

## ASX ANNOUNCEMENT

### PLEXOVAL I study disrupted by the COVID-19 response

#### HIGHLIGHTS

- PLEXOVAL is a world-first study using a cell free, platelet-derived exosome product manufactured using Exopharm's proprietary LEAP Technology for wound healing
- COVID-19 has impacted the progress of Exopharm's PLEXOVAL I human trial and will likely reduce recruitment numbers
- Initial results from Cohort 2 may be available in the coming months
- Planning is underway for the follow-on study using allogeneic (off-the-shelf) Plexaris

1 April 2020

**Melbourne, Australia:** As announced in the Exopharm Limited (ASX:EX1) Shareholder update of 26 March, previous timeframes around the PLEXOVAL I wound healing study are not being met as progress has been affected by COVID-19 factors. These are outside of the control of Exopharm and its research partners.

At this stage it is not clear when or if the PLEXOVAL study will be completed. Exopharm now expects that the numbers of participants will be reduced, neither Cohorts 1 and 2 will fully recruit and the study report will be delayed.

As previously announced, dosing of Cohort 2 in the PLEXOVAL I Study commenced first. Cohort 2 testing is planned to include histology of biopsied post treatment wound tissue for assessment of biological activity within the healed wound. Results from the limited Cohort 2 testing may be available in the coming months.

Preparations are being made to run a separate follow-on study using allogeneic (off-the-shelf) Plexaris (Plexaris OS). Exopharm will now place an increased focus on preparations and approval of the proposed Plexaris OS allogeneic study.

For additional information on the PLEXOVAL Study see the ASX announcement dated 26 August 2019 with the study details.

By the Board - this announcement has been authorised for release by the board.

#### ***Company and Media Enquiries:***

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## **ABOUT EXOPHARM**

Exopharm Limited (ASX:EX1) is a clinical-stage Australian regenerative medicine company developing therapeutic exosome products as alternatives to stem-cell therapies.

Exosomes are small particles naturally produced by cells, which deliver therapeutic ‘cargoes’ to other cells to reduce inflammation and promote regeneration. Exosomes are plentiful in our youth but decline with age. Recent research points to exosomes as a way to extend the number of healthy, functional years (extending health span).

Exosomes secreted by stem cells could be used instead of stem-cell therapy with equal or greater benefit – and without the problems of stem-cell therapies. They could be used to deliver targeted ‘novel’ drugs and have potential as diagnostics.

While trillions of exosomes are produced by stem cells, the real challenge is to ‘purify’ them as drug products. Exopharm owns a purification technology called Ligand-based Exosome Affinity Purification (LEAP). LEAP technology and associated know-how places Exopharm at the forefront of this emerging field worldwide. Exopharm is at clinical stage with pending and current trials for wound healing, dry aged-related macular degeneration and osteoporosis.

Exopharm was founded in 2013 by Dr Ian Dixon, co-founder of the ASX-listed stem-cell therapy developer Cynata Therapeutics. He was also a director of Cell Therapies, which produced adult stem cells for ASX-listed stem cell company Mesoblast. Exopharm listed on the ASX in December 2018.

## **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.

## **INHERENT RISKS OF INVESTMENT IN BIOTECHNOLOGY COMPANIES**

There are a number of inherent risks associated with the development of biopharmaceutical products to a marketable stage. The lengthy clinical trial process is designed to assess the safety and efficacy of a drug prior to commercialisation and a significant proportion of drugs fail one or both of these criteria. Other risks include uncertainty of patent protection and proprietary rights, whether patent applications and issued patents will offer adequate protection to enable product development, the obtaining of necessary drug regulatory authority approvals and difficulties caused by the rapid advancements in technology. Companies such as Exopharm are dependent on the success of their research and development projects and on the ability to attract funding to support these activities. Investment in research and development projects cannot be assessed on the same fundamentals as trading and manufacturing enterprises. Therefore, investment in companies specialising in drug development must be regarded as highly speculative. Exopharm strongly recommends that professional investment advice be sought prior to such investments.