

ASX Release

15<sup>th</sup> April 2015

## APPROVAL OF DOSE ESCALATION OF PHARMAUST'S PPL-1 DRUG IN HUMAN CANCER TRIAL

*APPROVAL HAS BEEN RECEIVED FROM THE TRIAL SAFETY COMMITTEE AND THE ROYAL  
ADELAIDE HOSPITAL RESEARCH ETHICS COMMITTEE TO PROCEED  
TO A 5 TIMES HIGHER DOSE OF PPL-1*

**PharmAust Limited** ("PharmAust") (ASX: PAA & PAAO) is pleased to report that it has received approval from both the Trial Safety Committee and the Royal Adelaide Hospital Ethics Committee to escalate the dose of PPL-1 in cancer patients. This approval follows the completion of treatment of the lowest dose patient cohort (5mg/kg) during recent months.

The escalation in dose will be a 5-fold increase from the currently evaluated 5mg/kg to 25mg/kg in accordance with the protocol approved in 2014. Key considerations of the Trial Safety Committee were:

- The low and acceptable adverse event profile of PPL-1 at the lowest dose of drug (5mg/kg) and
- The demonstration of inhibitory activity on a key tumour marker.

A further observation of the Trial Safety Committee was in regard to the taste and palatability of PPL-1. It was noted that as the quantity of drug being consumed orally increases with escalating doses, there may be some challenges in patients tolerating the treatment due to the taste.

With the successful demonstration of meaningful cancer marker suppression by PPL-1 (announced on 24 March 2015), PharmAust will now commit to developing a tasteless capsule formulation of PPL-1 to facilitate higher doses in both the present and future trials.

PharmAust's Executive Chairman Dr Roger Aston said "This is an important milestone for the Company and we will continue to report to shareholders on key elements such as recruitment rate, safety and efficacy as measured by suppression of tumour markers (p70S6K)."

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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