



**PharmAust**  
L I M I T E D

# CANINE TRIAL UPDATE

10<sup>TH</sup> FEBRUARY 2023

**ASX: PAA**

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# PHASE II CANINE CANCER TRIALS

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 diagnosed with B-cell lymphoma and which have not received any treatment for the lymphoma.

Thirty five dogs have so far been treated using MPL monotherapy (excluding the 5 dogs removed from the study) and PharmAust has successfully demonstrated that MPL used on its own, provides statistically significant effective anti-cancer activity. Further recruitment of pet dogs with untreated B cell lymphoma will allow a successful Phase 2 evaluation to be completed and due to the successful outcomes of the Phase 2 study, PharmAust is preparing for the commencement of a subsequent Phase 3 registration trial.

**Two dogs have had a partial response** 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 pregnant women and children should not be assigned the duty to clean up urine and faeces 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.

PharmAust is pleased to provide a video recording of the fireside chat with Anusha Aubert and Dr Kim Agnew providing a further update on the canine trials - <https://www.pharmaust.com/fireside-chat-with-dr-kim/>



## LOUIE SURPASSES 220 DAYS ON MPL ONLY

And he is doing great!! Louie is a 12 year old male Beagle and upon his recent recheck where he appeared in great health, some key findings were:

- Louie is finding his 3 tablets/day easy to take and has not experienced side effects from the MPL
- It appears his lymphoma has stabilised as blood tests did not indicate any progression from the previous examination and his peripheral nodes have increased by only 2% since October 2022
- He is experiencing some progressive weight loss but his Quality of Life (QoL) remains excellent
- Louie was also PD at D28! This is further support that that REGARDLESS of whether a dog has achieved SD by day 28, dogs given MPL + prednisolone (or in Louie's case MPL on its own) after the 28 day trial period are all living 3 times longer than expected with good quality of life and no nasty side effects

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

CURRENT STATUS OF ENTIRE STUDY ENROLLED DOGS (DAY 28 EVALUATION)

REQUIRE 8 OF A FURTHER 22 DOGS WITH SD AT D28 TO MEET BAYESIAN OUTCOMES FOR SUCCESSFUL PHASE 2 TRIAL

Study metric	# Dogs	#Dogs SD (Stable Disease)		#Dogs PD (Progressive Disease)	#Dogs (Plasma analysis)	#Dogs (On trial)
		#Dogs PR (Partial Response)	#Dogs SD (Stable Disease)			
Fully completed	24	2	8	14		
Partially completed*	4				4	
On trial	2					2
<b>Total # dogs</b>	<b>30</b>	<b>10</b>		<b>14</b>	<b>4</b>	<b>2</b>

\*4 dogs partially completed and awaiting plasma analysis to confirm RECIST outcome.

\*4 partially completed dogs are counted as recruits

### Dogs not included

4 dogs removed from the study due to lack of compliance with tablet administration instructions

5 dogs with plasma MPLS < target level (5 uM)

1 dog removed from study due to death on Day 4

### RECIST DEFINITIONS

PR = > 30% tumour reduction

SD = <30 % tumour reduction and not >20% tumour increase



# SHORT TERM PRIORITIES

- 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
- Expand the opportunities for collaboration for Phase 3 investment collaboration
- Continue with the enrolment of dogs into the current Phase 2b study
  - Two new enrolments in the NSW study site: 002-006 4 yr Female spay Mastiff, 002-007, 6 yr Female spay Labrador



# PLASMA ANALYSIS – WHY DOES IT SEEM TO TAKE SO LONG?

This is a great example of how something that sounds so simple can seem to take forever! To try and explain:

- 1) Specialist couriers need to be contracted as Pharmaust has to ship all plasma samples in specifically controlled packaging containing dry ice and temperature data loggers. If samples thaw before arrival at the lab, the sample can be lost entirely!
- 2) Scheduling such specialised couriers in recent times has not been easy
- 3) Documentation and permits for transferring biological samples must be 100% accurate. Mistakes in the paper work can create shipping delays and these will increase the risks to maintaining the low temperature of the sample. Careful preparation takes time.
- 4) It is good laboratory practice and more economic to assess as many samples as possible during each assay “run”. This reduces the chance that variations in plasma MPL data are due to the assay rather than the dosing or the dog. On occasions, we will hold the date of the analysis until more samples are collected.

