

ASX Release

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Initiation of Clinical Trial in Dogs for the Treatment of Canine Cancers

PharmAust Limited (“PharmAust” or “the Company”) (ASX: PAA & PAAO) is pleased to announce that it is now ready to initiate its trial of PPL-1 in dogs for the treatment of canine cancers. Following the approval from the Director General’s Animal Care and Ethics Committee to commence the evaluation of PPL-1 in the treatment of canine cancers, the Company discovered that the palatability of PPL-1 in dogs was not suitable for home administration by the dog owner. As such, in collaboration with the principal investigator and dog cancer specialist, Dr Angela Frimberger, the Company has successfully developed a “soft-gel” capsule containing PPL-1 suitable for conducting the clinical trial in canines.

To date, four dogs with untreatable progressive cancers (1x melanoma, 2x soft tissue sarcomas and 1x chemo-resistant lymphoma) have received PPL-1 either as “liquid” or “soft-gel” formulation on a compassionate use basis. PharmAust is pleased to report that no adverse events or toxicities were observed although the unpleasant taste of the drug in “liquid form” did cause vomiting in some dogs. Pet owners found advantages in the use of the “soft-gel” capsules over “liquid formulation” in terms of quality of life, handling, treatment and palatability of the drug in the dogs.

PharmAust Limited in conjunction with Veterinary Oncology Consultants Pty Ltd at the Animal Referral Hospital in Homebush, NSW, will now conduct a clinical trial to test the anticancer drug PPL-1 in pet dogs with soft-gel capsules. The trial will test the safety and efficacy (Phase I/II) of PPL-1 for treating naturally occurring superficial soft tissue sarcomas, chemo resistant lymphomas and metastatic melanomas. 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.

PharmAust’s Executive Chairman, Dr Roger Aston said, “Although the delay on drug palatability in dogs was unavoidable, it has enabled the company to successfully develop a drug presentation of PPL-1 which is essentially tasteless making future trials easier to conduct. We look forward to reporting the outcome of the trial.”

“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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