Update on PharmAust Canine Cancer Trials

HIGHLIGHTS:

- Ongoing results from canine cancer trials indicate that a combination of MPL and standard of care can more than double life expectancy of dogs. Further dosage refinements have potential to achieve further survival benefit
- US trials commenced and will treat up to 10 dogs according to FDA guidelines
- PharmAust is in confidential exploratory discussions with a leading global pharmaceutical company to co-develop and commercialise MPL for the treatment of veterinary cancers
- PharmAust will seek input for the canine cancer registration (Phase 3) trial from potential licensing partners
- New Zealand recruitment gathers momentum with five dogs successfully recruited

17 August 2022 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO), a clinical-stage biotechnology company, is pleased to provide this update on its canine cancer trials. Significant progress has occurred in the clinical trials of its primary drug candidate Monepantel (MPL).

Veterinary trial centres have been set up in Australia, New Zealand and the United States to evaluate the anti-cancer benefit of MPL in dogs newly diagnosed with B-cell lymphoma and have not received any previous cancer treatment. MPL is already approved for veterinary use for a different indication in food-chain animals. PharmAust is endeavouring to repurpose MPL as a safe and effective cancer treatment without the associated side effects of chemotherapy.

Following early Phase 2 success in Australia with MPL, and in preparation for registration trials, PharmAust is now also recruiting canine patients in New Zealand and expects the first enrolment in the US trial site this month. Five dogs have already been successfully recruited in New Zealand.

“During Phase 2a and Phase 2b trials Monepantel demonstrated effective anti-cancer activity and minimal side effects, which supports continued development into Phase 3 registration trials,” said Dr Kim Agnew, Principal Investigator of the trial.

“The commercial target is to develop and partner a product that supersedes the current standard of care (prednisolone) and provides a canine lymphoma treatment option that can be administered daily by the owner and enabling excellent quality of life for the dog during treatment.”

Commencement of US trial

Dr Meighan Daly DeHart and the medical oncology team at Pathway Vet Alliance dba as Thrive Pet Healthcare and Heart of Texas (HoT) Veterinary Specialty Center in the US have commenced screening and recruitment of pet dogs with B cell lymphoma trial. Heart of Texas will treat up to 10 dogs according to FDA pilot program guidelines.

This US expansion builds on PharmAust’s trial sites in Australia and New Zealand.

Dr Kim Agnew stated: “One aim of expanding the study sites is to accelerate the enrolment of case numbers required to enable PharmAust to close out the Phase 2 study as quickly as possible. The HoT and Pathways teams have been great to work with during the study planning phase and we are excited to bring Monepantel for canine lymphoma to the US for the first time.”

Status of current trial

Twenty-seven pet dogs have been treated using MPL monotherapy. With continued positive outcomes PharmAust is preparing for a successful Phase 2 completion and the commencement of a subsequent Phase 3 registration trial.

Of the 16 pet dogs with optimum blood levels, 13 have achieved stable target lesions. This includes one dog with a partial response (60% regression).

Nine of the 16 dogs with optimum blood levels have achieved stable disease by RECIST (Response Evaluation Criteria in Solid Tumours). Side effects were minimal or not detected.

PharmAust requires greater than or equal to 18 dogs with a clinical benefit out of 46 dogs to meet its statistical endpoint.

Dogs on MPL treatment enjoyed high quality of life

Post-trial, some veterinarians and the respective pet owners elected to continue the MPL treatment and, sometimes, in combination with prednisolone.

“The combination of MPL with prednisolone, which has provided average extension of survival to these pet dogs of 16-24 weeks, more than doubles the life expectancy than standard of care (palliative steroid therapy) that typically provides for 6-8-week survival in association with a range of adverse events. Pet dogs treated during and after the trial at this optimum level experienced a high quality of life with minimum adverse events,” said Dr Agnew

Commercialisation of MPL

PharmAust is in confidential discussions with a leading global pharmaceutical company to co-develop and commercialise MPL for the treatment of veterinary cancers. Dialogue with other potential partners are continuing.

Pet dogs in the MPL tablet Phase 2 trial enjoying time with their owners

This announcement is authorised by the Board

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About PharmAust Limited:

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 which generated $2.2 million in sales of goods & services 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.