**It is a simple but lengthy process that if rushed can result in significant data loss to the study**

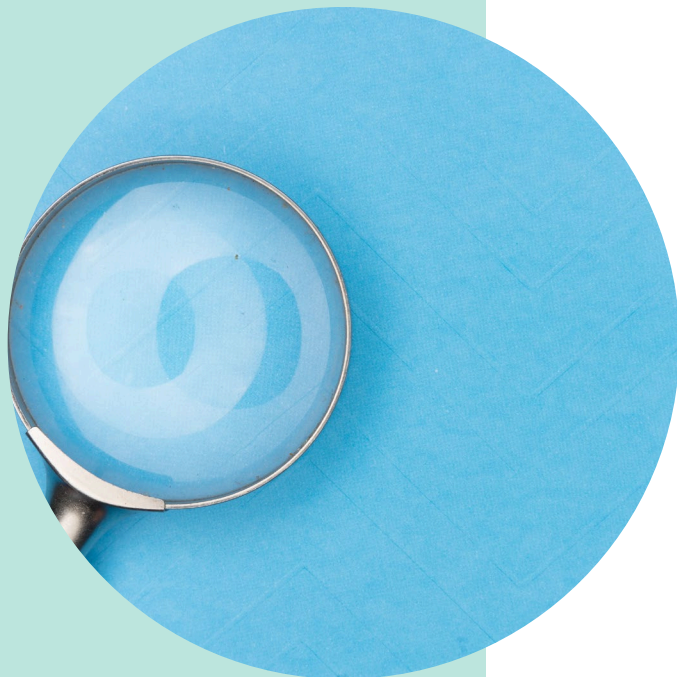


# NEW SITES

## Dr Renee Pigdon (pictured) located in Albury-Wodonga

- In July 2019, Dr Renee was awarded Albury-Wodonga Business Person of the year for her courage in business and her commitment to pets of the Border. Petfocus Vetcare was also awarded Excellence in Innovation for the new species segregated clinic and hospital on Wagga Road.

Dr Renee spends much of her spare time dedicated to further education and the needs of pets, even on her days off but also loves to spend time with her husband, seven children, five grandchildren, Scooter the dog, George the cat and a menagerie of chickens and cattle.



# OUTREACH PROGRAM TO ASSIST IN RECRUITMENT

## Ads in

- The Australian Veterinarian, Pet Life Magazine NZ, Your Pet Magazine

## Articles in

- The West Australian, The Border Mail, Stockhead, The Market Herald, Small Caps, Australian Dog Lover, K9 Online Mag, Pound Paws, Vetanswers, Pet Industry News, Animal Friendly Life, Pet Industry Association of Australia, 9Honey Pets, Petsforever, Border Collie Club of NSW, Companion Animal Network Australia, Bullmastiff Club of Queensland, Bullmastiff Club of Victoria

## Targeted emails to vets via

- Pets4Life, Vet Practice Magazine, Pet Industry News, Dogs NSW Weekly Woof, Australian Dog Lover Woof News, Vetanswers

Interview with Dr Sonya Yu from ARH Sydney on 2GB News

Fireside chat with Dr Kim Agnew

Dr Aston will attend the Animal Health, Nutrition and Technology Innovation Europe to be held in March 2023 in London.



## CANINE TREATMENT NAÏVE B CELL LYMPHOMA SUMMARY POINTS

- In dogs treated with Monepantel/Prednisolone 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 and recognised outcome accommodating treatments with MPL alone or in conjunction with prednisolone



MPL trial participant

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- 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 still an excellent outcome



MPL trial participant and friend

## 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

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

### PROPOSED:

The continuation of the MPL/Prednisolone 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/Prednisolone 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

## 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	

# TESTIMONIAL



Bella, MPL trial participant

Bella is aged six-and-a-half years and I have had her since she was a pup. She is family! Bella has a happy and friendly personality; her tail never stops wagging! She loves her food as well as getting her tummy scratched!

Towards the end of 2022, Bella was having a run on the beach when she tore the Anterior Cruciate Ligament in her back knee, and this was operated on at the start of November. As part of her rehab, I had to take her to the vet for check-ups.

It was at one of these check-ups that my local vet identified the lumps under her chin and behind her knees. She had bloods taken and sent away and they came back with the diagnosis of B cell Lymphoma. In hindsight, her knee injury meant that her lymphoma was diagnosed very early, and it also shows how quickly the cancer grows.

I was referred to a specialist who ran through my options for Bella which was primarily either do nothing and lose her in a couple of months or have chemotherapy and prolong her life for around 12 – 18 months. A lot of the discussion was centred around side effects from the drugs and how they would be managed with more drugs. Also, they would have to change the dosage of the chemo which would have an impact on the length of her survival.

The chemo would cost around \$20,000, it would not cure Bella and it would not be a pleasant experience for her. There were also precautions that we would have to take to ensure we weren't exposed to the chemo! All-in-all, not a great option.

I am a shareholder of PharmAust and have known about their Monepantel trial for dogs with B Cell Lymphoma. I informed the specialist that I would park the chemo option while I made enquiries about trying to get into the trial.

I live in Melbourne and the closest clinic that is participating in the trial is in Albury, some 400 km away. Dr Renee Pigdon is the doctor running the trial at this centre and she has been nothing short of amazing. She squeezed Bella into her busy schedule and so I drove Bella up to Albury at the end of January 2023.

Bella was accepted into the trial and away we went. So far Bella has had no side-effects from the Monepantel drug and her life goes on as normal. She still has a good appetite and loves her walks. I have changed her diet to one that is high in protein and low in carbohydrates. I have hit the Google machine and YouTube to get as much information as I can to do my best for Bella.

As much as the terminal diagnosis is extremely sad for our family, I'm glad that Bella can be a part of such an important trial that could benefit a lot of other dogs in the future.

It's one thing to be a shareholder of a company that is conducting a drug trial for canine lymphoma. But it takes on an entirely different meaning when my dog has lymphoma and her quality of life depends on this trial! I can't thank PharmAust enough for accepting Bella into the trial. I also thank Dr Pigdon for squeezing Bella into her busy schedule and for taking great care of her. **(Michael, Melbourne)**





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