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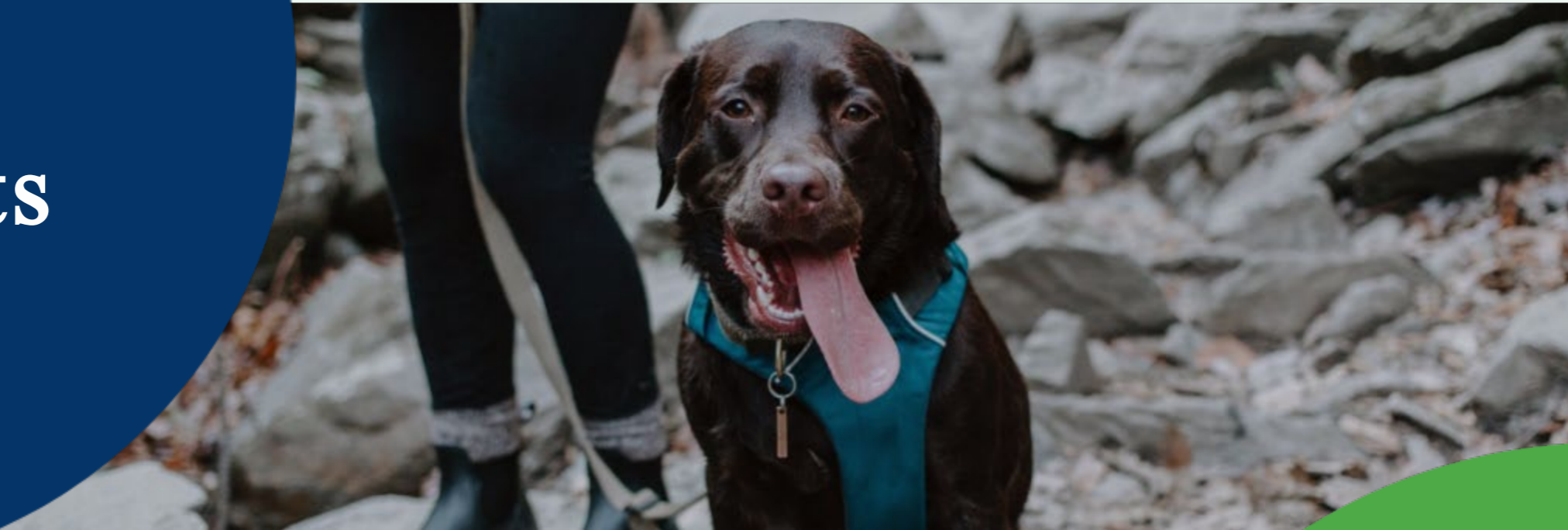
# PHARMAUST LIMITED

ASX : PAA

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# From sheep drench to the treatment of different types of cancers, viral & neurological diseases

