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Phase I Trial at Royal Adelaide Hospital Meets Safety and Cancer Marker End Points for Tumour Suppression

CLOSURE OF TRIAL WITH SEVEN PATIENTS ASSESSED FOR TUMOUR MARKERS

PharmAust Limited ("PharmAust") (ASX: PAA & PAAO) is pleased to report on the successful closure of its Phase I (Phase IIa) "first in man" trial at the Royal Adelaide Hospital and confirmation that the last patient, who was treated at the higher dose of PPL-1 (25mg/kg), showed meaningful suppression of key cancer marker p70S6K. Importantly, during the trial, both principal end points were successfully met, namely:

1. PPL-1 demonstrated a very good safety profile as compared with many other established anticancer drugs, and
2. PPL-1 showed activity against cancer through the suppression of a key cancer marker.

In the trial, seven patients were treated with PPL-1 for various time periods and measurements were successfully taken for anticancer activity through marker suppression (p70S6K). Three patients completed the full 28-day treatment period. One patient was not included in the cancer marker results as they only received a single dose of the drug. One patient received the higher dose of PPL-1 (25mg/kg).

PharmAust's contract research organisations (CPR and CMAX), which have managed the recruitment and implementation of the trial and have undertaken both pharmacokinetic and pharmacodynamic measurements (cancer markers), will now provide a report on the trial during September 2015, which will include further data on other cancer-specific markers (in addition to p70S6K) and levels of PPL-1 and its metabolites in patients' circulation.

PharmAust's Executive Chairman Dr Roger Aston said "We have now completed the "first stage" of studies with PPL-1 in humans and canines and we have shown that in both cases PPL-1 is well tolerated and importantly is active against cancer. The suppression of tumour marker, p70S6K, in man was 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 $p<0.002$). We have furthermore initiated the processes to move to the important next stage, which will include the treatment of patients with a combination of "Standard of Care" (chemotherapy drugs) in the presence of PPL-1. For the next stage of human work PharmAust will reformulate the drug into capsules, as the main challenge faced in both canine and human trials with liquid PPL-1 was the poor palatability of the formulation and nausea from the unpleasant taste".

The key activities moving forward following completion of first human and canine trials, are planned to be:

Human:

- Completion of further supportive preclinical studies to enable combination therapy with "Standard of Care" in a Phase II study;
- Preparation and submission of the clinical trial report to PharmAust by service providers CMAX Ltd and CPR Ltd;
- Preparation of a new clinical trial application for the ethics committee of the Royal Adelaide Hospital and other centres that may wish to participate in the Phase II trial (currently under discussion);
- Initiate discussions for licensing of the human cancer applications of PPL-1; and
- Agreement of commercialisation strategy relating to joint patents with a major Japanese group.

Canine:

- Two canines have now received PPL-1 with "Standard of Care" chemotherapy with no observed adverse events;
- Canine recruitment will continue and the Company will continue reporting on the outcomes in canine patients; and
- The Company will determine the next stages with Option partner (top 5 pharmaceutical company) for the veterinary applications of PPL-1 and related molecules.

Dr Aston said "Aberrant expression of p70S6K is believed to contribute to aggressive features of cancer such as growth, invasion and metastasis. p70S6K levels in peripheral blood immune cells are expected to correlate with similar changes in the patient's cancer. Studies in peer review journals have shown that factors that increase Mammalian Target of Rapamycin (mTOR)/ p70S6K signalling lead to increased metastasis in human breast cancer cells. Similarly, activation of p70S6K has been shown to increase viability of colorectal cancer cells. Published evidence also suggests that some globally used anticancer drugs (Paclitaxel) may operate through inactivation of p70S6K."

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

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