

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

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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

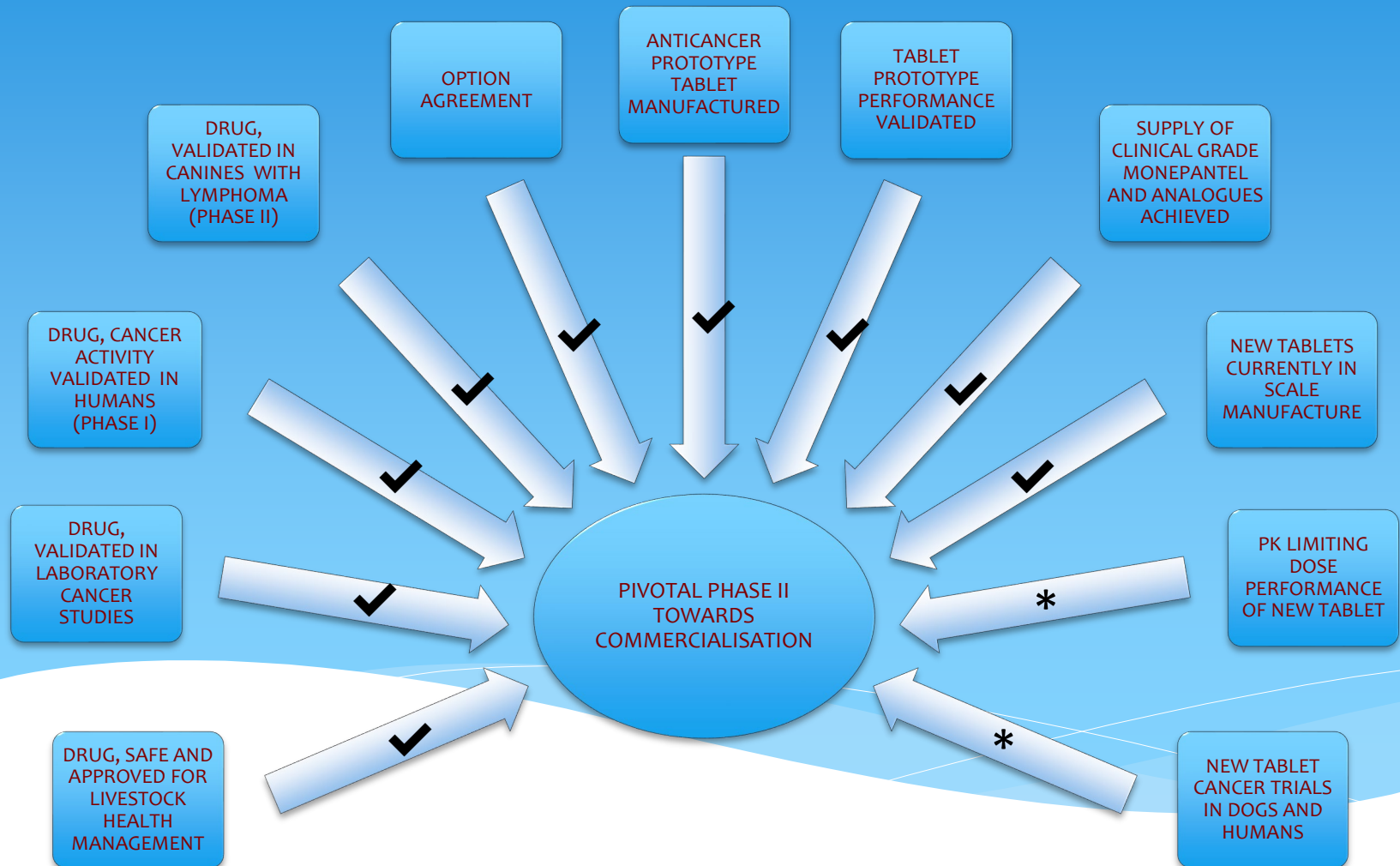
PHASE I HUMAN TRIAL

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