





ASX Release 1st December 2014

## Lowest Dosing Cohort with PPL-1 in Dogs Fully Recruited

**PharmAust Limited** ("PharmAust" or "the Company")) (ASX: PAA & PAAO) is pleased to announce that the Animal Referral Hospital (ARH) in Homebush NSW, with Principal Investigator Dr Angela Frimberger, confirm that three dogs suffering from different cancers have now been recruited for treatment with PPL-1 at the lowest dose of the drug. The completion of dosing for this group of dogs will be on the 23<sup>rd</sup> December 2014 and the Company will subsequently report on the safety and performance at the lowest dose of PPL-1 in canines.

This work was made possible by the successful reformulation of PPL-1 into "soft-gel" capsules during 2014 to improve palatability for dogs. Comparative performance of PPL-1 as free solution and in capsule formulation was evaluated in four dogs compassionately during 2014. Treatment of canine patients with higher dosing levels of PPL-1 will take place following a safe and satisfactory outcome of the lowest dose of PPL-1.

The trial evaluates the drug PPL-1, which has shown promising anti-cancer results in vitro and in mice. Previous safety studies in dogs have shown the drug is extremely well tolerated. The trial has been approved by the Director General's Animal Care and Ethics Committee for the treatment of dogs with soft tissue sarcomas, melanomas, and lymphomas, using PPL-1 in a "soft-gel" capsule.

The trial will test the safety and efficacy of PPL-1 in a phase I/II design. Once enrolled, dogs will receive baseline staging tests and then be treated with the drug by mouth daily by their owners at home, and will return to the ARH for rechecks to evaluate safety and efficacy. Groups of dogs will be administered higher doses only after safety and efficacy of the lower dose has been established. Tumour size will be measured before and after treatment using callipers and CT (X-ray computed tomography) scan.

"The US pet market is substantial with approximately 77.5 million pet dogs and 93.6 million pet cats\* It is estimated that 60 percent of dogs over the age of 6 develop some form of cancer, according to Petplan Pet Insurance's claims.

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. As PPL-1 is already approved for veterinary use by PharmAust's partner, a top player 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. <a href="http://www.vet-dc.com/25.html">http://www.vet-dc.com/25.html</a>

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

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