

ASX ANNOUNCEMENT

EXOPHARM SECURES ETHICS APPROVAL FOR THE PLEXOVAL CLINICAL TRIAL

22nd July 2019

HIGHLIGHTS

- Melbourne Health Human Research Ethics Committee has approved the PLEXOVAL study to test the Plexaris™ exosome product in wound healing;
- A world-first study using cell free exosome product manufactured using Exopharm's LEAP Technology; and
- Validation of Exopharm as a clinical stage drug development company and global leader in its field.

Melbourne, Australia – Exopharm Limited (ASX:EX1, Exopharm or the 'Company') has received approval from Melbourne Health Human Research Ethics Committee to commence the PLEXOVAL wound healing study with its Plexaris™ product under the Australian Clinical Trials Notification (CTN) arrangement.

This first-in-human clinical trial will investigate autologous (from the same person) Plexaris (exosomes from blood platelets) administered once and will track participants over 42 days from dosing. Cohort 1 involves 15 participants and Cohort 2 involves 5 participants.

The PLEXOVAL study is a Prospective open-Label, single dose proof of concept study to Evaluate the safety, tolerability and biological activity of Platelet-derived Extracellular Vesicles, on the augmentation of wound healing and is defined as a Phase I study.

Plexaris is an experimental exosome product derived from human blood platelets and purified using Exopharm's own LEAP Technology.

The main readouts of the study will be safety, wound closure and scar formation.

Study site contracts, study initiation and then commencement of participant recruitment are next steps.

Dr Ian Dixon, Exopharm's Founder CEO and Managing Director said "This approval is the result of some outstanding work by our team, together with key support from our partners. Exosomes represent a new modality to treat a variety of conditions and the PLEXOVAL study will be a world-first to apply this type of product in a Phase I study looking at both safety and signs of efficacy."

Exopharm has transitioned from being a manufacturing R&D company into a clinical stage drug development company over the past 12 months. The Exopharm team now comprises experienced experts in all areas of the business; including manufacture, analytics, testing, intellectual property, partnering and experimental biology.

Dr Dixon said “This PLEXOVAL study is just one piece of our comprehensive development program – all aiming to deliver partnerships and licence transactions. Potential partners are interested in access to our LEAP Technology, engineered exosomes and uses of Plexaris and Exomeres for various other medical indications.”

Recent pre-clinical research from peer reviewed papers points to exosomes as a regenerative medicine being relevant to many health span related medical conditions including skin, liver, brain, vascular, cardiac, joints, bones and eyes.

Pending a successful completion of the first-in-human PLEXOVAL study, Exopharm anticipates a further study with allogeneic (unmatched) Plexaris product.

The PLEXOVAL study is a part of Exopharm’s strategy to demonstrate its capabilities in manufacturing, clinical testing and scientific review.

ENDS.

ABOUT EXOPHARM

Exopharm Limited (“Exopharm” or the “Company”) (ASX:EX1) is a clinical stage Australian regenerative medicine biopharmaceutical company seeking to develop and commercialise exosomes as therapeutic agents – initially a product called Plexaris™ and later a product called Exomeres™.

These products are exosomes that are derived from human platelets in relation to Plexaris, and adult stem cells in relation to Exomeres, and purified using the LEAP Technology and referred to as biologic products.

As its primary focus, Exopharm aims to be a leader in the field of human therapeutics using exosomes as regenerative medicine products for health span related conditions.

The Development Program: The Company’s main objectives for the next 12 months are to complete the following stages of its Development Program:

1. manufacturing - make and supply clinical grade autologous Plexaris product and development of the Exomere manufacturing process;
2. clinical use - initial small-scale human clinical studies of autologous Plexaris in wound healing;
3. supporting research and development activities - conducting research activities to support the ongoing Development Program and the development of related intellectual property; and
4. to also investigate other LEAP Technology Opportunities.

FORWARD LOOKING STATEMENTS

This announcement contains forward-looking statements which incorporate an element of uncertainty or risk, such as ‘intends’, ‘may’, ‘could’, ‘believes’, ‘estimates’, ‘targets’, ‘aims’, ‘plans’ or ‘expects’. These statements are based on an evaluation of current corporate estimates, economic and operating conditions, as well as assumptions regarding future events. These events are, as at the date of this announcement, expected to take place, but there cannot be any guarantee that such events will occur as anticipated or at all given that many of the events are outside of Exopharm’s control or subject to the success of the Development Program. Furthermore, the Company is subject to several risks as disclosed in the Prospectus dated 6 November 2018.