

## Progress in Recruitment for Phase II Trial in Dogs

- The Animal Referral Hospital in Homebush, Sydney joins the trial and is now working with the University of Melbourne's U-Vet Werribee Animal Hospital (U-Vet).
- PharmAust expects four primary sites around Australia will recruit for this pivotal trial.
- Trial aims:
  - Validate the previous canine lymphoma trial results that showed MPL in liquid form was safe and significantly induced progression free survival, and
  - Evaluate the newly formulated MPL tablet for performance, palatability and ease of administration.
  - Recruit and treat canines with lymphoma for 28 days with an option for the owners and veterinary surgeons to continue treatment for up to 6 months.
- Interim announcement of progress and results expected by year end.

**4 November 2019 – Perth, Australia:** PharmAust Ltd (ASX:PAA), a clinical-stage oncology company, is pleased to announce recruitment guidance for its anti-cancer trial in dogs with treatment naïve B cell lymphoma.

Previously, PharmAust demonstrated that six of seven dogs with treatment-naïve B cell lymphoma achieved stable disease, or progression free survival, with reductions in tumour size following 14 consecutive days of gelatin encapsulated liquid monepantel treatment.

PharmAust is now repeating this study with the newly developed high dose and highly palatable GMP monepantel tablet formulation. As previously reported, dogs will be assessed at 14 and 28 days of treatment to compare tablet performance with the capsules used in the previous and successful Phase II trial as well as with already registered and marketed canine anti-cancer drugs. Respective dogs will then continue a long-term maintenance lower dose treatment following discussions between pet owners and veterinarians. PharmAust considers the drug will afford increasing success and value based upon achieving efficacy outcomes at 28 day, three month, six month and longer evaluation periods.

PharmAust reached agreement with U-Vet in Werribee, through the University of Melbourne's Department of Veterinary Clinical Sciences, to act as the trial manager. All inventory, including antibodies and blood collection tubes, have arrived on site. U-Vet acts in a hub-and-spoke system with surrounding veterinarians in the Melbourne area to recruit eligible dogs further afield for recruitment, referral and treatment at Werribee.

PharmAust and the University have now reached agreement with the Animal Referral Hospital in Homebush, Sydney, to establish a similar hub-and-spoke system within the Sydney area. All ethics and trial administrative documentation have been harmonised between sites, and recruitment will therefore now commence in Sydney. The Animal Referral Hospital in

Homebush conducted the previous trial using the gelatin encapsulated liquid capsules to successfully treat pet owners' dogs with cancer. PharmAust is delighted that the Animal Referral Hospital has chosen to participate in this second trial.

PharmAust and the University of Melbourne are planning to work with other centres that can establish their own hub-and-spoke systems with local veterinarians to facilitate recruitment.

Trial data release will occur when a clear and meaningful trend becomes apparent and this will depend upon dog recruitment rates across the participating sites. The total number of veterinary sites involved is therefore important. PharmAust anticipates an update to the market next month.

PharmAust's Chief Scientific Officer Dr Richard Mollard commented: "PharmAust is pleased to announce its preliminary guidance for trial recruitment and data release. PharmAust is looking forward to sharing the outcomes with shareholders as they become available."

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**About PharmAust (PAA):**

PAA is a clinical-stage company developing targeted cancer therapeutics for humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. PAA's subsidiary, Epichem, is a successful contract medicinal chemistry company that is forecasting \$4.2m revenues in FY2019/20.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a key driver of cancer. MPL has been evaluated in Phase 1 clinical trials in humans and dogs; was well tolerated and produced a significant reduction in key prognostic biomarkers. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as it advances the drug in Phase 2 clinical trials.

**About U-Vet:**

The University of Melbourne's U-Vet Werribee Animal Hospital is one of Australia's leading veterinary hospital facilities, based in Werribee. U-Vet offers complete animal care to the public including general practice (primary and preventative care, exotic pet care), a suite of specialist referral services, specialist support services, 24-hour emergency care and specialist referral equine services. The hospital also trains the next generation of veterinarians and veterinary specialists with the assistance of its academic staff, who are world leaders in clinical excellence and research.

**About University of Melbourne:**

Established in 1853, the University of Melbourne is a public-spirited institution that makes distinctive contributions to society in research, learning and teaching and engagement. It's consistently ranked among the leading universities in the world, with international rankings of world universities placing it as number 1 in Australia and number 32 in the world (Times Higher Education World University Rankings 2017-2018). The University's distinctive Melbourne experience helps graduates become well-rounded, thoughtful and skilled professionals – making a positive impact across the globe. Its research helps solve social, economic and environmental challenges the world is facing today and into the future.

**About the Animal Referral Hospital:**

ARH Homebush provides a 24 hour emergency service and referral services in surgery, internal medicine, diagnostic imaging, oncology, ophthalmology, behaviour, physiotherapy, dentistry and avian exotics. This is supported by a range of complimentary services including nursing, reception and intensive care.