PharmAust Commences GMP Tablet Manufacture for Phase 2 Trial in Dogs with Cancer

- Production run to generate sufficient tablets for a Phase 2 trial examining the anti-cancer effects of monepantel in dogs with B cell lymphoma.
- Manufacture to use 5kg of GMP grade monepantel.
- Successful anti-cancer trials in dogs pave the way for anti-cancer trials in humans.

4 June 2019 – Perth, Australia: PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, is pleased to announce commencement of GMP (Good Manufacturing Practice) tablet production with Catalent, the leading global provider of advanced delivery technologies and development solutions for drugs, biologics, and consumer health products, for its Phase 2 clinical trials in dogs with cancer.

Tablet production now follows the nine-day canine safety study that demonstrated excellent tolerance in healthy beagle dogs. Manufacturing to GMP standards enables regulators to compare drug integrity between different tablet batches. PharmAust expects that GMP manufactured monepantel (MPL) tablets will be fit for routine trial use in both dogs and humans.

PharmAust is targeting an August/September 2019 start for the recruitment of its pivotal Phase II canine trials subject to timely Ethics Committee approval. These trials will initially follow a 28-day treatment regimen but may be extended if pet owners request continued treatment of their pets. MPL dosing will be based on the company's historic experience with efficacious levels of MPL in cancer. Testing for anti-cancer activity will commence for dogs with B cell lymphoma, one of the more prevalent tumour types in dogs and for which have no enduring reliable curative treatment is currently available. PharmAust announced on 13 December 2017 that monepantel shows activity against B cell lymphoma.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented, "Scaled GMP manufacture has commenced on the back of very good data achieved from the pilot dosing programs conducted in recent months. These new monepantel tablets remedy the poor palatability problems and administration challenges encountered in past trials using the monepantel liquid formulation.

"PharmAust can now execute clinical trial testing for the anti-cancer activity of monepantel in pet owners' dogs with naturally occurring cancers in a repetitive, reliable and more robust fashion.

"PharmAust is pleased to be going back into the clinic and directly testing monepantel for anti-cancer activity. We also intend that these clinical trials in dogs with cancer will pave the way for registration and future clinical trials in human patients with cancer.

"GMP tablet manufacture is outsourced to specialist drug manufacturer Catalent Inc. (NYSE: CTLT), a large global provider of advanced delivery technologies and development solutions for drugs, biologics and consumer health products."

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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.

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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