ASX ANNOUNCEMENT & MEDIA RELEASE

EXOPHARM MAKES FURTHER ADVANCES IN CLINICAL TRIALS AND RECEIVES $2.1M IN R&D REBATE

HIGHLIGHTS

- PLEXOVAL II – Exopharm's world-first Phase I study using a cell-free, allogeneic (unmatched) platelet-derived exosome product manufactured using Exopharm's proprietary LEAP technology is underway
- First human dosing for wound healing off-the-shelf Plexaris™ has occurred and enrolment is complete
- COVID-19 suspended PLEXOVAL I study now superseded and terminated
- R&D Tax Incentive for $2.1 million received

22 October 2020

Melbourne, Australia:

PLEXOVAL II study underway

Leading exosome medicine company Exopharm Limited (ASX:EX1) announces first dosing has occurred in the PLEXOVAL II Phase I study. This is Exopharm's second human clinical trial using extracellular vesicles (EVs) isolated from human platelets and further highlights Exopharm's leadership position in the exosome therapeutics field.

PLEXOVAL II is testing for safety and benefits in wound healing. Further participants are expected to soon follow in this study of up to 15 participants.

Exopharm is in a world leadership position in the EV medicine field – as the only company to initiate first dosing in two separate human trials. The first study (PLEXOVAL I) validated our process for manufacturing autologous Plexaris product.

PLEXOVAL II is a further advance using allogeneic off-the-shelf Plexaris manufactured using Exopharm's unique LEAP manufacturing process.

"EV medicines are new, not only for clinicians, but for regulators as well. We have a very clear, step-wise clinical pathway for validating our manufacturing and addressing any safety concerns of EV products," said Dr Angus Tester, Exopharm's Head of Product Evaluation. "With a successful outcome from PLEXOVAL II, Exopharm will be well-positioned to initiate Phase II studies with off-the-shelf Plexaris and Phase I studies with our mesenchymal stem cell EV product Cevaris™."

Plexaris is part of Exopharm's Naïve EV (NEV) program. NEVs show great promise as regenerative medicines across a range of age-related medical conditions including problems with mobility (e.g. osteoarthritis and tendinopathy) and sensory function (e.g. hearing loss and age-related macular degeneration).

Exopharm was granted Human Research Ethics Committee approval to commence the PLEXOVAL II wound healing study with Plexaris under the Australian Clinical Trials Notification (CTN) scheme in September 2020.

As announced on 1 April 2020, the PLEXOVAL I study was suspended due to COVID-19 restrictions. With the successful initiation of the more advanced PLEXOVAL II study with off-the-shelf product, Exopharm has decided to terminate further recruitment into the PLEXOVAL I study that relied upon autologous product.

"The world wants next-generation cell-free off-the-shelf regenerative medicine products to treat important age-related medical conditions. With PLEXOVAL II we are validating our manufacturing process and preparing for Phase II clinical trials," said Dr Ian Dixon, Chief Executive Officer.

"One exciting aspect of PLEXOVAL II was the manufacturing process. All doses were produced from a pool of donor platelets. As far as we know, this is the largest scale clinical grade manufacture of an EV product performed anywhere. It is further evidence of the manufacturing capability of Exopharm," said Alison Mew, Director of Manufacturing and Development at Exopharm.

PLEXOVAL II is a randomised, double blinded, placebo-controlled phase I clinical study designed to assess the safety and biological activity of Plexaris OS in wound healing following a skin punch biopsy in healthy volunteer adults. A Data Safety Monitoring Board (DSMB) for PLEXOVAL II is in place to review study data and to ensure the safety of subjects participating in the study. After reviewing the data summary for the sentinel (first) participant who was enrolled, treated and followed up to Day 7, the DSMB has recommended that the study continue.

PLEXOVAL II is fully enrolled with 15 participants and dosings are expected to continue in October and November. The readouts for the Phase I study will primarily be safety followed by wound healing activity (wound closure and scarring). Subject to successful recruitment and dosing, the study is on track to complete in CY 2020.

R&D Tax Incentive for $2.1 million received

Exopharm has received a cash refund (R&D Rebate) of $2,110,891 from the Australian Taxation Office under the Federal Government's Research and Development (R&D) Tax Incentive scheme. "This is a substantial increase on the previous year's refund and is indicative of the levels of innovation occurring at Exopharm," said Dr Chris Baldwin, Chief Commercial Officer. "With the R&D Rebate and the proceeds of the recent $10m capital raise coming in, Exopharm's cash position is now much improved and we see a runway through to the end of CY 2021 in our present budget."

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

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ABOUT EXOPHARM

Exopharm Limited (ASX:EX1) is a clinical-stage Australian exosome medicine company developing naive exosome products for regenerative medicine and engineered exosomes for new precision medicines.

Exosomes (or EVs) are small particles naturally produced by cells, which deliver therapeutic 'cargoes' to other cells to reduce inflammation and promote regeneration. EVs are plentiful in our youth but decline with age. Recent research points to naïve EV medicines as a way to extend the number of healthy, functional years. EVs secreted by stem cells could be used instead of stem-cell therapy with equal or greater benefit, without the problems associate with stem-cell therapies.

Engineered EVs (EEVs) are the most significant emerging technology for precision medicine. By altering proteins on the surface of EVs and adding custom cargoes such as RNA and small molecules, EEVs hold promise in a variety of untreatable diseases. This promise has led to a number of major development deals within the small community of EEV capable companies such as Exopharm.

While trillions of EVs are produced by stem cells, the technology has been hampered by the challenge of purifying EVs into 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, hearing loss and osteoporosis.

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.