PharmAust Canine Trial Update

20 December 2022 – Perth, Australia: PharmAust Limited (ASX: PAA & PAAO) ("PharmAust" or "the Company"), a clinical-stage biotechnology company, provides a clarification to the presentation released this morning. The statement of needing 8 more SD dogs from 22 new enrolments should read 8 more dogs from 18 more enrolments. The error was not including the 4 dogs pending plasma analysis into the calculations. The corrected presentation is attached.

This ASX release has been approved for release by the Board of Directors.

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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 $3.4 million in sales of goods & services in FY 2022.

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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CANINE TRIAL UPDATE

20TH DEC 2022

ASX: PAA

ACN 094 006 023

CANINE TRIAL ROADMAP

2015 - 2016 Phase 1 trial commenced in early 2015 and completed in 2016.Phase 2a commenced in 2016

MAY 2020 First Partial Response,at least a 30% decrease in the sum of the LD target lesions

JUL 2021 Stage 1 Bayesian design statistical outcomes met for both overall clinical benefit and overall response rate.

Significant as it showed anti cancer activity as a monotherapy

JUL 2021 15 dogs enrolled in study 0

AUG 2021 Retrospective analysis begins on dogs prescribed MPL/Pred after day 28.Crucial for commercial success viability

MAR 2022 Establish new study site in NZ

NOV 2022 37 dogs enrolled in study

AUG 2022 Establish new study site in US

DEC 2022 Second Partial Response,at least a 30% decrease in the sum of the LD target

Next steps:

- Completion of Phase 2b trial
- Licensing deal with Big Pharma
- Commencement of Phase 3 trial

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STATUS OF CURRENT TRIAL

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.

- PharmAust is recruiting pet dogs with untreated B cell lymphoma to finalise the Phase 2 evaluation of the drug MPL, which has demonstrated effective anti-cancer activity and minimal side effects.
- Thirty three dogs have been treated using MPL monotherapy (excluding the 4 dogs removed from the study) . With continued positive outcomes, PharmAust is preparing for a successful Phase 2 completion and the commencement of a subsequent Phase 3 registration trial.
- Two dogs have had a partial response (latest dog confirmed yesterday) as assessed by the administering veterinarians. Partial response is a decrease in tumour size (sum of longest diameter as defined by RECIST criteria) of >30%, no new lesions
- Side effects were minimal or not detected. In comparison, the most common side effects of a dog being treated with chemotherapy include gastrointestinal effects (vomiting, diarrhea or loss of appetite) and decreases in blood cell counts. Also, during chemotherapy, owners need to take precautions when handling their pets and their waste. Drugs may be excreted in the urine and faeces, so it is not advisable for children to play with their pets for the duration of therapy.
- PharmAust requires greater than or equal to 18 dogs with an overall clinical benefit out of 46 dogs to meet its statistical endpoint.

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SHORT TERM PRIORITIES

Expand the opportunities for collaboration for Phase 3 investment

Utilize in depth market and competitor research to build greater understanding of the potential new market segment that Monepantel use in B Cell lymphoma can deliver for pets/owners and veterinarians

Continue with the enrolment of dogs into the current Phase 2b study

- New enrolment in the US study site: 009-002, 8 yr Male Neuter Terrier mix;
- New enrolment in Brisbane – 005-008, 6 yr Male Neuter Staffy X

PET DOG PHASE 2 TRIAL: TREATMENT NAÏVE B CELL LYMPHOMA

CURRENT STATUS OF ENTIRE STUDY ENROLLED DOGS

(DAY 28 EVALUATION)

Study metric	# Dogs	Definition of data
# Dogs fully completed study	24	Fully completed - All study assessments complete, final grading confirmed PLUS blood testing for Monepantel completed. **Monepantel levels are in optimum range**
# Dogs partially completed study	4	Partially completed – All study assessments complete, final grading confirmed. Blood testing for Monepantel **NOT completed**
# Dogs fully completed study - suboptimal blood levels	5	All study assessments are complete, Final grading confirmed PLUS blood testing for Monepantel completed. Monepantel **levels in sub-optimum range**
# Dogs withdrawn from study	4	Dogs withdrawn from the study due to lack of compliance with study protocol (usually due to dosing dogs incorrectly or given therapy not allowed in protocol)
Total # dogs enrolled to date	37	

