ASX Release **21st October 2015**

Clinical Trial Report Following Phase I Trial at Royal Adelaide Hospital

TRIAL SHOWS SAFETY, SUPPRESSION OF TUMOUR MARKERS AND STABLE DISEASE IN TWO PATIENTS

PharmAust Limited ("PharmAust") (ASX: PAA) is pleased to report that it has received the Phase I Clinical Trial Synopsis from CPR Pharma Services, who have worked with CMAX-IDT to successfully complete PharmAust's first-in-man clinical trial of PPL-1 at the Royal Adelaide Hospital.

The trial, **A Phase I Study of the Tolerability, Safety and Pharmacokinetics of Oral Monepantel (MPL or PPL-1) in Individuals with Treatment-Refractory Solid Tumours,** was intended to investigate:

PRIMARY OBJECTIVES

- Describe the safety, tolerability, dose-limiting toxicities and maximum tolerated dose (if achieved) of PPL-1 in humans with treatment-refractory solid tumours.
- Describe the multiple-dose pharmacokinetics of PPL-1 in participants with treatment-refractory solid tumours.

SECONDARY OBJECTIVES

- Evaluate evidence for PPL-1's anti-cancer activity in humans, using conventional measures of cancer response and disease progression, and exploratory pharmacodynamic and tumour markers.
- Establish a recommended starting dose for Phase II studies of PPL-1 in participants with treatment-refractory cancer.

Outcomes of Clinical Trial

SAFETY

PPL-1 demonstrated a very good safety profile as compared with many other established anticancer drugs. Whilst PPL-1 was well tolerated in humans, adverse events (AEs) deemed to be related to study medication included nausea, vomiting, diarrhoea, and decreased appetite. The poor palatability of PPL-1 is believed to be the major contributor to these AEs. PharmAust is investigating a number of reformulation options for PPL-1 to rectify the palatability challenges of the Phase I Trial and to develop a more commercially attractive product.

ORAL ABSORPTION

The pharmacokinetics of PPL-1 indicate rapid absorption and peak blood levels (4-6 hours) following oral administration of the drug. The blood levels of PPL-1 are in line with the levels observed for other anticancer drugs.

ANTI-CANCER ACTIVITY

PPL-1 showed activity against cancer through the suppression of tumour marker p70S6K which is highly significant when the data from 7 patients is combined and analysed (at day 3 of treatment $p<0.0004$ and at day 7 of treatment $p<0.002$). Furthermore, evaluation of white blood cells of patients who have received PPL-1 for either three or seven consecutive days has shown that the levels of p-4E-BP1 cancer marker are significantly reduced as compared to its levels at Day 1 before treatment started. Of the 4 subjects with post-dose RECIST assessment (tumour measurements) at a dose level of 5 mg/kg, 2 were classified as stable disease and 2 were classified as progressive disease.

Dr Aston said "This is a very strong result for our Phase I trial which will now allow us to proceed as soon as possible to a Phase II evaluation of PPL-1. Preliminary discussions with physicians at both the Royal Adelaide Hospital and at Clinical Research Centres in the UK signal strong interest to evaluate PPL-1 where first line therapy has failed. Following some additional contractual studies, which we will report upon, we expect to be able to select what chemotherapy is preferred to be used in conjunction with PPL-1 in the next trial. Furthermore, the Phase I study has confirmed that PPL-1 is absorbed orally in quantities that result in suppression of the cancer marker p70s6k in peripheral immune cells; this gives us much confidence that the drug is active on markers that have been correlated with aggressive features of cancer, such as growth, invasion and metastasis."

The full report of the trial will be a document that can be submitted to regulators such as the FDA. PharmAust will continue to report on clinical strategy and progress.

The next stage is for clinical trials with PPL-1 and chemotherapy. The Company has shown that PPL-1 can significantly enhance chemotherapy in model systems without associated enhancement of toxicity commonly seen with chemotherapy drugs. Today, if one includes palliative therapies, the chemotherapy market has topped US$100 billion[1] ([1]Reuters). Dr Aston said, "If successful, this will be a defining trial for PharmAust as our drug will need to be initially used on the backdrop of the chemotherapy "Standard of Care"".

The Company is expecting to meet with its commercial partner that holds an Option over the veterinary anti-cancer applications, in early December 2015.

Note: 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 14th February 2014:
http://www.researchandmarkets.com/reports/335548/chemotherapy_market_insights_20062016_a

For further details please contact:

Dr Roger Aston
Executive Chairman
Tel: 0402 762 204
rogeraston@pharmaust.com

Mr Robert Bishop
Executive Director
Tel: 0417 445 180
robertbishop@pharmaust.com