



## Shareholder Update - Progress and Strategy

**13 December 2021 – Perth, Australia:** PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, is pleased to provide an update on its activities.

### PharmAust's strategy:

1. Following the phase II study of monepantel (MPL) tablets in canines with B-cell lymphoma, PAA will apply for registration of MPL for canine cancer with confirmation of the data in a phase 3 trial format. Plans are to conduct the phase 3 study in canines with B-cell lymphoma in Australia, New Zealand and the USA. The trial is expected to start with GMP<sup>1</sup> compliant tablets around May 2022.
2. In parallel to preparing for phase 3, PAA has commenced discussions with several potential major corporate veterinary licensees.
3. In the early part of 2022 (May) PharmAust plans to initiate two separate human trials aimed at determining safety and primary measures of efficacy of MPL tablets in both COVID-19 and Motor Neurone Disease (MND). The anticipated trial start dates are based on the expected availability of tablets from our manufacturer (Catalent San Diego). Catalent San Diego has successfully demonstrated the ability to manufacture smaller size tablets that will enable provision of a lower MPL dose anticipated to be compatible with treating these diseases.
4. Slowing down viral proliferation (COVID-19) or cell death in the neurons that control the muscles, leading to loss of muscle control and eventually paralysis (MND) could have a transformational impact on the business.

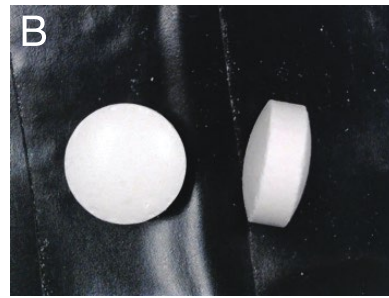
### Product Development Summary:

- Data from PharmAust's phase 2 trial in canines with B-Cell Lymphoma to date has demonstrated that MPL provides anticancer activity. An optimum drug blood plasma level has been nominated. Post-trial, some veterinarians and the respective pet owners have elected to continue MPL treatment, and sometimes in combination with prednisolone. This combination has provided average extension of survival to these pet dogs of 16-24 weeks, comparing favourably to standard of care (palliative steroid therapy) that typically provides for 6-8 week survival in association with a range of adverse events. Canines treated with MPL during the trial and after the trial at this optimum level experienced a high quality of life and minimum adverse events were reported. These canine outcomes bode well for further human cancer trials to be pursued in CY 2022.



Pet dogs in the MPL tablet Phase 2 trial enjoying time with their owners

- Based on preclinical studies and on its mechanism of action (mTOR inhibition), PharmAust is initially targeting MPL evaluation in two human clinical trial settings: MND and COVID-19 both starting around May 2022
- Protocols and ethics/regulatory approvals are now in place for the evaluation of MPL in Motor Neurone Disease. Principal Investigators Professor Dominic Rowe and Dr Sue Mathers will recruit patients and oversee the trial. Funding for the trial (\$880,000) is gratefully received from the Australian FightMND charity. This funding enables the safety and tolerability of MPL to be tested in patients living with MND during 2022. The trial is also set up to look for signs that MPL can slow the progression of MND. This data, in conjunction with concurrent animal studies, will determine whether MPL should go on to be tested in larger phase 2 studies.
- Trial sites to participate in the evaluation of tablet formulated MPL in COVID-19 are currently being identified by the Company's CRO partner in Europe. PharmAust has filed a PCT application which, amongst other aspects, is directed towards the use of MPL and aminoacetonitrile derivatives as antiviral agents and claims an earliest priority date of 11 May 2020. The application is open for public inspection.
- GMP manufacturing of monepantel for the FightMND and COVID-19 trials is progressing well, with MPL shipment now expected for tablet manufacture in January 2022. This is three weeks later than previously anticipated, due to the detailed requirements for provision of the necessary standards of Phase 3 GMP goods. Demonstration batch tablet manufacture for the smaller size tablets has now been successfully completed, with stability testing started. GMP tablet manufacture is booked-in for the second week of February and the trial start date is still anticipated for early May 2022.