REQUIRE 8 OF A FURTHER 18 DOGS WITH SD AT D28 TO MEET BAYESIAN OUTCOMES FOR SUCCESSFUL PHASE 2 TRIAL

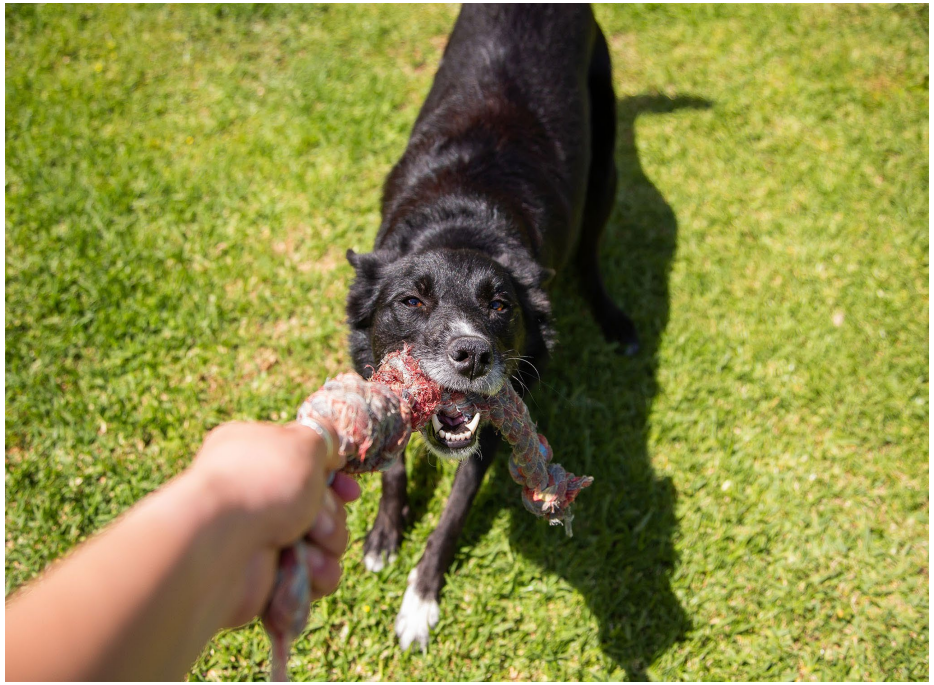
PET DOG PHASE 2 TRIAL: TREATMENT NAÏVE B CELL LYMPHOMA

RECIST OUTCOME FOR MONEPANTEL ALONE

(24 COMPLETED DOGS)

Total # dogs fully completed to date	#Dogs SD Target nodes	# Dogs SD VCOG RECIST*
24	17	10

REQUIRE 8 OF A FURTHER 18 DOGS WITH SD AT D28 TO MEET BAYESIAN OUTCOMES FOR SUCCESSFUL PHASE 2 TRIAL



MPL trial participant

*Dog - 002-005 – Partial response (PR) RECIST
*Dog – 003-001 – Partial response (PR) RECIST

**PR = a decrease in tumour size (sum of longest diameter as defined by RECIST criteria) of >30%, no new lesions

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PET DOG PHASE 2 TRIAL: TREATMENT NAÏVE B CELL LYMPHOMA EVALUATION DAY 28 VCOG RECIST VS OST (OVERALL SURVIVAL TIME)

DAY 28 – VCOG RECIST (SD)

Study #	# Days (Monepantel monotherapy)	#Days (OST- Overall Survival Time)	Day 28 VCOG RECIST
002-002	28	**177**	**SD**
004-006	106	**144**	**SD**
004-005	42	**77**	**SD**
002-004	63	**191**	**SD**
005-005	71	**182**	**SD**
008-001	30	**38**	**SD**

DAY 28 – VCOG RECIST (PD)

