ASX Announcement

CORPORATE DIRECTORY

Non-Executive Chairman
MR JASON WATSON

Founder, Managing Director
DR IAN DIXON

Non-Executive Director
and Company Secretary
MR DAVID PARKER

CORPORATE INFORMATION

Issued Capital: 80.5m FPO

Share Price: $0.58

Market Cap: $46.7m

CONTACT DETAILS

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EXTENDING HEALTH SPAN THROUGH CELL FREE REGENERATIVE MEDICINE

5 FEBRUARY 2019

Positive outcomes in first animal study involving Plexaris and Exomeres

HIGHLIGHTS

- **Manufacturing of both Plexaris and Exomeres in house using the LEAP Technology was achieved and the exosome products demonstrated safety with no adverse events;**
- **Wound tissue tensile strength showed signs of a positive dose-response with Plexaris treatment, being the explorative primary efficacy outcome of the study; and**
- **Exopharm will now undertake further non-clinical studies in wound healing and other indications and progress preparations for first in human use of autologous Plexaris in wound healing.**

PILOT PLEXARIS AND EXOMERES STUDY

Exopharm Limited ('Exopharm' or the 'Company') is pleased to report on its early-stage proof of concept (POC) animal study that investigated the safety, efficacy and biochemistry of treating rodents with either Plexaris or Exomeres in a model of wound healing.

The main purpose of this study was to test the manufacturing using Exopharm's LEAP Technology and test the exosome products for safety and possible adverse events.

The key outcomes from this study are positive - i.e. manufacturing using LEAP Technology was achieved and the exosome products demonstrated safety with no adverse events.

This study was conducted for Exopharm by a Contract Research Organisation (CRO) as a paid study under Animal Ethics Committee oversight and in conformance with the Australian Code for the care and use of animals for scientific purposes. Plexaris and Exomeres were manufactured by Exopharm's manufacturing group in-house and were tested for sterility by an external party before release.

Attention is drawn to the following points:

1. This testing was the first time that sterile Plexaris (exosomes from Platelets) and Exomeres (exosomes from adult stem cells) have been manufactured and administered to animals.
2. Preparation for this testing has:
    - demonstrated the application of Exopharm's LEAP Technology to a biologic product for the first time; and
    - tried and tested the in-house upstream process (USP) and downstream process (DSP) developments, the suitability of equipment used in the USP and DSP, and Exopharm's ability to increase its manufacturing scale.
3. Both Plexaris and Exomeres were reported to be safe and there were no adverse reactions reported.
4. Administration of either Plexaris or Exomeres did not produce any significant adverse histological (i.e. microscopic biological) features in the samples assessed.
5. Despite the small scale of this present study, wound tissue tensile strength, an essential feature of wound healing and the explorative primary efficacy outcome measure of the study, showed signs of a positive dose-response with Plexaris treatment.
6. The study was designed as a pilot proof of concept study to inform future wound healing studies in both small and large animals to be conducted by Exopharm and CROs.

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Point 6. (cont) Only a total of 20 rats were involved (including two controls) and each dose group only contained 3 animals, so this study was not statistically powered to provide more than proof of concept outcomes.

Based upon these generally positive outcomes, Exopharm will now undertake further non-clinical testing of both Plexaris and Exomeres and accelerate preparations for its clinical trial using autologous Plexaris in wound healing.

Details of the Study

The study used a total of 20 rodents, including one rat that had treatment with formulation buffer alone (no exosomes) and one rat that had no treatment.

All animals were treated under Animal Ethics Committee oversight and in conformance with the Australian Code for the care and use of animals for scientific purposes. At the conclusion of the 7 day study the animals were euthanised. 7 days was chosen to allow histological analysis of resolving wounds. A longer future study will assess wound healing in more detail.

Treatments involved single dosing of three concentrations of the exosome product – either Plexaris or Exomeres - and a seven day period for incision healing. More details are anticipated to be published as part of a scientific publication at a later date.

Dosing was well tolerated at each of the concentration levels with no study mortalities or adverse effects detected.

This was not a maximum tolerated dose (MTD) study, and doses were calculated to be in a range that had been previously tested in in-vitro models in-house. Product was injected into the wound edge.

The results of the study will direct future wound healing studies in both small and large animals, with the aim to support our clinical programs which are planned for mid CY 2019.

Comments

This reports the first time that our Plexaris and Exomeres products have been made in sufficient quantity and quality (including sterility) for animal testing. Making these materials has demonstrated the LEAP Technology and the upstream and downstream process equipment and protocols used by the Exopharm team to make the Plexaris and Exomeres products.

This study has allowed us to look at the potential similarities and differences between the Plexaris (from platelets) and Exomeres (from adult stem cells). In the future we will consider which medical problems better suit Plexaris and which medical problems better suit treatment with Exomeres.

The report also highlights the safety and tolerability of the Plexaris and Exomeres products at all three concentrations tested – albeit that the total number of animals treated was only 18 in this study.

Exopharm's Managing Director & CEO, Ian Dixon commented:

"This study represents a significant step forward for Exopharm across a number of parts of our business. Although it is a very limited study, there are positive outcomes for Exopharm and it now opens the door to larger and more significant studies with our initial Plexaris product. The first in human clinical trial with Plexaris for wound healing is planned to begin in the first half of CY 2019."

"In this initial study we have shown that we can apply the LEAP Technology to a biologic product, that the product is safe and well-tolerated by animals when injected and that there are signs of a dose-response with Plexaris (but not Exomeres) in a critical parameter in wound healing being wound tensile strength."

"This study is a credit to the Exopharm team, whose dedication allowed us to get this study underway. Our decision in early 2018 to conduct manufacture and product analytics in-house has been rewarded."

ENDS.

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ABOUT EXOPHARM

Exopharm Limited ("Exopharm" or the "Company") (ASX:EX1) is an Australian regenerative medicine biopharmaceutical company seeking to develop and commercialise exosomes as therapeutic agents – initially a product called Plexaris™ and later as 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 clinical human therapeutics using exosomes as regenerative medicine products for heath span related conditions.

The Initial Development Program: The Company's main objectives for the next 12 months are to complete the following stages of its Development Program using the funds raised from the Prospectus Offer:

1. manufacturing - make and supply clinical grade autologous Plexaris product and development of the Exomere manufacturing process;
2. clinical use - completing animal studies, pre-clinical testing and 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.

Exopharm Limited is listed on the Australian Securities Exchange (ASX:EX1).

For more information please visit: exopharm.com or contact Dr Ian Dixon on (03) 9111 0026 or via email, info@exopharm.com.

FORWARD LOOKING STATEMENTS

Exopharm Limited ("Exopharm" or the "Company This announcement contain 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.