

ASX ANNOUNCEMENT & MEDIA RELEASE

Cevaris testing shows positive results in models of erectile dysfunction

HIGHLIGHTS

- Exopharm is a world leader in the manufacture of exosome products. Its two core exosome products are Plexaris and Cevaris
- Exosomes have the potential to treat a range of medical conditions
- Independent testing by PELVIPHARM shows potency of Cevaris in models of erectile dysfunction and provides a basis for further testing and future potential clinical trials in post-operative erectile dysfunction

19 February 2020

Melbourne, Australia:

Independent testing of Exopharm's exosome Cevaris product in ex vivo models of erectile dysfunction (ED) has demonstrated that a Cevaris treatment provided statistically significant improvement in muscle contraction and release.

"These very positive results come from a leading independent commercial test group PELVIPHARM in France that tested two of our exosome products in erectile dysfunction – a problem facing many of us. What's most exciting for us is that Cevaris offers new hope for men who have tissue damage that prevents other medicines from working. Exopharm seeks to provide patients with new treatment alternatives," said Dr Ian Dixon, CEO of Exopharm.

ED is common among middle-aged and older men, and increases in prevalence with age. The condition affects a majority of men over 50, and current treatments provide considerable benefit to many. However, ED can also be the result of prostatectomy and rectal surgery, where localised tissue damage can prevent any benefit from existing treatments.

Unlike current treatments, Cevaris enhanced the nitrenergic relaxations of isolated corpus cavernosum strips compared to control substance with high statistical significance ($p < 0.01$). The cavernous smooth musculature is contracted when in the flaccid (non-erect) state, and smooth muscle relaxation is essential for an erectile response. This means Cevaris could restore erectile function. See figure 1. below.

These test results will be published in more detail at a later time.

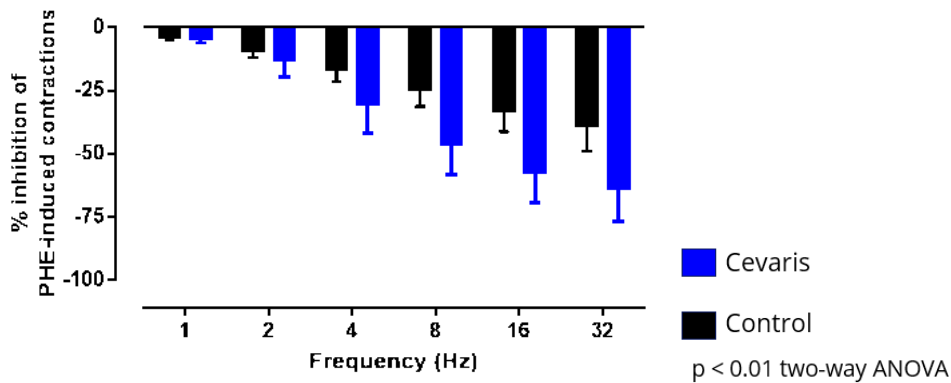


Figure 1. Enhancement of nitrergic relaxations of isolated corpus cavernosum strips.

Note: The test result is BLUE for treatment with Cevaris exosomes and BLACK is the control.

This testing provides a basis for further non-clinical testing of Exopharm’s products in erectile dysfunction. After that, human clinical trials involving patients with this problem are the next step.

“Exopharm is continuing a clinical approach that translates early exosome science into real and compelling results using our well-characterised exosome products. We expect this to open collaboration opportunities for Exopharm with pharmaceutical companies around the world,” said Dr Chris Baldwin, Chief Commercial Officer.

More details

PELVIPHARM is a leading scientific and medical preclinical testing contract research organisation (CRO) with expertise and experience in pathophysiology, pharmacology, clinical research and medical practice across a range of therapeutic areas including urology (including bladder control), sexual medicine (including erectile dysfunction [ED]) and cardiovascular <https://www.pelvipharma.com>.

Limitations of the PELVIPHARM testing include:

- The number of tissue samples is limited.
- The results of the PELVIPHARM testing may not translate to future testing in non-clinical or clinical trials. Unforeseen product safety issues may arise at later stages of testing. The PELVIPHARM testing does not replace specific toxicology testing and is not sufficient to permit a human trial with the experimental products.
- The PELVIPHARM testing results have not been reviewed by external ethics committee or regulatory agency.

The results of the PELVIPHARM testing will help Exopharm plan its next studies with additional insights and confidence.

Glossary

Biologically active	Means the substance has an effect on living matter. The opposite would be substances are biologically inactive or inert. Medicines need to be biologically active.
cholinergic stimulation	Cholinergic agents are compounds which mimic the action of acetylcholine and/or butyrylcholine and tend to be inhibitory

Corpus cavernosum	erectile tissue forming the bulk of the penis
Cytotoxic	Toxic to cells
Erection biology	Whether a penis is soft or erect is determined by smooth muscle tone - smooth muscle relaxation leads to erection through increased blood flow - nitric oxide (NO) is the principal agent responsible for relaxation of penile smooth muscle, increased blood flow and erection. NO comes from two sources (i) non-adrenergic non-cholinergic parasympathetic nerves and (ii) the endothelium lining cavernosal sinusoids and blood vessels in response to cholinergic stimulation.
Ex vivo	Ex vivo means that which takes place outside an organism. In science, ex vivo refers to experimentation or measurements done in or on tissue from an organism in an external environment with minimal alteration of natural conditions.
Nitregic	mediated by nitric oxide
Nitric oxide (NO)	Oxides of nitrogen
NO effect	nitric oxide (NO) is the principal agent responsible for relaxation of penile smooth muscle, increased blood flow and erection
PBS	PBS is phosphate-buffered saline, a mainly inactive material – a form of salt water. Usually delivered in the same volume as the test material but without the active ingredient
Statistical significance	Statistical significance is a measure of how likely a test result is likely to be due to chance – e.g. a P-value of 0.05 means there is a 5% likelihood that the result is a false positive and a 95% likelihood that it is real. A P-value of 0.0001 means there is a .01% likelihood that the result is a false positive and a 99.99% likelihood that the result is real. In general, the larger the study size, or the larger the effect, the lower the P-value.

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 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.