



Pitney Pharmaceuticals  
Pty Limited



## Motor Neurone Disease and COVID-19 Phase 1 Monepantel Clinical Trials On-Track

- FightMND supported motor neurone disease trial start date anticipated early May 2022
- COVID-19 trial centres being identified and start dates anticipated May 2022
- PharmAust commences manufacture of smaller size monepantel tablet demonstration batch for the FightMND supported clinical trial
- Manufacture in collaboration with Syngene
- Scale-up of GMP manufacturing of monepantel progressing well

**17 November 2021 – Perth, Australia:** PharmAust Limited (ASX: PAA & PAO), a clinical-stage biotechnology company, is pleased to provide an update on its Phase 1 trials start dates testing the effects of monepantel (MPL) in individuals living with motor neurone disease (MND) and people affected by COVID-19.

GMP manufacturing of monepantel for the FightMND and COVID-19 trials is progressing well with the MPL tablet shipment now expected at the end of December 2021. This is three weeks later than anticipated due to the detailed requirements for Phase 3 GMP goods. Demonstration batch tablet manufacture for the smaller size tablets will commence this week, with GMP tablet manufacture now booked-in for the second week of February and the trial start date is still anticipated in early May 2022.

Dr Mahesh Bhalgat, Chief Operating Officer, Syngene International, said, "We are very pleased to partner with PharmAust to reach this milestone. The project had multiple and complex challenges including initial purity, chiral purity and the desired form. The team at Syngene worked as an extension of PharmAust's internal scientific teams and created innovative, flexible and efficient approaches to achieve the desired product quality with improved purification parameters. We look forward to providing the GMP material for the human trials."

For the COVID-19 trial PharmAust has successfully completed primary diligence on potential trial sites with six centres expressing interest. PharmAust is preparing trial design while engaging local contract research associates to assist running these trials at clinical trial sites using an appropriate monepantel study protocol.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "We are satisfied that all parties are striving for rigorous and timely studies that may ultimately see MPL help individuals with motor neurone disease and COVID-19."

This announcement is authorised by the Board

GMP: Good Manufacturing Practice

### Enquiries:

**Dr Roger Aston**  
Executive Chairman  
[rogeraston@pharmaust.com](mailto:rogeraston@pharmaust.com)

**Dr Richard Mollard**  
Chief Scientific Officer  
[rmollard@pharmaust.com](mailto:rmollard@pharmaust.com)

**P +61 (8) 9202 6814**  
**F +61 (8) 9467 6111**  
**W [www.pharmaust.com](http://www.pharmaust.com)**

### **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.

### **About Syngene**

Syngene International Ltd. (BSE: 539268, NSE: SYNGENE, ISIN: INE398R01022) is an integrated research, development and manufacturing services company serving the global pharmaceutical, biotechnology, nutrition, animal health, consumer goods and specialty chemical sectors. Syngene's more than 4700 scientists offer both skills and the capacity to deliver great science, robust data management and IP security and quality manufacturing at speed to improve time-to-market and lower the cost of innovation. With a combination of dedicated research facilities for Amgen, Baxter, Bristol-Myers Squibb and Herbalife, as well as 2 Mn sq. ft of specialist discovery, development and manufacturing facilities, Syngene works with biotech companies pursuing leading-edge science as well as multinationals, including GSK and Merck KGaA. For more details, visit [www.syngeneintl.com](http://www.syngeneintl.com)

### **About FightMND**

Founded in 2014, FightMND was established in Australia with the purpose of finding effective treatments and ultimately a cure for Motor Neuron Disease (MND), also referred to as ALS or Lou Gehrig's Disease. FightMND, with its vision of a world without MND, is the largest independent funder of MND research in Australia. Since 2014, FightMND has investment more than \$63 million into MND research and care equipment to improve the lives of those fighting the disease. FightMND is determined to help facilitate the translation of the growing body of new knowledge about the disease into a cure for MND patients in Australia and abroad. For more information about FightMND, visit the website at <https://fightmnd.org.au>.