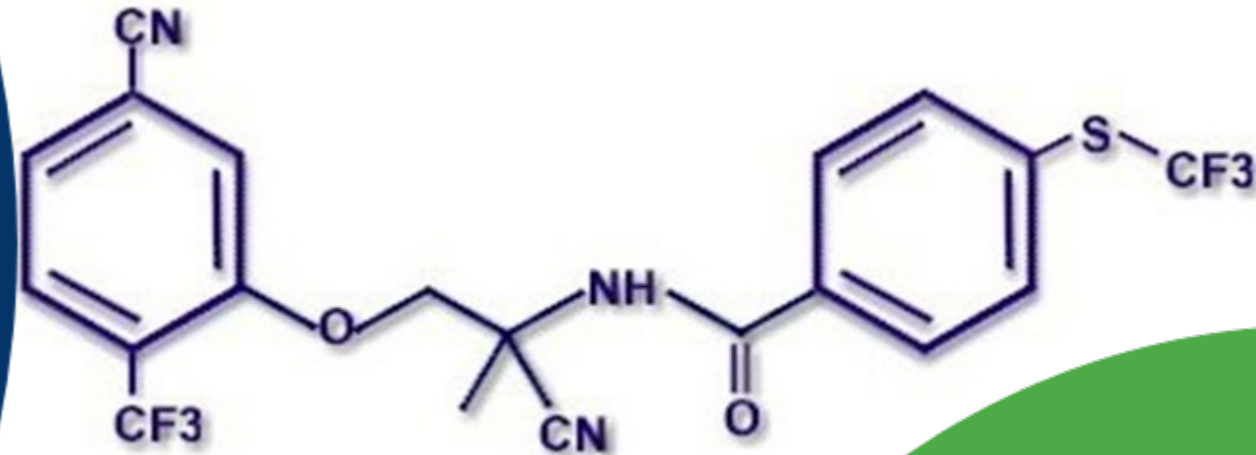




## Lead drug candidate

# Monepantel (MPL)

- Small molecule currently registered and marketed as a treatment for parasite infections in food chain animals
- A safe and potent modulator of the mTOR pathway which is central in metabolism and cell replication. Influencing cell metabolism is key to anti - cancer activity



