Following Extension of Survival, PharmAust Prepares Phase 3 Trial in Dogs with B Cell Lymphoma

- PharmAust identifies optimum monepantel (MPL) drug plasma range for treatment of pet dogs with B cell lymphoma
- Retrospective data analysis of the phase 2 trial shows the combination of MPL + prednisolone more than doubling life expectancy of pet dogs compared with standard-of-care (prednisolone alone[2])
- With the prohibitive pricing of canine chemotherapy PharmAust believes that subject to phase 3 results, MPL could be commercially compelling
- PharmAust will seek input for the phase 3 trial from potential licensing partners
- Further benefit of the MPL combination treatment was pet owners reported very high quality of life for their dogs
- PharmAust is planning for additional phase 3 trial sites in New Zealand and the US

18 October 2021 – Perth, Australia: PharmAust Limited (ASX:PAA), a clinical-stage biotechnology company, is pleased to provide an update on its Phase 2b trial testing the anticancer activity of monepantel (MPL) in pet dogs with B-cell lymphoma.

To date, 24 pet dogs with treatment naïve B cell lymphoma have qualified for evaluation across the two trial programs. A further two pet dogs were admitted to the trial but were not evaluated due to incorrect dosing.

During the course of PharmAust's trial programs, pet dogs have been administered MPL as gelatin encapsulated liquid or as a tablet. MPL tablets have been administered at four doses. Based on this, PharmAust has calculated an optimum drug plasma range for anticancer activity and minimal side effects.

Of the seven pet dogs with drug plasma levels in the optimum range, six achieved stable disease and one had a partial response, with some tumours completely disappearing, as assessed by the administering veterinarians. Side effects were minimal or not detected. Below this optimal drug plasma range efficacy was suboptimal while above the range, some occasional weight loss was observed as a side effect.

Of the six pet dogs that achieved stable disease, five continued to take MPL after the trial in combination with prednisolone. To date, these five dogs have achieved much higher than expected mean and median survival times, at 125 and 138 days, respectively. This 138 day median survival compares favourably with a recently reported 60 day median survival for similar pet dogs treated only with standard-of-care prednisolone[1]. All pet dog owners reported very high quality of life for their pet dogs while taking MPL. A testimonial page has been added to the PAA website.

Trial Principal Investigator Kim Agnew stated, “We have made clear progress in a short timeframe in better understanding the monepantel/B-cell lymphoma dose/response relationship and now have clearer understanding of the effective plasma range required for monepantel as a mono-therapy. It is exciting to begin planning an extension of study sites outside of Australia to explore these findings in more detail. We are actively investigating options for sites in NZ and the US to broaden enrolments.”

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PharmAust's Chief Scientific Officer Dr Richard Mollard stated, "The trial data are becoming more interesting. Although this analysis examining the effects of combination with prednisolone is retrospective in nature, it enables the making of robust hypotheses and provides justification for their formal testing in Phase 3 studies. Quality of life may be the most important outcome for pet dogs as we do not know how pet dogs balance expectations of their quality of life with expectations of quantity of life. Extended overall survival time with good quality of life is the most important outcome for pet owners and veterinarians. PharmAust is pleased to proceed with development of monepantel while aiming to satisfy both of these outcome measures."

[1]. Rassnick et al., 2021 Survival time for dogs with previously untreated, peripheral nodal, intermediate- or large-cell lymphoma treated with prednisone alone: the Canine Lymphoma Steroid Only trial JAVMA 259(1): p62

[2]. Prednisalone is a steroid therapy that is often used to reduce inflammation from allergy or infection

This announcement is authorised by the Board

Enquiries:
Dr Roger Aston
Executive Chairman
rogeraston@pharmaust.com

Dr Richard Mollard
Chief Scientific Officer
rmollard@pharmaust.com

P +61 (8) 9202 6814
F +61 (8) 9467 6111
W www.pharmaust.com
T @PharmAust

About PharmAust (PAA):
PharmAust Limited is listed on the Australian Securities Exchange (code: PAA) and the Frankfurt Stock Exchange (code: ECQ). PAA is a clinical-stage company developing therapeutics for both humans and animals. The company specialises in repurposing marketed drugs lowering the risks and costs of development. These efforts are supported by PAA's subsidiary, Epichem, a highly successful contract medicinal chemistry company that generated $2.2 million in revenue in FY 2021.

PAA's lead drug candidate is monepantel (MPL), a novel, potent and safe inhibitor of the mTOR pathway – a pathway having key influences in cancer growth and neurodegenerative diseases. MPL has been evaluated in Phase 1 clinical trials in humans and Phase 2 clinical trials in dogs. MPL treatment was well-tolerated in humans, demonstrating preliminary evidence of anticancer activity. MPL demonstrated objective anticancer activity in dogs. PAA is uniquely positioned to commercialise MPL for treatment of human and veterinary cancers as well as neurodegenerative disease as it advances a reformulated version of this drug through Phase 1 and 2 clinical trials.

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