



PharmAust and WEHI to Investigate Monepantel in HTLV-1 Viral Infections

- 10-20 million HTLV-1 sufferers. Virus associated with pulmonary disease, inflammatory disorders and leukaemia/lymphoma
- Adds to PharmAust's COVID-19 virus work by broadening the scope of potential monepantel antiviral activity
- Expected to provide preclinical models of high relevance to support clinical trials

12 July 2021 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage biotechnology company, has executed a Research Services Agreement with the Walter and Eliza Hall Institute (WEHI), Melbourne to investigate the effects of monepantel (MPL) upon human T-lymphotrophic virus-1 (HTLV-1) infections *in vitro*.

HTLV-1, like HIV the causative agent for Acquired Immunodeficiency Syndrome (AIDS), is an oncogenic (cancer inducing) virus that targets the immune system. The virus can cause a type of cancer called adult T-cell leukaemia/lymphoma (ATL) and is transmitted primarily through infected bodily fluids including blood and breast milk.

Approximately 10-20 million people worldwide are infected with HTLV-1 with high recorded incidence in Japan¹. Several central Australian indigenous populations have infection rates of over 60%. Infection is associated with pulmonary disease, inflammatory disorders and, in some cases, a rapidly progressive leukaemia/lymphoma. In 10% of patients serious morbidities and mortality is observed.

This work follows upon PharmAust's COVID-19 program, aiming to broaden the scope of targets for MPL's potential antiviral activity. The study of HTLV-1 is of particular significance due to the readily available nature of highly and particularly relevant *in vitro* and *in vivo* preclinical virus infection models, potentially providing PharmAust with further data to support future human trials.

Like the COVID-19 work, the HTLV-1 work will be conducted at WEHI by a group led by Professor Marc Pellegrini. Work will commence upon cell lines in culture. Dependent upon outcomes and subsequent agreement, the group aims to then move to *in vivo* preclinical models. The fee payable under the agreement is not material to the company. Preliminary data are anticipated in December 2021.

PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "PharmAust is pleased to have the opportunity to work again with Professor Marc Pellegrini's group at the WEHI. While PharmAust continues MPL manufacture and tablet production for clinical trials, this work provides an excellent opportunity to build our MPL antiviral knowledge base. While our COVID-19 work is ongoing, having a more extensive preclinical data package describing MPL's antiviral activity in more general terms would strengthen PharmAust's position going into any antiviral clinical trial, including for COVID-19."

¹ https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/geographical-distributionareas-high-prevalence-HTLV1.pdf

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 \$3.5 million in revenue in FY 2020.

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 The Walter and Eliza Hall Institute of Medical Research

The Walter and Eliza Hall Institute is one of Australia's leading biomedical research organisations, with a national and international reputation for performing highly influential basic and translational research. The Institute is addressing some of the major health challenges of our time, with a focus on cancer, immune health and infection, and development and ageing. The Institute is at the forefront of research innovation, with a strong commitment to excellence and investment in research computing, advanced technologies and developing new medicines and diagnostics. For more information visit <u>https://www.wehi.edu.au</u>.