MPL

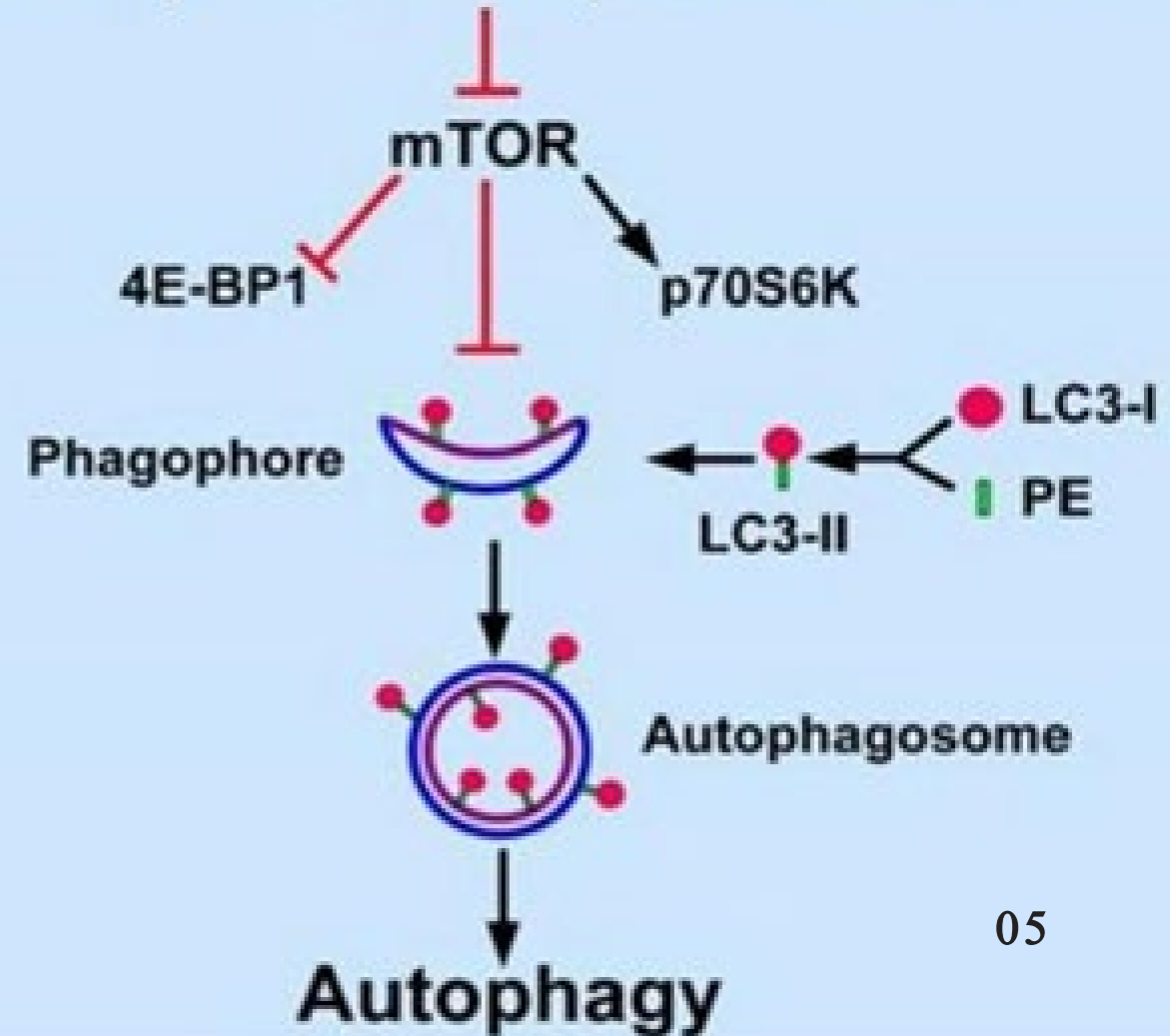
# mTOR Pathway

- mechanistic Target Of Rapamycin pathway, a key pathway influencing cancer growth and metabolism, neurodegenerative diseases and even viral activity
- Global mTOR inhibitor market now exceeds US\$2.5Bn annually



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## Monepantel/ Monepantel sulfone



# Lead drug candidate

## WHY MPL?

- Drug already registered in 38 countries & APVMA approved
- Substantial time and cost savings
- Very low toxicity provides a significant advantage over existing mTOR antagonists for the treatment of oncological and neurodegenerative diseases
- Crosses Blood-Brain barrier (MND)



**MPL**  
**CANINE**  
**CANCER**

# Treatment for B -cell Lymphoma in dogs



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





Prednisolone\*

Median Survival (60 days)

MPL + Prednisolone\*\*  
Excellent QoL

Median Survival 1147 days  
Range (28-191 days) with stable disease  
observed

Chemotherapy (CHOP)\*\*\*  
Typical Chemotherapy Side-Effects and \$10k+

Median Survival (345 days)

\*Rassnick et al, **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, JUL 1, Vol 259 No 1

\*\*PharmAust Internal data: Retrospective Cohort study Interim data

\*\*\* (From Vail DM. Hematopoietic tumors. In Ettinger SJ, Feldman EC, eds. *Textbook of Veterinary Internal Medicine*. 6th ed. St. Louis: Elsevier; 2005.)

CHOP

Monepantel

Quality of life

Simple Daily oral  
tablet

Safe for pregnant  
women/small children

Normal family/Pet  
interactions

Pregnant women/small  
children restricted access

4-6 months of  
intensive treatment

Potential for side  
effects

Decision  
process of  
CHOP  
vs Monepantel



## Results so far

### PIVOTAL 12MTH PERIOD

- In combination with MPL/prednisolone, it has provided an average extension of median survival of 21 weeks with excellent QoL



Now engaging with  
Global Veterinary  
Companies for Licensing



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

**MPL**  
**NEUROLOGICAL  
DISORDERS**

**Treatment for Motor  
Neurone Disease (MND)**



MPL

# WHAT IS MND?

- Group of progressive neurological disorders
- Attack the motor neurones that control skeletal muscle activity such as walking, breathing, speaking and swallowing
- As muscles are unable to receive signals, muscle weakness and wasting becomes widespread
- Diseases includes amyotrophic lateral sclerosis (ALS), progressive bulbar palsy, primary lateral sclerosis, progressive muscular atrophy, spinal muscular atrophy, Kennedy's disease and post polio syndrome



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# ALS/MND

addressable  
market is  
US\$3.6bn



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The first approved drug treatment, called Riluzole, became available in 1995 and is believed to extend survival by only 3-4 months, with many side effects. Despite this, Riluzole is already reaching ~US\$1Bn annual sales



# MPL

## FightMND

- Australia's largest MND charity, reviewed properties of MPL and its performance in cancer, and awarded PharmAust \$880,000 to clinically evaluate MPL in MND progression
- PharmAust expects that MPL will be an antagonist to mTOR and slow down the production of misfolded proteins and hence reduce localised inflammation and associated motor neuronal damage



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**FIGHT  
MND.  
IT TAKES PEOPLE**



# Results so far

## MND Trial Progressing

- In conjunction with Macquarie University, NSW & Calvary Health Care & Statewide Progressive Neurological Disease Service have treated the first cohort of six patients for a period of 28 days and elected to remain on treatment after the completion
- Cohort 2 has commenced screening and recruitment now that the Safety Committee for the trial has approved progression to the next dosing level
- Interim analysis on Cohort 2 completion to determine prognostic MND outcomes



