PharmAust Clinical Trials Update

- MPL tablet manufacturing program successfully completed
- Motor Neuron Disease (MND) trial completion of paperwork expected May 2022
- Patient recruitment to begin June 2022
- PharmAust to undertake a Phase 2 study in COVID-19 rather than a Phase 1 study

24 May 2022 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, is pleased to provide an update on its clinical trial and manufacturing development programs:

MPL tablet manufacturing program

The program including the production of API (Active Pharmaceutical Ingredient) in India, tabletting in the US, as well as stability and purity analysis, has been successfully completed. Human trials can now proceed. Monepantel (MPL) tablets specifically designed for the MND trial, have been shipped to Sydney and Melbourne. These tablets have passed all required stability and formulation testing.

The FightMND-grant second instalment of $99,230 is now payable to PharmAust after the completion of the one-month accelerated stability testing of the newly prepared MPL tablets, while the third instalment of the grant ($173,035) will be payable upon commencement of the trial.

Phase 1 Human Trial in Motor Neurone Disease

The Phase 1 clinical study is on track to complete formalities in May with the appointment of the Safety Monitor and then with patient recruitment to begin in June. PharmAust will report on the recruitment and treatment of the first patient that fulfills the inclusion criteria and provide updates thereafter.

Phase 2 Human Trial in COVID-19

PharmAust has been identifying clinical centres capable of sourcing patients with the required COVID-19 progression and vaccination status. Our search has focussed on Eastern Block European states where there remain a significant number of unvaccinated patients. Encouragingly, three clinical centres in Romania and Bosnia have expressed interest in participating and recruiting sufficient numbers of qualifying patients for the study.

Next steps include providing protocols for the study and qualification of the identified clinical centres. We continue to search for contingency sites including in Poland. This critical step of site selection, both in terms of clinical suitability and patient recruitment numbers, has resulted in a delay in the commencement of the Phase 1 COVID-19 trial.

However, this has enabled us to further review the trial rationale and, given the timing of the commencement of the MND trial, the Board has decided to rely on the MND trial to provide the important Phase 1 pharmacokinetic (PK) data for both the MND and COVID-19 trials. We believe this will allow PharmAust to undertake a Phase 2 study in COVID-19 rather than a Phase 1 study. This will facilitate faster recruitment as we have been advised by the CRO that COVID-19 infected patients generally prefer participating in a Phase 2 study. This strategy also benefits from a financial saving to PharmAust of about $1.5 million.

Further, PharmAust has signed an agreement to evaluate MPL in transgenic “humanised” mice, which will express the receptors that the COVID-19 virus binds to in humans. Efficacy in this anti-viral model will provide further evidence of the anti-viral effects of MPL.

This announcement is authorised by the Board.

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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 sales of goods & services 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.