Study #	# Days (Monepantel monotherapy)	#Days (OST- Overall Survival Time)	Day 28 VCOG RECIST
005-002	43	**150**	**PD**
007-002	28	**191**	**PD**
005-006	32	**157**	**PD**
008-002	14	**28**	**PD**
005-007	32	**>168**	**PD**

MPL trial participant

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CANINE TREATMENT NAÏVE B CELL LYMPHOMA SUMMARY POINTS

- In dogs treated with Monepantel/Prednisone as ongoing therapy after Monepantel alone, PD outcomes at D28 do NOT appear to be associated with poorer clinical outcomes and/or shorter (OST - Overall survival times) over the life of the dog
- No matter the treatment protocol, most dogs with Lymphoma will die from Lymphoma
- Stabilisation (as opposed to regression) of lymphoma with good Quality of Life (QoL) is an excellent outcome

MPL trial participant

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PET DOG PHASE 2B TRIAL HYPOTHESIS: TREATMENT NAÏVE B CELL LYMPHOMA

The continuation of the Phase 2b prospective study will do two things:

- Continue to add data towards achieving the outcomes of the Bayesian design requirements of 18 SD outcomes out of 46 dogs with therapeutic plasma levels of monepantel

- Provide more dogs that can be considered for inclusion into an MPL/Prednisolone therapeutic program
  - If selected, this program is started post study and will be retrospectively assessed

MPL trial participant

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PET DOG PHASE 2B TRIAL HYPOTHESIS: TREATMENT NAÏVE B CELL LYMPHOMA

PROPOSED:

The continuation of the MPL/Prednisone program will allow more in-depth analysis of:

- Disease and Animal Factors potentially impacting OST outcomes
- QoL experienced by dogs during treatment
- The impacts of differing dose regimens of MPL/Prednisone on both OST and QoL outcomes

MPL trial participant

PET DOG PHASE 3 TRIAL HYPOTHESIS: TREATMENT NAÏVE B CELL LYMPHOMA

- Preliminary efficacy demonstrating anticancer activity in current Bayesian designed Phase 2 clinical trial
  - On track for successful Phase 2 completion
  - Optimum plasma drug levels very close to being finalised

- Median OST ~ 153 days in combination with prednisolone = 2.5 -3.0 fold extension c.f. prednisolone alone
- Sufficient data to plan Phase 3 registration trial: +pred/ + doxorubicin warranted

- Very safe drug
- Independent manufacturing capabilities
- High quality of life, minimal side effects
- Pet Owner testimonials on PharmAust website: https://www.pharmaust.com/veterinary-trial-testimonials/

MPL trial participant

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WILL MONEPANTEL ALLOW GP VETS TO GROW A NEW CANINE ONCOLOGY MARKET SEGMENT?

Therapy	Median OST (days)	Cost (USD)	Side effects	Vet Responsible
None	40 days	0	Reducing QoL	GP
Prednisone	58	100	PU/PD, Soiling in house, increased appetite	GP/Oncologist
CHOP	300-360	8,000-12,000	GI disturbance, no contact with family members for a period, reduced appetite, fatigue	Oncologist

Therapy	Median OST (days)	Cost (USD)	Side effects	Vet Responsible
Monepantel/ Prednisone	153	TBC	Owner surveys from 8 dogs indicate excellent QoL score feedback. Usual Prednisone side effects have not been reported (Requires larger dataset to confirm)	GP and/or oncologist

HOW DOES MONEPANTEL/PREDNISONE COMPARE TO NON-CHOP CANINE LYMPHOMA THERAPEUTIC OPTIONS?

Product Trade name	Active	Therapeutic target	Dosing	Survival metrics	Treatment side effects	User safety cautions	Commercial deal
Laverdia*	verdinexor	Canine lymphoma	Orally (2-3x/week)	Median TTP (29.5 days)	Anorexia, weight loss, GI upset, lethargy, elevated liver enzymes	No contact with pet body fluids for 3 days post treatment	Global licence for Laverdia *Total deal: $ US 64.5M Upfront: $US 19 M
Tanovea**	rabacfosidine	Canine lymphoma	IV (every 3 weeks)	Median PFS 134 days	Vomiting, diarrhoea, weight loss, anorexia, dermatopathy Grade 4 - neutropaenia	No contact with pet body fluids for 5 days post treatment	Development and commercialization agreement (Elanco /Vet DC) Value undisclosed
TBD	Monepantel/ Prednisone	Canine lymphoma	Oral (daily)	Median OST 150 days	Occasional Grade 1 weight loss and elevated liver enzymes	Keep out of reach of children.	

