

ASX Release

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## First Two Patients in Clinical Trial for Canine Cancer Begin Treatment

**PharmAust Limited** (“PharmAust” or “the Company”) (ASX: PAA & PAAO) is pleased to announce that it has now initiated its trial of PPL-1 in dogs for the treatment of canine cancers. Within the last week, two dogs have begun treatment with PPL-1 formulated in “soft-gel” capsules to determine the safety and efficacy of PPL-1 in various canine cancers.

Dr Angela Frimberger of the Animal Referral Hospital (ARH) in Homebush, NSW and Principal Investigator in the trial said, “The palatability issues of PPL-1 in dogs have largely been resolved by reformulation of PPL-1 into a tasteless, soft-gel capsule making administration to pets by their owners far more practicable. Following our call for accrual of canine patients, we are seeing good progress in patient recruitment.”

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

Pet dogs admitted in to the trial will be treated with the drug by their owners at their homes. To determine the safest and most effective dose, the trial design will incorporate incremental increases in drug dose to different groups of dogs. 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. PPL-1 is already approved and on sale for the treatment of parasitic helminthic infections of the gut in farm animals, as such an extensive database of manufacturing and safety information has been established by a third party global player in animal health business.

PharmAust’s Executive Chairman, Dr Roger Aston said, “The veterinary applications of PPL-1, particularly for dog cancers, is under a “Research and Option Agreement” with a global company marketing animal health products. The outcome of this trial will be an important milestone for PharmAust”.

“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.

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

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

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