ASX ANNOUNCEMENT & MEDIA RELEASE

Cevaris testing shows positive results in bladder control model

HIGHLIGHTS

- Positive PELVIPHARM testing provides a basis for further testing and future potential clinical trials in urinary bladder control
- Treatment with Exopharm's Cevaris could improve bladder control by improving contractile performance and strength

20 February 2020

Melbourne, Australia: Independent testing of Exopharm Limited's (ASX:EX1) Cevaris has shown that the exosome product could be a potential treatment for bladder control dysfunction, which affects more than five million Australians.

Exopharm, a world leader in the manufacture of exosome products, outsourced the testing of Cevaris and Xevaris to independent French group, PELVIPHARM. The testing in ex vivo models of bladder control demonstrated that treatment with Cevaris could improve bladder control by improving contractile performance and strength.

This provides a basis for further non-clinical testing of Exopharm's products in bladder control. After that, human clinical trials involving patients with bladder control problems would be the next step.

"Exopharm is using its manufacturing strengths to support a growing panel of testing initiatives headed up by our development manager Dr Angus Tester," said Dr Ian Dixon, founder and CEO of Exopharm. "Our testing program is gathering momentum and issues of safety and manufacture are looking very positive for us. Exopharm seeks to provide patients with better new treatment alternatives."

"The testing from leading independent commercial test group PELVIPHARM delivered results that support the application of our exosome products in improving bladder control – a problem facing many of us as we age," said Dr Dixon. "These results will also be of interest to potential partners."

Bladder control dysfunction, also known as urinary incontinence, affects both males and females and involves leaking urine or urgent urges to urinate. Urinary incontinence (UI) affects around 37% of Australian women and around 13% of Australian men. The incidence increases with age. Urinary and faecal incontinence are reported to affect more than 50% of nursing home residents.

Cevaris treatment increased the contractile effect of carbachol on bladder strips compared to control substance (Vehicle i.e. phosphate-buffer saline (PBS)) with high statistical significance ($p<0.001$). Carbachol is a non-selective muscarinic agonist that mediates the parasympathetic nervous system controlling bladder contractions. This means that treatment with Cevaris could enhance bladder control by improving contractile performance. See figure 1 below.

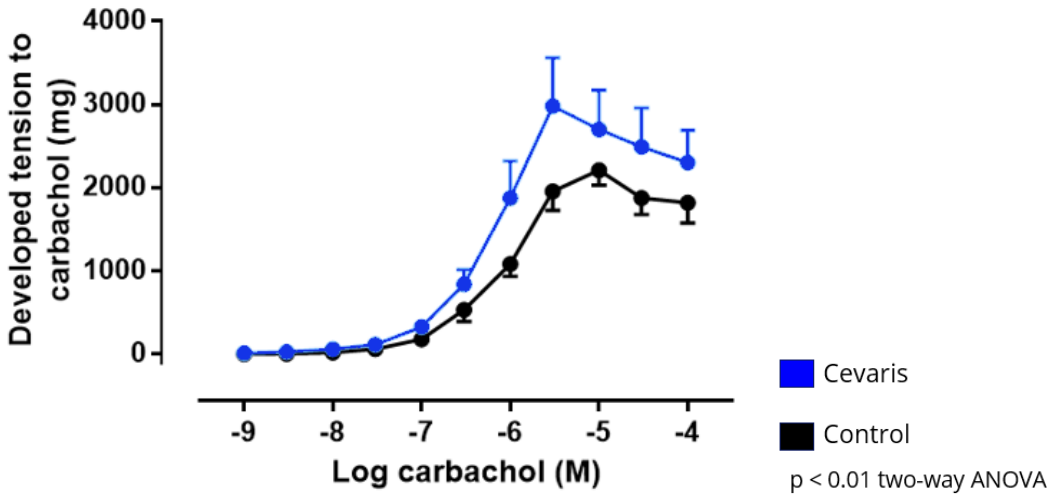

Figure 1: Contractile effect of carpabachol on bladder strips

Note: Data in BLUE is for treatment with Cevaris exosomes and BLACK for control samples.

In a second functional test Cevaris increased the strength of electrical field stimulation (EFS) induced contraction on bladder strips compared to control substance as a trend ($p<0.066$). This means that treatment with Cevaris could improve bladder control by improving contractile strength.

Conclusion: Cevaris product (exosomes from adult stem cells) warrants further investigation as a new treatment for bladder control. Cevaris increased the contractile effect in both models, one significantly and one as a trend. Therefore, Cevaris could be considered for the potential treatment of underactive bladder. Underactive bladder is associated with diabetes, ageing, or injury to spinal cord.

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

PELVIPHARM Testing

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.pelvipharm.com.

Limitations of the PELVIPHARM testing reported here 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

Autonomic nervous system	Regulates body processes, such as urinary control, blood pressure and the rate of breathing - works without conscious effort
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.
Cytotoxic	Toxic to cells
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.
Muscarinic agonist	An agent that activates the biological activity of the muscarinic (involved in parasympathetic effects) acetylcholine receptor
Parasympathetic	The parasympathetic nervous system restores the body to a less alert state
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.