



PharmAust

L I M I T E D

PharmAust is a clinical-stage company developing novel targeted cancer, neurodegenerative and antiviral therapeutics for humans and cancer therapeutics for animals. The company specializes in repurposing marketed drugs lowering the risks and costs of development

ASX: PAA

ACN 094 006 023

PharmAust

Company Snapshot

Summary

ASX Code:	PAA
Market Cap at \$0.091	\$28.87M
Cash (June 2021)	3.02M
Debt	\$0k
Total Shares on Issue	317M
Options (Unlisted)	5.3M
Top 20 Own	37%
Board/Exec Own	9.3%

Share Price Movement



Monepantel (MPL) and mTOR

MPL from Sheep Drench to Anticancer, Anti-neurodegenerative and Antiviral Agent

~Repurposing

1. MPL: AChR - mTOR
2. Viagra: cardiovascular - men's health
3. Tamoxifen: contraceptive - anti-cancer
4. Exanatide: diabetes – weight loss

Anti-Wormicide: AChR



Rufener et al., 2013

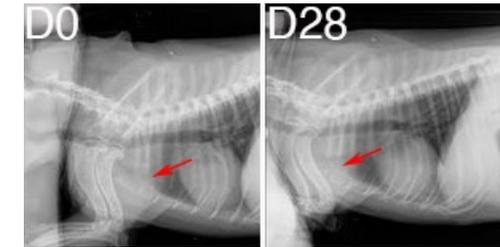


Easter Island: mTOR



Aurbina

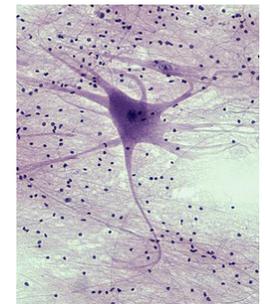
Anti-Cancer: dog and human



PharmAust

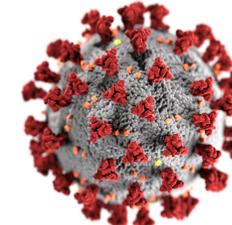


Anti-MND



Berkshire Community College

Anti-Covid19; Anti-HTLV1



Eckert and Higgins

PharmAust Patent Portfolio

Patents and Expiry

1. USE OF AMINOACETONITRILES (MPL) IN
CANCER
~2032

2. TREATMENT OF DISEASES WITH
AMINOACETONITRILES OPERATING THROUGH
mTOR PATHWAY
~2032

3. MPL IN COMBINATION WITH OTHER
CANCER DRUGS
~2034

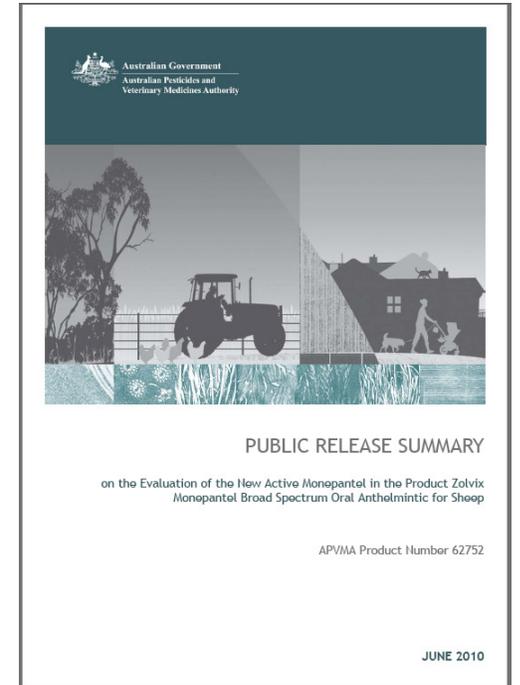
4. MPL ANALOGUES IN CANCER
~2034

5. MPL IN VIRAL DISEASE
COVID-19 and HTLV1
~2040

MPL composition of matter patent owned by major company expires in 2024 in most jurisdictions.

Dosage Form

From Sheep Drench to At-Home Tablet



Exceptional Safety Profile

Convenient at-home tablet

PharmAust: Canine Anticancer

Pet Dog Phase 2 Trial

Participant	Plasma Drug	Weight loss	Outcome Observer	Outcome Veterinary	How red?	Mpl Dose	
001-001	↑	Some to Minor			ambiguous	Adverse Events	
001-002					ambiguous		
001-003							
004-003							
007-001					clear		
004-002	↑	None			marginal	Optimal Dose and Outcome	
002-002							
003-001							
002-004							
004-006							
005-002							marginal
004-005							
005-001	↓	None or Not Determined			clear	Suboptimal Efficacy	
002-003					clear		
002-001					clear		
006-001					clear		
006-002					clear		

- Prednisolone alone = 4 to 6 weeks OST
- Post trial MPL + prednisolone, 4 of 6 dogs OST > 14 weeks
- High QOL indices
- CHOP alternative = 26 weeks @ \$10 000 and many side effects



