

# CANINE TRIAL UPDATE



## Treatment for B-cell Lymphoma in dogs

13 JULY 2023

# CANINE CANCER TRIAL

Current options:

- Early euthanasia of the animal (usually within eight weeks from diagnosis)
- Chemotherapy (CHOP)
- AEs such as vomiting, diarrhea and restriction of pet contact due to toxicity
- Can cost upwards of \$12,000

## B-Cell Lymphoma **FEEDBACK FROM OWNERS**

Achieving stable disease for up to eight months with good quality of life is by far the best option for the pet dog as opposed to 9-12 months survival associated with five rounds of chemotherapy



# HIGHLIGHTS

- Phase 2 trial continues in canines with B-cell lymphoma in Australia, New Zealand and USA
- Two dogs have had a partial response (>30% decrease in cancer tumour) and ten others have enjoyed a stable disease response
- One patient (Louie – pictured) surpasses one year with stable disease and continued excellent Quality of Life (QoL)
- MPL/Prednisone extends survival three-fold, to a median of 150 days, while maintaining QoL
- MPL Phase 2 Trial expected to be completed Q1 FY24
- PharmAust's commercial strategy aimed at bridging the options of standard-of-care with chemotherapy is on target
- PharmAust in advanced confidential discussions with potential licensing partners for canine cancer



# RECRUITMENT ACTIVITY UPDATE

## Six new recruits in the previous two months

- Perth Veterinary Services – Two new recruits
- ARH Brisbane – One new recruit
- WAVES – One new recruit
- ARH Homebush – One new recruit
- Heart of Texas – One new recruit

## Additional Specialist Oncology expertise added to sites

- Dr Raelene Wouda (pictured) BVSc(Hons) DACVIM (Oncology) MANZCVS (Small Animal Medicine) BA(Hons)
- Recently joined VSS (Veterinary Specialist Services) Brisbane

## Additional USA study sites

- Additional study site in Austin, TX (Thrive)
- Dallas, TX site (Thrive) which has an experienced clinical study co-ordinator on site

New Australian sites actively being pursued



# ANALYTICAL UPDATE

- 9/11 assay results are received and RECIST outcomes determined. Post plasma analysis RECIST allocations of these dogs are outlined in table below.
- Notes
  - Dog 002-006\* was unable to be assayed due to sample identification issues. The plasma will be assayed at the next series of samples.
  - Dog 007-005 – Day 28 not reached before plasma assays conducted.

Dogs excluded	Allocated to PD	Previously allocated to PD	Allocated to SD	Previously allocated to PR/SD
Low MPLS plasma assay				
005-010**	005-007	005-008	004-008	002-005
009-002	005-011		002-007	
	009-001			

\*002-006 – Previously allocated to PD so plasma results wont change PD numbers unless MPLS < 4.5 uM  
 \*\*005-010 – Previously allocated to PD but MPLS plasma levels were 3.3 uM so was excluded from study.

- Due to recent enrolments, there will be 6 new plasma samples requiring assay. Plasma results from 8 dogs should be available end of August 2023.

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

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

REQUIRE 6 OF A FURTHER 7 DOGS WITH SD AT D28 TO MEET BAYESIAN OUTCOMES FOR SUCCESSFUL PHASE 2 TRIAL

Study outcome	Dogs with Monepantel blood results	Dogs without Monepantel blood results	Total # Dogs
Partial Response	2	0	12
Stable Disease	10	0	
Progressive Disease#	19	2+~	21
Completed but waiting for blood results before assignment		4~	4
On study		2	2
			39

NOTE: \* Maximum dogs to enrol is 46 (A further 7 dogs can be enrolled)  
 NOTE: + Dogs without blood results complete assigned to PD (x2) where the results will not change the stated outcome  
 NOTE: ~ 8 dogs will receive blood results by end Aug 2023. (This will include the 2 dogs currently on study)  
 NOTE: # Dog (005-001) moved into PD group due to change in accepted MPLS plasma concentration

**Dogs not included**  
 6 dogs removed from the study due to lack of compliance with tablet administration instruction  
 1 dog removed due to being T Cell lymphoma  
 1 dog removed due to death on Day 4  
 6 dogs with plasma MPLS < target level (4.5 uM)

**RECIST DEFINITIONS**  
 PR = > 30% tumour reduction  
 SD = <30 % tumour reduction and not >20% tumour increase

# DOES DAY 28 VCOG RECIST OUTCOME IMPACT OST (OVERALL SURVIVAL TIME)?

Off Study Retrospective Evaluation of MPL/Prednisolone post study treatments

## DAY 28 – VCOG RECIST (PR/SD)

Dog Study #	# Days (Monepantel monotherapy)	#Days (Monepantel/Prednisolone therapy)	#Days (OST- Overall Survival Time)	Day 28 VCOG RECIST
002-002	28	149	177	SD
004-006	106	38	144	SD
004-005	42	35	77	SD
002-004	63	128	191	SD
005-005	71	111	182	SD
008-001	30	8	38	SD
002-005	81	68	149	PR
002-007	63	14	77	SD
004-008	84	26	110	SD

## DAY 28 – VCOG RECIST (PD)

Dog Study #	# Days (Monepantel monotherapy)	#Days (Monepantel/Prednisolone therapy)	#Days (OST- Overall Survival Time)	Day 28 VCOG RECIST
005-002	43	107	150	PD
007-002	28	163	191	PD
005-006	32	125	157	PD
008-002	14	14	28	PD
008-003**	>375	NA	>375	PD
005-007	32	155	187	PD
005-008	14	9	23	PD
005-010	14	84	98	PD
005-011	28	30	58	PD
009-003*	28	18	>46	PD



MPL trial participant

# SUMMARY

## CURRENT DOG OUTCOMES



Dogs on trial - 2 dogs

- 004-009 - (WAVES enrolment)
- 002-009 - (ARH Homebush enrolment)

Dogs completed study – RECIST not allocated - waiting for plasma assays

- 007-006 – RECIST PD at Day 28
- 007-007 – RECIST SD at Day 28
- 007-005 – RECIST SD at Day 28
- 009-003 – RECIST PD at Day 28

Dogs completed study – RECIST allocated and waiting for plasma assays

- 002-006 – Allocated PD due to euthanasia D 23. Her plasma will be assayed but RECIST numbers wont change.
- 005-012 – RECIST PD at Day 19 due to hind limb oedema. Her plasma will be assayed but RECIST numbers wont change

Dog removed from study

- 002-008 – **Removed from study** as no plasma samples taken
- 007-008 – Typing indicated T Cell lymphoma





# POTENTIAL LICENCING PARTNERS

PharmAust in advanced confidential discussions with potential licensing partners for canine cancer.

A licensing deal would mark a significant commercial outcome and support funding for future clinical trials.

The Company wishes to clarify that the confidential negotiations are an incomplete proposal and negotiation and, although advancing, no conclusions can be drawn from the discussions at this time. This includes there being no certainty that a binding contract will result.

The negotiations to date are consistent with the Company's strategy of the licensing or sale of MPL's vet cancer applications following commercially valuable Phase 2 outcomes.

The Company will keep the market informed in the event of a material development from ongoing discussions.

Chemotherapy

Monepantel

Pregnant women/small children restricted access

4-6 months of intensive treatment

Significant side effects

Quality of life

Simple Daily oral tablet

Safe for pregnant women/small children

Normal family/Pet interactions

**Decision  
process of  
Chemotherapy  
vs  
Monepantel**

For more info visit  
[www.pharmaust.com](http://www.pharmaust.com)



**PharmAust**  
LIMITED

