

ASX Release

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## **Modification of Clinical Trial in Dogs for Treatment of Canine Cancers**

### ***Amendment of Protocol to Accelerate Recruitment and Shorten Treatment Periods***

**PharmAust Limited** (“PharmAust” or “the Company”) (ASX: PAA & PAAO) is pleased to announce that it has received approval from the Department of Primary Industries (NSW) to amend the current trial protocol for the treatment of cancer in dogs so that the treatment period is shortened to 7 days and the drug, PPL-1, is administered as a Soft-Gel capsule. The previous protocol implemented during 2014 required treatment of dogs for 28 days, which the owners found challenging, particularly as the dogs often had late stage cancers.

A further important factor in modifying the trial was the recent success by the Company in showing that a key tumour marker (p70S6K) was rapidly and meaningfully reduced in blood cells of human patients following treatment with PPL-1 after 3 days. This observation will now allow PharmAust to evaluate this marker in dogs without the necessity for protracted treatment periods.

Principal investigator and dog cancer specialist, Dr Angela Frimberger, based at Veterinary Oncology Consultants Pty Ltd and the Animal Referral Hospital in Homebush, NSW will now move to implement the new protocol. Dr Frimberger said “We’re very excited because this revision will allow us to fast-track development of this promising drug. The trial is aimed at primarily showing safety of this new anti-cancer drug in dogs and, secondly, demonstrating that PPL-1 is biologically active in the cancer setting. We know from PharmAust’s human trial that there were no adverse events in the low dosage cohort and that p70S6K was suppressed providing a platform for us to explore whether a similar positive outcome can be seen in canines”.

PharmAust will advise on the progress as soon as recruitment and dosing begins. To date, four dogs with untreatable progressive cancers (1 melanoma, 2 soft tissue sarcomas and 1 chemoresistant lymphoma) have received PPL-1 either as “liquid” or “soft-gel” formulation on a compassionate use basis without adverse events or toxicities.

The US companion pet market sales (est. 2011) are in the region of US\$14 billion whilst cancer therapies are estimated at \$550 million with a price point of around \$1,500 per treatment.

Executive Chairman Dr Roger Aston said, “As PPL-1 is already approved for veterinary use by PharmAust’s partner, a major global corporation in the Animal Health Industry, we believe that if successful in this trial, PPL-1 will be able to be approved quickly for the treatment of dog cancers following a further pivotal study”.

**\*References:**

2011-2012 National Pet Owners Survey Gabelli & Company, Inc. 2004. The US Veterinary health market.

<http://www.vet-dc.com/25.html>

American pet products manufacturers association, Inc. 2011-2012 National pet owner’s survey

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