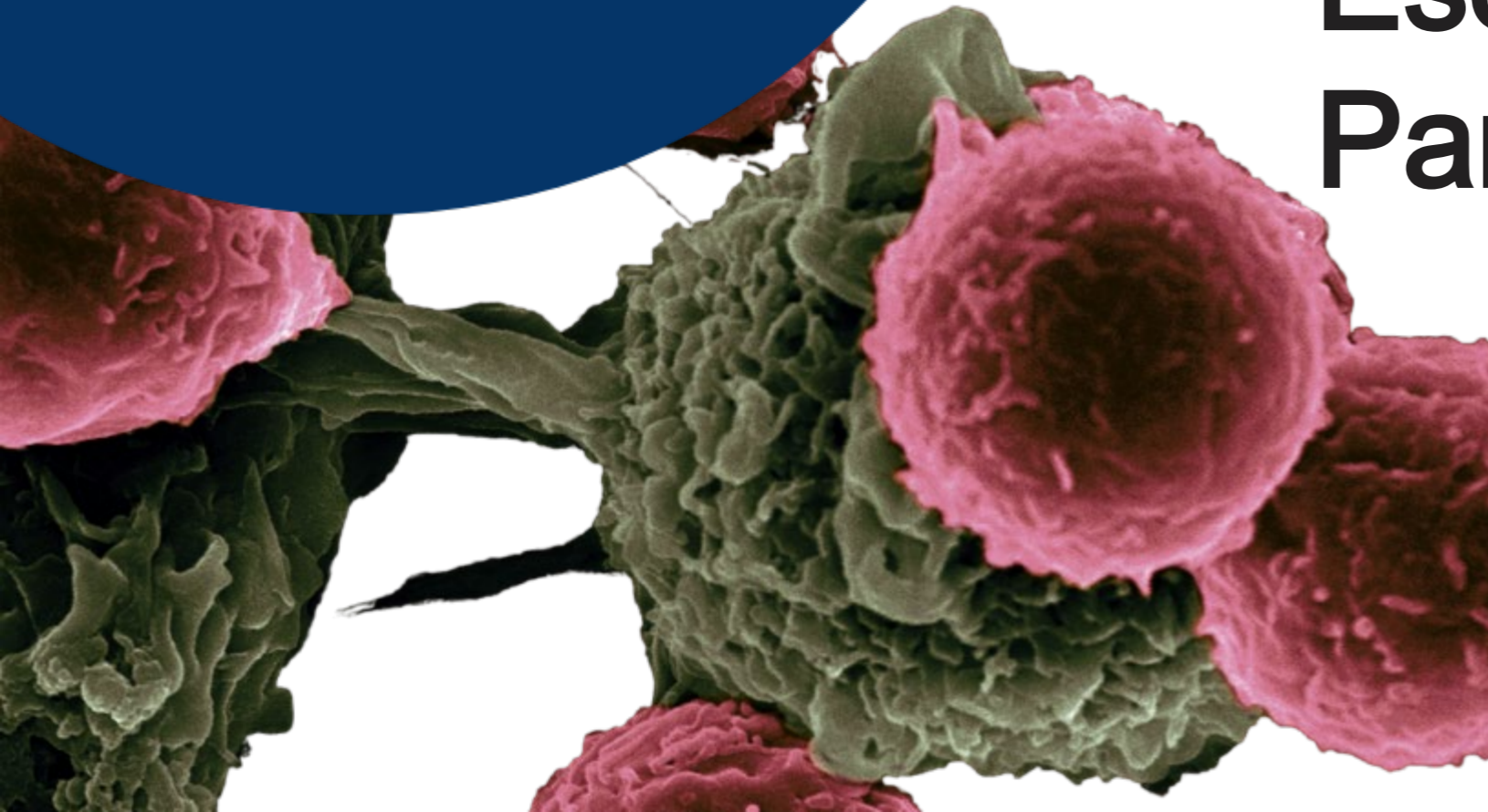
MPL

# HUMAN CANCERS



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## Glioblastoma, Esophageal & Pancreatic cancers



# MPL

## WHY CANCER?

- Strong data from the aggressive B -Cell Lymphoma cancer trial in canines suggests positive correlation/translation for targeting multiple cancers in humans
- During 2023 PharmAust will examine the value of MPL in at least one human cancer type
- A Principal Investigator identified in the US to evaluate the new MPL tablet in human Phase 2 cancer trials, as a follow on from the Phase 1 human clinical trial undertaken at the Royal Adelaide Hospital in 2015