Dogs on trial going camping and playing in the park

PharmAust: Motor Neurone Disease/ Fight MND

MND/ALS

Motor Neurone Disease

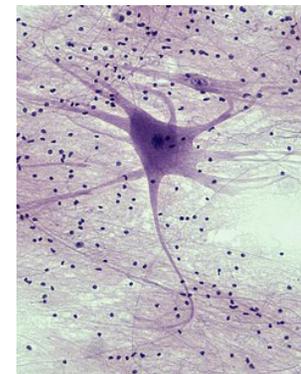
- Amyotrophic lateral sclerosis (ALS); Lou Gehrig's Disease
- Brain and spinal nerve stop working.
- Associated with “proteinopathy” or toxic protein build up in nerve cells.
- Life Expectancy 1-5 years
- About 1 in 400 people
- There are no cures

Preclinical Data

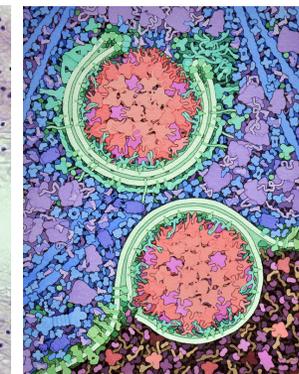
- Hypothesis: MPL induces autophagy to clear protein build up in nerve cells

FightMND

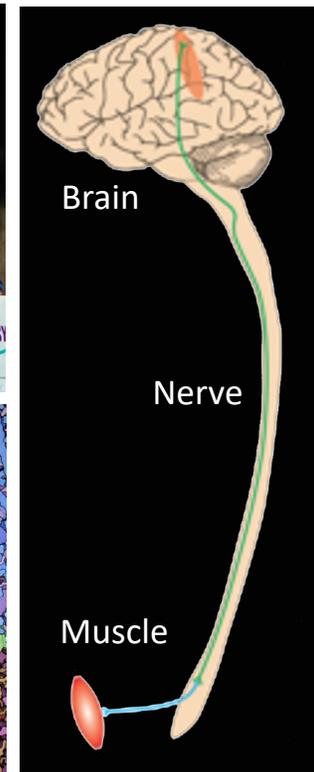
- AUD 881 085 funding for a Phase I/II clinical trial
 - Associate Professor Susan Mathers, Calvary Health Care Bethlehem, Melbourne
 - Professor Dominic Rowe, Macquarie University
- Commencing early next year



Berkshire Community College



David Goodsell, Cell, 2016



FightMND

PharmAust: Antiviral

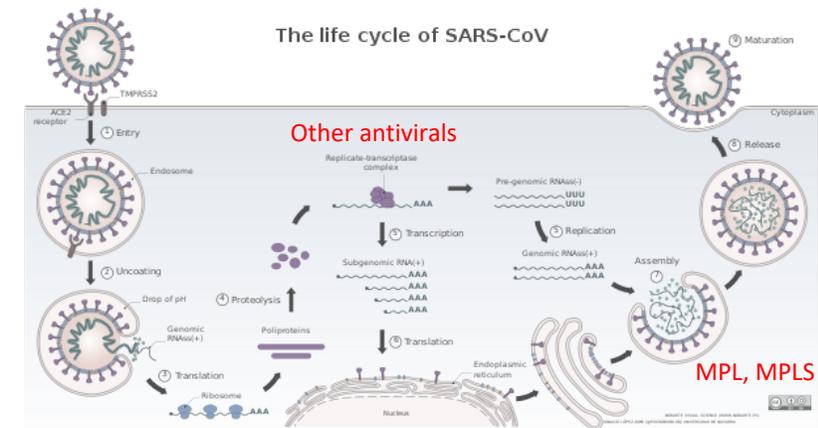
COVID-19/ HTLV-1

Preclinical Data: SARS-CoV2

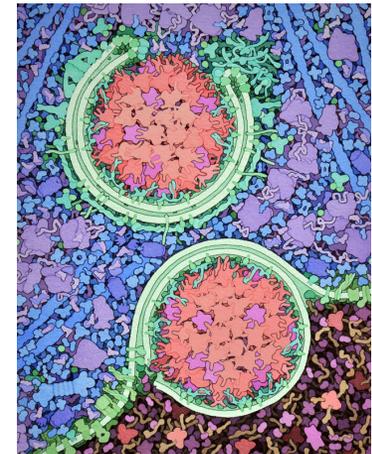
- Three laboratories: MPL and MPLS both protect against SARS-CoV2 induced cell death
- Two of two laboratories: MPL and MPLS reduce viral RNA in culture media
- Two of two laboratories (similar conditions): MPL and MPLS reduce viral secondary infection
- Very different conditions in third laboratory give no effect on secondary infection – good data for determining method of action
- Combined: secondary infection data suggest late-stage viral lifecycle inhibitor
- Consistent with hypothesis for autophagy-mediated mechanism
- Hypothesis: MPL competes to prevent hijacking of host autophagy machinery and permits virus destruction

