



## PHARMAUST SHAREHOLDER UPDATE

**24 June 2020 – Perth, Australia:** PharmAust Limited (ASX:PAA), a clinical-stage oncology company, is pleased to update shareholders on the continuing development of the business and progress with its primary drug candidate, monepantel (MPL).

### **Monepantel shows “remarkable” results against COVID-19**

In April PharmAust started working with the Walter and Eliza Hall Institute of Medical Research in Victoria to test the effects of its primary drug candidate MPL on the SARS-CoV-2 virus that causes COVID-19 infections.

The results from this work investigating the effects of monepantel and monepantel sulfone on cells infected with SARS-CoV-2 in tissue culture have been very positive. Repeat cell culture work has confirmed the initial promising data, which showed that:

- Monepantel and monepantel sulfone treatment both reduce SARS-CoV-2 (COVID-19) cell-to-cell infectivity in cell culture;
- Virus infectivity was suppressed by approximately 95% in cell culture; and
- The quantities of monepantel required to inhibit virus infectivity were in the clinically acceptable range

Walter and Eliza Hall Institute researcher Professor Marc Pellegrini (*MBBS BSc FRACP PhD FAHMS*), joint head of the Institute’s Infectious Diseases and Immune Defence division and an infectious disease clinician at the Royal Melbourne Hospital, stated “These exciting repeat results validate the results of the initial test and form strong grounds for progressing the drug to the next step. Demonstrating twice, that infectivity of SARS-CoV-2 virus particles can be suppressed by up to approximately 95% in cell cultures is a remarkable outcome.”

PharmAust, together with the Walter and Eliza Hall Institute, will now conduct a comparative analysis with MPL and other mTOR inhibitors, such as rapamycin and current anti-viral drugs authorised by the FDA for emergency use to treat COVID-19, such as remdesivir.

As regards next steps, PharmAust will prepare an Executive Summary and an Investigator’s Brochure to permit discussions with clinicians about a Phase I trial in a small number of human patients to treat COVID-19. Monepantel has already been evaluated in human patients with cancer (ASX announcement 21 October 2015), so human safety data is already available to facilitate the next steps.

### **Monepantel Canine Trial Achieves Successful Anti-Cancer Outcome**

PharmAust achieved a successful outcome in the veterinary Phase II clinical trial investigating the effects of monepantel on dogs with treatment naïve B Cell lymphoma.

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The Principal Investigator observed 100% survival rate during the trial (typically 50% of untreated dogs would not survive for 28 days). One pet dog achieved greater than 60% reduction in tumour burden, with one of its tumours completely disappearing within 14 days. The outcome provides a meaningful trend, comparing favourably with the treatment used in the original “liquid” monepantel formula reported on 3 December 2017.

Dr Richard Mollard, PharmAust’s Chief Scientific Officer, further commented “We had a number of key goals for this trial including:

- Determining the safety and efficacy of monepantel tablets as compared with the liquid formulation previously used in canine and human studies
- Evaluating the drug delivery capabilities of the newly developed monepantel tablets in pet dogs with cancer
- Deriving sufficient positive and indicative data to enable Phase III trials
- Producing sufficient data to enable further discussions with Vet Major with which PharmAust has an Option Agreement.

PharmAust considers that all these goals have been met”.

A dossier is to be presented to the MPL compound owner and option partner (Vet Major) in July 2020, providing the opportunity for Vet Major to activate its 6-month exclusive option over the licensing of MPL for veterinary uses. Vet Major supported the Phase II trial by providing 25kg of MPL.



*Sampson (left) successfully completed PharmAust’s 28 Day Phase II Canine Trial*

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## Phase II Human Cancer Trial

PharmAust continues to make key steps towards progressing the evaluation of MPL in human trials.

PharmAust has submitted the MPL human trial paper for publication in a peer review journal describing the historic trial undertaken in Adelaide and the performance of MPL.

PharmAust has conducted further tablet formulation and pharmacokinetic studies aiming to increase uptake of monepantel into the blood and reduce tablet numbers for future human trials.

PharmAust has also investigated changes in tablet size to enable more specific targeting of calculated optimum dose levels. PharmAust currently has two separate batches of GMP-grade monepantel under stability studies testing the shelf-life of the formulation. These stability studies show a robust tablet and will support relevant submission filings to human trial ethics committees.

Depending on associated activities, PharmAust is currently aiming to conduct a third GMP manufacture program for monepantel tablets in or around quarter 3 of CY 2020 to cater for future human trials.

PharmAust is seeking to identify suitable Clinical Oncology Unit to evaluate the new MPL tablet in humans in a Phase II trial, as a follow on from the Phase I clinical trial undertaken at the Royal Adelaide Hospital in 2015.

## Current R&D

PharmAust is undertaking RNAseq profiling upon human cancer cell lines in vitro to investigate the mechanism of action of monepantel in autophagy/apoptosis causal to monepantel's anti-cancer effects. These studies aim to further dissect the involvement of mTOR signalling pathways in these processes which would allow further optimisation and flexibility in dosing for both vet and human therapy in future.

## Epichem Pty Ltd

Epichem, a fully owned subsidiary of PharmAust, is a profitable and award winning medicinal and synthetic chemistry company with expertise and capability in the field of drug development, discovery and design. Epichem provides specialised products and technical expertise to a worldwide customer base in the pharmaceutical, mining, agriculture and animal health sectors.

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Epichem also manufactures Pharmaceutical Reference Materials and Fine Chemicals and supports the PharmAust Drug Development Pipeline with Lead Drug Development and Validation, Drug Candidate Pipeline Manufacture and Analysis, Drug reformulation, GMP synthesis and stability support as well as Drug Inventory dispensing to clinical trial centres.

Epichem's projected revenue forecast is on track to deliver \$3.46 million for the FY2020, which is an increase on the forecast of \$3.34 million (as per ASX Announcement 7 January 2020).

Epichem continues to pursue opportunities to create our own IP portfolio with the assignment of specific projects to individual chemists. This will also allow Epichem to maximise the R&D Tax incentive as well as act as an R&D project incubator for PAA.



*Epichem CEO, Colin La Galia with the first batch of Chemistry-Grade Hand Sanitiser*

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## Virtual Investor Briefing

Executive Chairman, Dr Roger Aston provided an update on the status of the development of monepantel earlier this month, including discussion on the significant progress in recent trials. If you would like to view a recording of this Virtual Investor Briefing it can be found here <https://pharmaust.com/pharmaust-videos/>

## Ticker TV

PharmAust's Chief Scientific Officer Dr Richard Mollard spoke to *Ticker TV's* Ahron Young about the company, its origins, trial successes and plans for the months ahead. You can watch the interview on the homepage of the PharmAust website <https://pharmaust.com/>

***This announcement is authorised by the Board***

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## About PharmAust (PAA):

PAA is a clinical-stage company developing targeted cancer therapeutics for humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. PAA's subsidiary, Epichem, is a successful contract medicinal chemistry company.

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 I clinical trials in humans and dogs; 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 in Phase II clinical trials.

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