

ASX Release

7<sup>th</sup> August 2014

## HUMAN CANCER TRIAL – FIRST PATIENT INITIATES TREATMENT Royal Adelaide Hospital

**PharmAust Limited** (“PharmAust”) (ASX: PAA & PAAO) is pleased to report that following the approval to begin a “First in Man” study by the Royal Adelaide Hospital Research Ethics Committee, the Company has recruited, screened and has now commenced treatment of the first patient with its anti-cancer drug PPL-1. The patient is suffering from colorectal cancer with lung and liver metastases.

The trial is being led by Professor Michael Brown (the principal investigator), and managed by Contract Research Organisations for clinical services (IDT CMAX) and analytical services (CPR Pharma Services).

PPL-1 is an approved drug launched in recent years by one of the leading global animal health corporations for the treatment of parasitic diseases in animals. PharmAust, through its wholly owned subsidiary, Pitney Pharmaceuticals Limited, owns patents on the use of PPL-1 in cancer and malignant disease. Furthermore, through New South Innovations (NSi), PharmAust has received royalty-free assignments of the intellectual property relating to the use of PPL-1 in cancer from the University of NSW. Research into the mechanism of action of PPL-1 by PharmAust and the St George Hospital indicates that important cancer inhibitory pathways are involved in the action of the molecule.

The trial is structured as a rising dose study with the first three patients being treated at the lowest dose of drug. Recruitment and screening of additional patients continues and, in total, the trial expects to involve 12 to 15 patients. Subsequent patients will receive progressively higher doses of PPL-1 to determine both safety and drug activity. The trial envisages three dosing levels plus a further dosing level to be determined at the end of the study as necessary. Each patient will receive PPL-1 daily, for 28 days and will be given the option to continue on the drug passed this initial treatment period. Being “Open Label” in design, the trial will allow periodic reporting to shareholders on recruitment, safety and activity of the drug. Typically, the patients in the trial will have failed all “Standard of Care” for their cancers and not be taking other medications for treating their cancers.

The trial is being conducted to full GCP (Good Clinical Practice) enabling the results to be used in submissions to regulators (Therapeutic Goods Administration, Food and Drug Administration, European Medicines Agency) towards registration. The clinical trial managers and service providers, IDT-CMAX and CPR Pharma Services, are audited by the Food and Drug Administration.

PharmAust’s Executive Chairman, Dr Roger Aston said, “As a First in Man study, the drug will be potentially administered to patients suffering from diverse cancers. Recruitment will include selection of patients suffering from lung, pancreas, oesophageal, gastric, colorectal, ovarian, breast, prostate, liver, sarcoma, lymphoma, and melanoma” “PharmAust has reached an exciting stage in its evolution and we look forward to reporting outcomes on the safety and activity of PPL-1”



The cancer chemotherapy market (estimated at \$42 billion/annum)\* is currently the fastest growing sector within the pharma industry, mainly driven by the identification of new potential therapeutic targets. This growth is further fuelled by the magnitude of the disease worldwide, currently estimated at more than 25 million people suffering from cancer globally, and an estimated 5 million people dying each year from the disease.

\*Reference: Research and Markets.com accessed 14<sup>th</sup> February 2014:  
[http://www.researchandmarkets.com/reports/335548/chemotherapy\\_market\\_insights\\_20062016\\_a](http://www.researchandmarkets.com/reports/335548/chemotherapy_market_insights_20062016_a)

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