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**CANCER**

# MULTIPLE AVENUES TO A US\$ 1BILLION+ SUCCESS

MPL's targeted cancer, MND and COVID-19 therapies all represent multiple \$1Bn+ addressable markets currently serviced by more toxic alternatives

# UPCOMING CATALYSTS

- Completion and results from fully funded Phase 1/2 - Human MND trial. Interim results may provide PK and PD data
- Initial safety & PK data from Phase 1 MND trials to fast track Phase 2 human anti-cancer and COVID-19 trials
- Phase 3 vet cancer trial commencement combined with prednisolone
- Corporate outcome targeted CY23 on the licensing or sale of MPL's vet cancer applications following commercially valuable Phase 2 outcomes

# Bo a r d o f Dire c t o r s



Dr Roger Aston  
Executive Chairman



Robert Bishop  
Executive Director



Neville Bassett AM  
Non-Executive Director



Sam Wright  
Finance Director

# Testimonials



Ryley is our 5-year-old Border Collie x Kelpie. She is friendly, energetic, loyal, obedient, intelligent and inquisitive. She got her name from the country town where she was born – Rylestone.

Ryley is our companion and the reason why we go for walks or runs, even when we don't feel like it. She loves chasing waves, playing tug of war with her fluffy and squeaky toys, chewing large bones and burying them around the yard, exploring hidden places and greeting everyone walking past our house by racing up and down the fence line.

Ryley was diagnosed with B-cell lymphoma in July 2021 by our local vet. My husband was giving Ryley a pat and noticed a few lumps on her neck. We had also heard her coughing a few times. When we took her to our vet at Burwood Road Veterinary Clinic, we never thought it was anything serious, as she never seemed unwell. She had her usual appetite and energy levels.

We were amazed when our vet said it was lymphoma and that her life expectancy was weeks to months. It was confronting to have that diagnosis. We didn't want to put her through anything drastic, which would make her more unwell and affect her quality of life. We felt that chemotherapy was not an option as life expectancy is still not much more than 1 year. Our main aim was to hopefully extend her life, but more importantly maintain her quality of life.

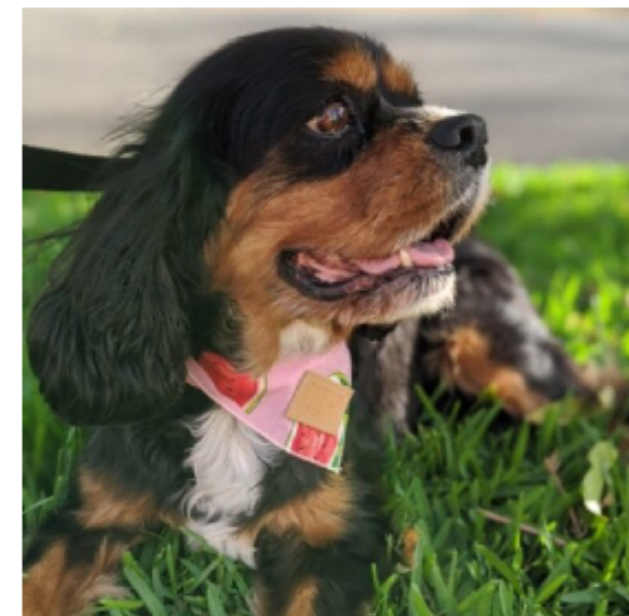
We immediately started researching clinical trials and found Dr Sonya Yu (Animal Referral Hospital), who is involved in the MPL Trial. I am a nurse with some experience in clinical trials, so I had a bit of an idea of what I thought would be a suitable trial. This trial guaranteed that she would actually be on the medication – not a placebo – and it didn't involve an excessive amount of invasive investigations and clinic visits.

The MPL trial has been a positive experience for us. Dr Sonya is fantastic and has been wonderfully supportive to Ryley and us. It's been easy to give Ryley two tablets a day and fortunately we live quite close to the Animal Referral Hospital, so it's been easy to take her for the visits.

Our GP vet was also supportive of the trial, and it felt reassuring to do something.

**Sharon, Sydney**





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**

Thank you

