

ASX Release

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FINAL PATIENT IN LOWEST DOSE COHORT DEMONSTRATES REDUCTION IN KEY TUMOUR MARKER

TREATMENT WITH PPL-1 DEMONSTRATES REDUCTION IN KEY TUMOUR MARKER p70S6K

PharmAust Limited ("PharmAust") (ASX: PAA & PAAO) is pleased to report that the third and final patient in the lowest dose cohort for the trial at the Royal Adelaide Hospital has been assessed for reduction in the blood marker, p70S6K, following treatment with PPL-1. The patient, suffering from lung cancer with metastases to the liver, brain and bone received PPL-1 for 28 days and demonstrated approximately a 50% reduction of p70S6K levels at both days 3 and 7 of treatment.

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.

Professor David Morris of the St George Hospital, Sydney said, "We have consistently observed that PPL-1 inhibits the p70S6K blood marker in patients with different cancers (6 out of 6 patients). The degree of inhibition has varied between 10% and 65% as compared to the levels of p70S6K in patient's blood before treatment with the drug (Day 1, pre-treatment). Although only three patients completed the 28-day treatment regimen, we have managed to determine the levels of p70S6K in a total of 6 patients who have received the drug for 3 days or more. Thus, despite the delays in completing the treatment of the first cohort due to patient withdrawals (unrelated to drug), we have managed to obtain p70S6K data from a larger group of patients giving higher statistical significance to the result ($p < 0.0005$ at day 3).

Professor Michael Brown, Principal Investigator of the study at the Royal Adelaide Hospital said, "The use of surrogate tumour markers in the diagnosis of cancer and assessment of progression is now ubiquitous in clinical oncology. Although many cancers have a specific "marker association", p70S6K appears to be a common indicator of malignancy. Typically, information on drug efficacy is hard to observe in phase I safety studies, particularly at the lowest doses being tested. The results so far indicate that PPL-1 is well tolerated at the lowest dose and it appears to be physiologically active in that it reduces a key indicator associated with malignancy."

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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