

ASX Release

2nd October 2014

Clinical Trial in Dogs is now open for accrual

PharmAust Limited (“PharmAust” or “the Company”) (ASX: PAA & PAAO) is pleased to announce that following reformulation of PPL-1 into “soft-gel” capsules to improve palatability for dogs, the Animal Referral Hospital (ARH) in Homebush NSW, with Principal Investigator Dr Angela Frimberger, announced today initiation of accrual of canine patients. This announcement is intended to alert dog owners with pets diagnosed with cancer that the trial is open for recruitment.

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 dogs treated to date have shown no measurable adverse effects, which is very encouraging,” says Dr Angela Frimberger, veterinary oncologist and principal investigator. “We are starting treatments at a dose that we know from previous safety studies in healthy dogs should be well within a safe range for our more delicate cancer patients. What we need to do now is gradually increase the dose until we find the right dose for our patient dogs. Then the efficacy of the treatment can be more fully evaluated. We’re very excited to get this promising new trial underway for dogs with these cancers!”

PharmAust’s Executive Chairman, Dr Roger Aston said, “We are delighted that the trial is underway following the issues with the palatability of PPL-1, now that this issue is resolved we are hoping to see good progress in patient recruitment.”

“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 option 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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