* Laverdia FOI, Dechra Pharmaceuticals PLC acquired Worldwide Rights to Verdinexor from Anivive Lifesciences, Inc. for $64.5 million. | MarketScreener

** Tanovea leaflet

PFS – Progression Free Survival
TTP - Time to progression
CR - Complete response
OST – Overall survival time

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TESTIMONIALS

Ruby is our 12-year-old, black and tan Cavalier King Charles Spaniel. She is just the sweetest, gentle girl.

We got Ruby as a mate for our other Cavalier, Lily. They were inseparable, bringing us so much joy and laughter. Besides loving food and sneaking off to steal some of our cat's dinner, Ruby just spends her time loving on everyone and snuggling up to me.

Ruby was diagnosed with B-cell lymphoma in June 2022 by our local vet at Chelmer Graceville Vets after my daughter Ella found lumps under Ruby's jaw. She had no other symptoms. This diagnosis was confirmed by Dr Kathleen O'Connell at Animal Referral Hospital (ARH) in Brisbane.

After our consultation and investigation with ARH, I was given two pages of possible treatments. Dr O'Connell discussed the possibility of the Monepantel (MPL) trial over the phone as I was home sick with Covid. I did some research about MPL and found Ryley and Chica's testimonials which made me feel more comfortable about the trial.

I decided to do the trial as I felt that with her age, pancreatitis issues and thyroid issues, chemotherapy would be too much for Ruby. The Monepantel trial would allow us to have longer with her and with good quality of life, which was very important to me.

So far, our experience on the trial has been very positive. We have been delighted to get an extra four months with Ruby. She still enjoys doing much of what she previously did, albeit a little slower, but she has no health issues since being on the trial and the team at ARH have been wonderful.

Each month that we pop in for her check-up we can't believe that another month has passed, and we still get to have her in our lives. I try and tell everyone about this trial because I think it is so valuable and is another option that is more cost effective for the average person.

Carrie, Brisbane

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TESTIMONIALS

Chica was a Black Kelpie born on a farming property in WA. She was a very active and very smart little dog with and incredible capacity to respond to your mood.

We got Chica when we were living in rural WA having returned from 5 years living in Peru where we had to leave our family dog. She was named Chica as it means little girl in Spanish.

We went to a farmer's market and our daughter's friend had a litter of puppies for sale. Chica was being pushed around in pram with a baby's bonnet on. We bought her for $25 and the farmer threw in a couple of bales of hay. He regretted that decision later when she turned out to be a very good herding dog.

Chica's favourite thing to do was to be by your feet in the paddock "helping" with whatever we were doing! She was diagnosed with lymphoma in April 2021 when I took her for a check-up as she had a small lump on her face and had been a little under the weather.

When she was diagnosed, we began looking for alternatives to chemotherapy. My vet had heard about the Monepantel trial and researched it for me before referring us to the Animal Referral Hospital in Brisbane, which was participating in the trial.

The trial was very straight-forward, clearly explained and did not require much from us in terms of input or reporting; just a simple diary and to give the medication (tablet) every second day.

Unfortunately, we had to have Chica put to sleep on October 10th. Until the last week she was almost completely normal, with occasional periods of quieter behaviour than unusual.

She was originally given 2 – 4 weeks to live and went on to have a great quality of life for nearly six months, so we are very grateful.

My advice to other pet owners is early detection and knowing what is and isn't normal for your dog is important. Diagnosing the lymphoma early gave us time to do something about it to slow it down.

The trial gave us an alternative to chemo (which wasn't an option for us), slowed the progression and gave us more time with Chica. We would really like to support the trial to continue as I really think it gave us a significant increase in time and quality of life for Chica. I'd love to see others have the same opportunity without the invasive treatment of chemo.

Gemma, Brisbane

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THANK YOU

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