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PHARMAUST LIMITED

ASX : PAA

ACN 094 006 023



- Costs
- Safety
- Toxicology
- New Patents

Pharmaceutical
Repurposing of
Monepantel

MPL mTOR

- Central regulator of metabolism and growth
- Several targets

Global view of PharmAust

- Halfway through Phase 1/2
- Calls for interim analysis

Motor Neurone
Disease (MND)

MPL almost
triples Median
Survival over
Standard of
Care

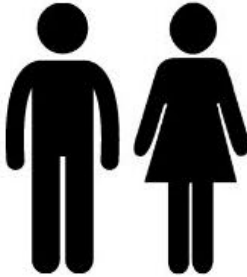






- B-Cell Lymphoma in canines
- Safe in human
- High QoL

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)



Compound	Discovery	Screening	Preclinical	Phase 1	Phase 2	Phase 3
 MPL	 Solid Tumors					
	 Motor Neurone Disease (MND)					
	 Viral Diseases					
	 Other Neurodegenerative diseases					
 MPL	 B-Cell Lymphoma					

MPL

WHAT IS MND?

- Group of progressive neurological disorders
- Attacks 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

MIND.

IT TAKES PEOPLE

Results so far

MND Trial Progressing

- All 12 patients for Cohorts 1 and 2 have been recruited
- Interim analysis recommended by the Principal Investigator – results expected in May
- First patient remains stable after 6 months on MPL
- In conjunction with Macquarie University, NSW & Calvary Health Care & Statewide Progressive Neurological Disease Service



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

TYPICAL SURVIVAL PERIODS

Prednisolone*

Median Survival (60 days)

MPL + Prednisolone**
Excellent Quality of Life

Median Survival 147 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.)

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

- ~6 million new cancer diagnoses are made in US dogs every year*
- 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

WHY HUMAN 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 . Sufficient tablets currently available

Abraxane market size to hit over **US\$11.16 billion** by **2030***

- Only adds 8 -12 weeks of survival time

* - <https://www.precedenceresearch.com/paclitaxel-injection-market#:~:text=According%20to%20Precedence%20Research%2C%20the,US%24%2011.16%20billion%20by%202030>

UPCOMING CATALYSTS

- Completion and results from fully funded Phase 1/2 - Human MND trial. Interim results expected in May
- Initial safety & PK data from Phase 1 MND trials to fast track Phase 2 human anti-cancer
- Phase 2 vet cancer trial to be completed mid 2023
- Phase 3 vet cancer trial commencement of MPL combined with prednisolone
- Corporate outcome targeted CY23 on the licensing or sale of MPL's vet cancer applications following commercially valuable Phase 2 outcomes

For more info visit
www.pharmaust.com



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