HTLV-1

- Retrovirus – like HIV
- But makes blood cells divide like cancer
- 20 million people worldwide; certain Australian indigenous populations
- Very good preclinical models
- Hypothesis: MPL competes to prevent hijacking of host autophagy machinery and permits virus destruction while also exerting anticancer effects



NIAID



David Goodsell, Cell, 2016

Arsenio, Nature, 2020

PharmAust: Human Anticancer

Human Phase I, Moving to Phase II

Clinical Data: Phase I

- Treatment refractory progressing cancer patients
- Three of four Level 1 patients had stable disease by CT scans
- Three of four Level 1 patients had reduced mTOR (increased autophagy) markers
- 92% of adverse events were mild
- No myelosuppression (immune system still intact unlike chemo)
- Very good blood plasma drug data

Phase II: Set up

- Anticancer activity plasma levels from tablets in pet dogs
- Plasma levels from FightMND and Covid trials for tablet dosing
- Preclinical data shows very effective combination
- Physicians excited by combination: pancreatic, gastric and esophageal

Cancer Chemotherapy and Pharmacology
<https://doi.org/10.1007/s00280-020-04146-5>

ORIGINAL ARTICLE

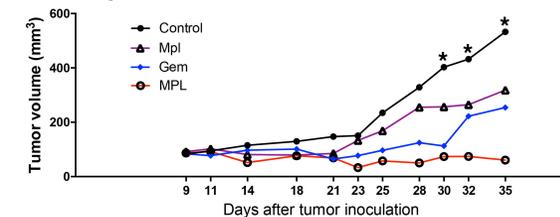
A preliminary assessment of oral monepantel's tolerability and pharmacokinetics in individuals with treatment-refractory solid tumors

Anna Mislav¹ · Richard Mollard^{2,3} · Gonzalo Tapia Rico^{1,8} · W. Douglas Fairlie^{4,5,6} · Erinna F. Lee^{4,5,6} · Tiffany J. Harris⁴ · Roger Aston² · Michael P. Brown^{1,7,8,9}

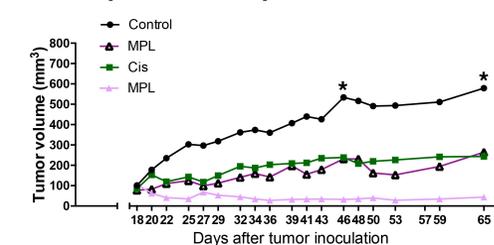
Received: 18 April 2020 / Accepted: 8 September 2020

© Springer-Verlag GmbH Germany, part of Springer Nature 2020

Monepantel + Gemcitabine: OVCAR3 Xenografts



Monepantel + Cisplatin: OVCAR3 Xenografts



PharmAust: Clinical Programs

Target Activity Timelines

	Sept 2021- March 2022	March 2022	April 2022	October 2022
Activity	Ongoing Pet Dog Cancer Trials	Phase 3 Pet Dog Cancer Trials	FightMND and COVID19 Human Trials	Human Cancer Trials
Indication	Lymphoma	Lymphoma	ALS/MND, SARS-CoV2 infections	Pancreatic, Gastric, Esophageal
Source	Existing Mpl; Existing Catalent tablets	Existing Mpl; New Syngene tablets	New Mpl; New Catalent tablets	New Mpl; New Syngene tablets
Trial Phase	Phase II/III	Phase III	Phase I/II	Phase I/II
Tablet No	~ 12 000	~ 25 000	~ 11 000	~ 25 000
Treatment	CHOP, pred and Mpl	e.g. CHOP, pred and Mpl	MND: Riluzole COVID: e.g. Remdesivir	e.g. Gemcitabine e.g. Platinum drugs
General Market size	US\$ 500M – 1000M	US\$ 500M – 1000M	MND: US\$ 1B COVID: US\$ 7.7B	US\$ 125B

EXPERIENCED BOARD AND EXECUTIVE

Dr Roger Aston, Executive Chairman & CEO

- > 35 years experience in the pharmaceutical & healthcare industries
- Director or chairman on a number of boards carrying out late-stage drug development
- Former CEO of Mayne Pharma Ltd

Robert Bishop, Executive Director

- > 35 years experience in corporate finance & equity capital markets
- Lawyer & investment banker

Sam Wright, Finance Director & Co Sec

- > 20 years experience in biotech & healthcare
- Extensive experience in relation to public company responsibilities, including ASX & ASIC compliance, corporate governance & statutory financial reporting

Neville Bassett, Non-Executive Director

- Member of the Order of Australia (AM)
- > 35 years working in accounting, finance & stockbroking
- Chairman of Westar Capital Ltd

Dr Richard Mollard, Chief Scientific Officer (CEO Pitney Pharmaceuticals)

- > 25 years national and international pharmaceutical and biotech
- CEO of subsidiary Pitney Pharmaceuticals Pty Limited
- Honorary Fellow, Faculty of Veterinary and Agricultural Science, University of Melbourne