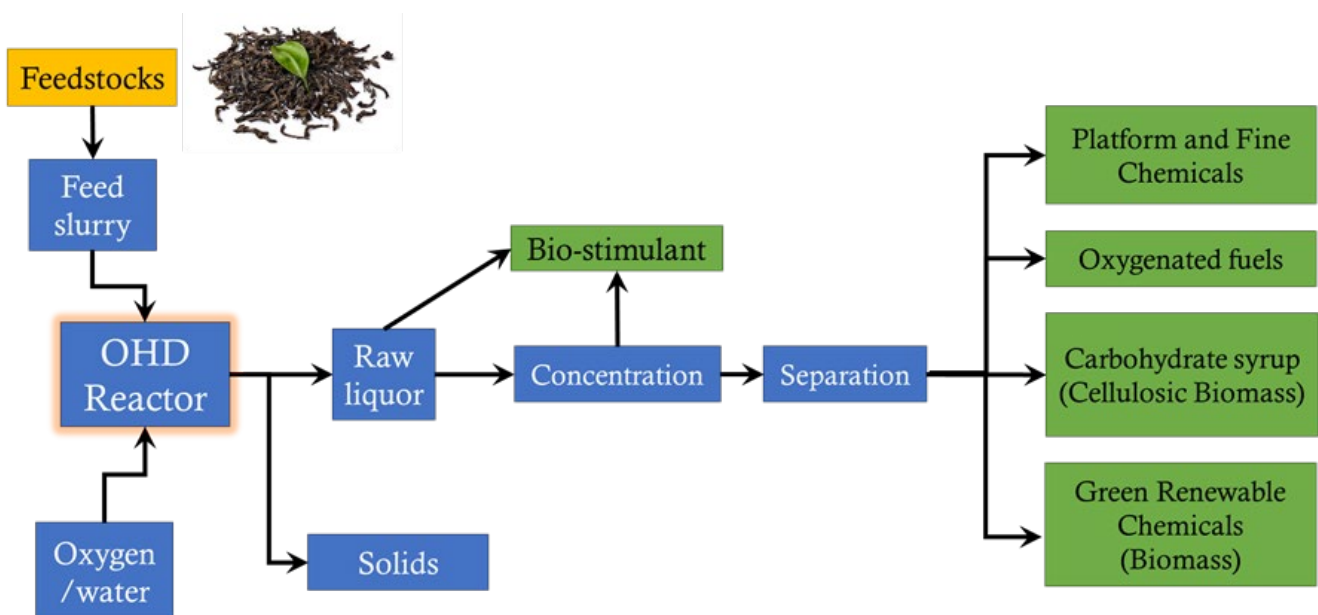


MPL tablets produced for use in the MND and COVID-19 trials.  
A) Low magnification. B) High magnification of two tablets

- Researchers in the Cell Death and Survival Laboratory at the Olivia Newton John Cancer Research Institute led by Associate Professor Doug Fairlie and Dr Erinna Lee conducted a comprehensive RNA-Seq (RNA sequencing) screen investigating how the entire genome of cancer cells responds when treated with MPL. A select subset of genes was found to be either switched on or off by MPL in cancer cells, but not in non-cancer cells. The tested non-cancer cells' mRNA profiles were relatively unaffected by MPL treatment. Proteomic identification and matching with the mRNA profiles for target pathway deconvolution is ongoing.

## Epichem

PharmAust's wholly owned subsidiary, Epichem Pty Ltd, continues to advance its innovative, novel and disruptive waste conversion and re-purposing technology, Oxidative Hydrothermal Dissolution (OHD). A benchtop flow reactor has been built and commissioned for operation. Proof of concept work has been carried out and determined on Coal and Ligno-cellulosic Biomass.



Epichem is currently undertaking a WA Government New Industries Fund WasteSorted e-waste Grant project to convert e-waste using OHD. The grant funding will see Epichem use Oxidative Hydrothermal Dissolution technology to convert e-waste into useful end products, recover valuable metals and produce useful high value chemicals. The research and development program will support a new and innovative solution to process collected e-waste and reduce the amount of e-waste ending up in landfill. The WasteSorted e-Waste grants support the WA Waste Avoidance and Resource Recovery Strategy 2030 objectives - to avoid waste, recover more value and resources from waste and protect the environment from the impacts of waste

Epichem is also partnering with the Curtin University WA School of Mines to research and develop OHD for use in mineral extraction. This project will investigate the potential of OHD liquors for hydrometallurgy and mineral processing applications.

Epichem was recently recognised and awarded as the 2021 WA Exporter of the Year for International Health. Epichem has been widely recognised having won the coveted WA Exporter Award on five occasions and is in the WA Export Hall of Fame.

More information at [www.epichem.com.au](http://www.epichem.com.au)



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#### About PharmAust (PAA):

PharmAust Limited is listed on the Australian Securities Exchange (code: PAA) and the Frankfurt Stock Exchange (code: ECQ). 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 that generated \$2.2 million in revenue in FY 2021.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a pathway having key influences in cancer growth and neurodegenerative diseases. MPL has been evaluated in Phase 1 clinical trials in humans and Phase 2 clinical trials in dogs. MPL treatment was well-tolerated in humans, demonstrating preliminary evidence of anticancer activity. MPL demonstrated objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as well as neurodegenerative disease as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.