

Phase II Strategy Update

Phase II (Canine) in Progress with Phase II (MAN) in Preparation

PharmAust Limited (“PharmAust”) (ASX: PAA) is pleased to update on its clinical strategy in both man and canines.

As a drug already approved by regulators for the treatment of veterinary parasitic infections (Novartis Animal Health), monepantel (“MPL”) has undergone a substantive research, development and registration programme. The subsequent discovery by PharmAust that MPL has potent cancer suppressing activity in preclinical model systems has led to PharmAust targeting MPL for the treatment of both Veterinary and Human Cancers.

Having completed Phase I in both man and canines with a good safety profile and evidence of anticancer activity, we are now proceeding with an exploratory Phase II study in canines as a prelude to embarking on Phase II in man.

Our approach is driven by the fact that translation of new cancer treatments from pet dogs to humans is a lower risk strategy than initiating both human and canine trials simultaneously. Studies of pet animals with cancer are now increasingly “integrated ” into the development pathways for new cancer treatments. Cancers naturally occurring in dogs share many features with human cancer and more closely reflect what one might expect in man during a clinical evaluation.

Currently, two centres are participating in the canine Phase II (The University of Cambridge, Department of Veterinary Medicine in the UK and the Animal Referral Hospital in Homebush, NSW). Following recruitment and treatment of sufficient numbers of dogs (6-8) with MPL, we will report on the preliminary outcomes.

A key focus is on the effect of MPL on a range of cancers, including using MPL in conjunction with standard chemotherapy drugs, in order to identify the optimal combinations and the cancers most susceptible to treatment with MPL.

The intended timetable of events for our work on canines and in Man is as follows:

Q2 2017 - Evidence for tumour suppressive activity in canines	<ul style="list-style-type: none">• Tumour regression or• Stable disease
Q3 2017 - Seek Option Exercise by Novartis Animal Health	<ul style="list-style-type: none">• Canine anticancer market estimated at \$500M per annum
Q1 2017 - Reformulation of MPL into a dry powder in capsule for Phase II (MAN)	<ul style="list-style-type: none">• Minimises the number of capsules to be taken by patients• Better stability and ease of storage
Q3/Q4 - 2017 Initiate Phase II in Man	<ul style="list-style-type: none">• Centres to be identified in the US and Australia

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