

ASX ANNOUNCEMENT

Preclinical Data from Osteoarthritis Animal Study

HIGHLIGHTS

- Plexaris™ and Cevaris™ are safe and well tolerated following multiple (4 x weekly) dosing in rodents
- In conjunction with prior preclinical work, results from *in vivo* study direct product development to target mild-to-moderate stage osteoarthritis

1 April 2021, Melbourne, Australia: Exopharm Ltd (ASX:EX1) is delivering transformative medicines based on extracellular vesicles (EVs) including two naïve EV (NEV) products, Cevaris (a stem cell-derived EV product) and Plexaris (a platelet derived EV product).

An *in vitro* BioMAP study was conducted to investigate safety and function of Exopharm's Cevaris product. Cevaris was determined to be non-toxic at the tested concentrations supporting previous in-house non-clinical, *in vitro* results. Furthermore, Cevaris demonstrated immunomodulatory, tissue remodeling & inflammatory activities in addition to exhibiting proliferative effects in fibroblasts indicating utility in wound healing and related activities.

Following on from the PLEXOVAL II clinical study and validation of the safety profile of products manufactured using the LEAP technology, an *in vivo* animal study investigating induced osteoarthritis in the knee and treatment with the Cevaris and Plexaris products was conducted at Cellvax, an independent French CRO. The investigative study demonstrated the products to be well-tolerated by the animals with no toxicity, no adverse effects or knee swelling observed through to termination.

The study safety results were encouraging for future use of Cevaris and Plexaris. The initial test model, where the chemically induced OA caused a severe condition, was however not optimal for testing tissue regeneration. The model produced defects which in the human clinical setting would warrant knee replacement rather than medicinal treatment. This result points to a potential study in a mild to moderate OA model more reflective of the targeted indication in humans.

"Initially, we were surprised to see no beneficial effect of either Plexaris or Cevaris over control until we looked at the knee scans. We realised that in this testing, the knee joints were damaged beyond repair, with no obvious cartilage cells available to respond to the exosome treatment. To accurately evaluate the exosome efficacy, we will need to have a model that has a less severe joint damage as the baseline to gather meaningful efficacy data," said Dr Angus Tester, Head of Product Evaluation.

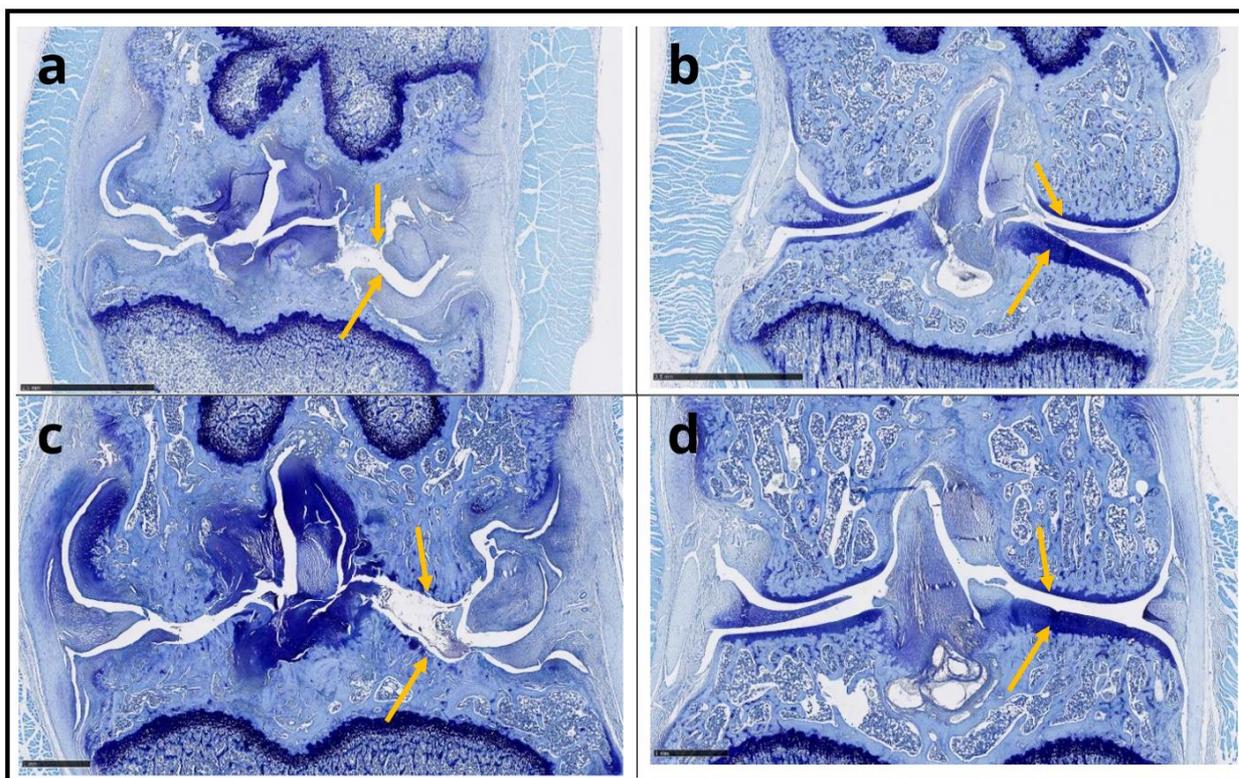


Figure 1. Example histological sections of rat knees from osteoarthritis study. Right knees with no induced OA (b, d) show normal, smooth meniscus surfaces, stained dark blue. In the left knees (a, c) the OA induction is so severe that the surfaces are destroyed, showing very little meniscus remaining and substantial bone involvement for both the placebo treated knee (a) and the Cevaris treated knee (c).

In summary, this study validated the international transport of Cevaris and Plexaris product, safety of the product and points to using less severe animal models of human OA to look for therapeutic effects.

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

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ABOUT EXOPHARM

Exopharm (ASX:EX1) is a clinical stage biopharmaceutical company using exosomes (extracellular vesicles (EVs)) from cells to generate a new class of transformative medicines.

Various Exopharm EV products harness the powerful natural ability of EVs to efficiently target cells and transfer selected materials into cells and across barriers. Exopharm has two exclusive proprietary technologies that extend the utility of EVs into engineered EV medicines (EEVs): the LOAD technology improves loading of nucleic medicines into EVs, and the EVPS technology allows EVs to be directed towards selected cell types. Exopharm uses combinations of LOAD and EVPS to develop a pipeline of EEV products aimed at treating a wide scope of medical problems including neurological diseases, infectious diseases, cancer, and fibrosis.

Exopharm's LEAP technology solves the challenge of purifying EVs at large scale. With LEAP, Exopharm is also developing naïve (or natural) EVs (NEVs) from adult stem cells and platelets as regenerative medicine products. NEVs have the potential to deliver the regenerative benefits of cells without the challenges of administering cells to patients. NEV products target a broad range of medical problems including osteoarthritis, autoimmune conditions, acute injury and chronic injury.

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.