials

- Catalent to manufacture a scaled-up run of MPL (monepantel) tablets for canine cancer studies in Australia,
- Trials will be conducted at sites around Australia with MPL tablets manufactured to GMP (Good Manufacturing Practice) standards, enabling the emerging data to form part of a U.S. FDA submission package,
- The development of the new tablet formulation is designed to enable easier administration by veterinarians and owners, and a more palatable treatment for dogs,
- The tablets that Catalent manufactures will be adopted for the next Phase II study in canines with lymphoma, building on the successful Phase II study data reported on 13th December 2017.

13 November 2018 – Perth, Australia: PharmAust Limited (ASX: PAA), a clinical-stage oncology company, is pleased to announce that it has reached an agreement with Catalent Pharma Solutions (NYSE: CTLT), for the scaled-up manufacture of GMP-grade monepantel tablets suitable for use in the upcoming trials in dogs with cancer. Catalent, the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products, will provide scaled GMP tablet formulation and manufacture for clinical trials from its facility in San Diego, USA.

GMP tablet manufacture is a key component for undertaking GCP (Good Clinical Practice) trials, and will enable the data emerging from forthcoming trials to be admissible to the U.S. FDA to support new drug registration programs. Furthermore, the availability of GMP-tablets not only provides a more palatable and easier-to-use product, it also provides dogs, owners, veterinarians and PharmAust with the highest standards of product development. Furthermore, adoption of GMP standards ensures products meet the highest standards of safety and efficacy.

Initially, sufficient tablets will be made to undertake the required dose escalation Phase I study in healthy beagle dogs. The Phase I clinical study will determine the numbers of tablets and the optimal frequency of administration to ensure maximum safety and provide information on the optimum dosing levels for the efficacy studies.

Phase II studies will follow, with the aim to confirm the anticancer activity of monepantel capsules in dogs with B-cell lymphoma as previously announced by PharmAust on 13 December 2017. The December study demonstrated that monepantel in capsules has anticancer activity and no demonstrable side-effects.

PharmAust's Chief Scientific Officer, Dr Richard Mollard, commented, "Commencing scale manufacture of GMP grade monepantel tablets is a tremendous milestone. PharmAust has demonstrated that the tablet prototypes can deliver a significant level of drug within the blood of healthy dogs as recently announced in our absorption study on 15th October 2018. PharmAust is now looking forward to studying the safety and anticancer activity of monepantel at these higher blood levels."

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.

About Catalent

Catalent is the leading global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products. With over 85 years serving the industry, Catalent has proven expertise in bringing more customer products to market faster, enhancing product performance and ensuring reliable clinical and commercial product supply. Catalent employs over 11,000 people, including over 1,800 scientists, at more than 30 facilities across five continents, and in fiscal 2018 generated approximately $2.5 billion in annual revenue. Catalent is headquartered in Somerset, New Jersey. For more information, visit www.catalent.com.

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