

# PHARMAUST LTD

## AGM 2018

# REPURPOSING MPL FOR CANCER



# What is MPL (Monepantel)?

## **Monepantel is a small molecule that:**

- is readily distributed throughout the body
- has proven activity as a livestock healthcare product – to kill parasites invading the gut
- has been approved for such veterinary use in Australia, New Zealand, 27 European countries and Uruguay in South America.
- has a very good safety record following years of use in these food chain farm animals and in these countries

Novartis Animal Health  
Australian Regulatory Authorities Brochure



# What is MPL (Monepantel)?

## **Monepantel is a small molecule that:**

- has demonstrated good anticancer activity against many different cancer types in the laboratory setting
- has demonstrated early anticancer activity in pet dogs with cancer
- has demonstrated preliminary evidence of anticancer activity in humans
- has been successfully reformulated into a druggable form, changing from a farm product to a product suitable for use in dog and human patients with cancer in the clinic



# Companion Market is Changing Fast- Pets are Part of the Family

The Past



The Present



Owners and Insurance Policies Cover Pet costs running in 1000s dollars

# Development Strategy

1. **Demonstrate Value in Canines with global partner**
2. **Validate and commercialise in man**

## 1. Advantages of Dog Models in Cancer

Domesticated dogs (*Canis lupus familiaris*) are excellent models of human complex diseases for several reasons:

- Dogs generally develop similar cancers to humans
- Over \$40B (USD) is spent annually on dog health care, and is second only to humans in the level of health care received
- There are 65 million dogs and 32 million cats in the United States. Of these, roughly 6 million new cancer diagnoses are made in dogs and a similar number made in cats each year. See <http://ccr.nci.nih.gov>.

## 2. Advantages of Human Market

- Many cancers with unmet need
- Human anticancer market = \$155B (USD) by 2025

# PHASE II CANINE LYMPHOMA TRIAL





# PHASE II CANINE LYMPHOMA TRIAL



## **Seven dogs with B-Cell lymphoma**

- Open-label 14-day treatment, then proceed to conventional chemotherapy
- Different sized dogs: small and large
- Different dog breeds
- Six of seven dogs had smaller tumours and stable disease
- No remarkable adverse events
- Poor taste and low dose

# PHASE I HUMAN TRIAL

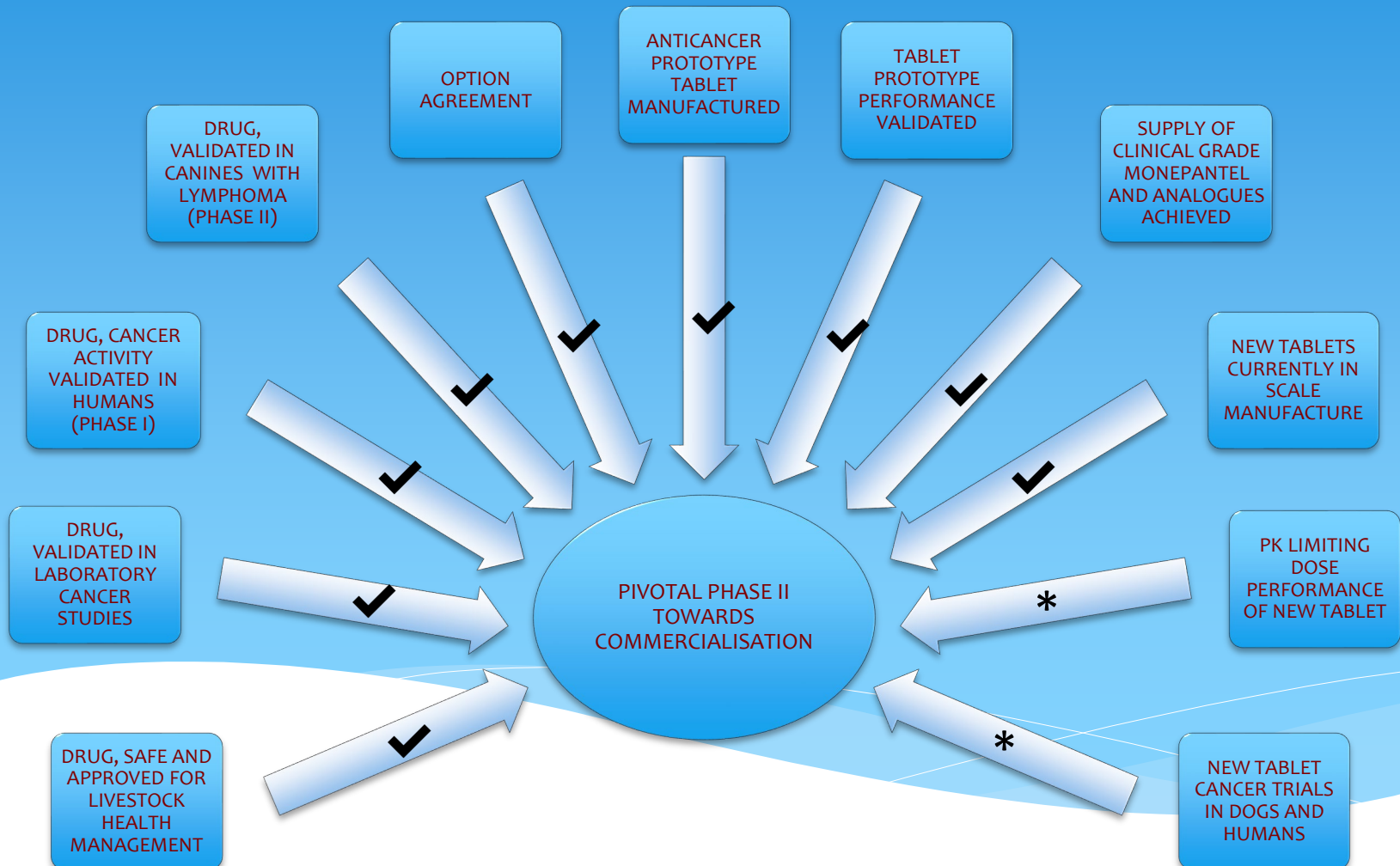
## **Four patients with different cancers**

- Failed conventional treatments
- Open-label 28-day treatment
- Three patients 28 days; one patient 14 days
- Three patients with stable tumour size
- All patients with reduced monepantel anticancer activity markers
- Safety margin permissible to higher dosing, but not completed due to poor taste





# STRONG FOUNDATIONS IN SAFETY AND EFFICACY OF MPL



# MPL COMMERCIALISATION

Q1/3 2018

NEW DRUG FORMAT (TABLET) DEVELOPED

Q3-Q4 2018

APPROVAL IN CANINES FOR LARGER TRIALS

Q2 2019

PHASE II IN CANINES - THE PIVOTAL TRIAL FOR MOVING FORWARD: CANCER CONTROL

SECOND HALF 2019

EXPAND INDICATIONS AND TREATMENT DURATION IN CANINE CANCER – DISEASE FREE INTERVAL AND LONG TERM SURVIVAL

MID 2019

POTENTIAL DATE FOR EXERCISE OF OPTION

MID 2019

RETURN TO HUMAN TRIALS FOLLOWING DATA FROM CANINES AND EXPLORE FAST TRACK REGISTRATION