

ASX ANNOUNCEMENT & MEDIA RELEASE

Independent Plexaris and Cevaris testing shows positive and unique results

HIGHLIGHTS

- Exopharm is a world leader in the manufacture of exosome products
- Exosomes have the potential to replace stem cells as medicines
- BioMAP external testing validates possible safety and mechanism of action
- Positive BioMAP testing provides a basis for further testing and future potential clinical trials

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Melbourne, Australia:

BioMAP testing of Exopharm's exosome platform has validated safety and mechanism of action (MOA) and found that they have different and distinct activities compared to 4,500 other drugs. This confirms this therapeutic approach is a distinct and potentially new class of medicine.

Exopharm submitted its exosome products for testing under the BioMAP testing program operated by Eurofins, a European-based group of laboratories.

The headline results of the BioMAP® Diversity Plus® screen testing are:

Exopharm's Plexaris product (exosomes from platelets) was compared with 4,500 experimental and sold medicines across a panel of 12 human primary cell-based systems. Plexaris was found to be safe (by comparison and absolute measures) and had notable biological activity in (i) tissue remodelling (ii) immunomodulatory and (iii) inflammatory-related activities.

Exopharm's Cevaris product (exosomes from adult stem cells) was compared with 4,500 experimental and sold medicines across a panel of 12 human primary cell-based systems. Cevaris was found to be safe (by comparison and absolute measures) and had notable biological activity in (i) tissue remodelling, (ii) inflammatory and (iii) immunomodulatory-related activities.

"These are very positive results from a detailed external test of two of our experimental exosome products," says Dr Ian Dixon, founder and CEO of Exopharm.

“The testing showed that both Plexaris and Cevaris had different and distinct activities to comparison drugs. This confirms our belief that exosomes are a distinct and potentially new class of medicine, different from existing medicines,” he adds. “Importantly, neither was shown to be cytotoxic, and neither caused antiproliferative effects at the concentrations tested.”

The BioMAP results “have a positive impact” across Exopharm’s business, and “will be of interest to potential partners,” Dr Dixon says. “Our testing is looking at issues of safety, mechanism of action and potency, and these results point to an expected safety profile and where these products could be best directed to serve patients.”

In summary, Dr Dixon says, the BioMAP results point to the potential value of Exopharm’s world-leading exosome products as medicines. Further testing is required to validate these products.

The BioMAP testing provides a basis for further non-clinical testing of Exopharm’s products in selected indications based upon improved MOA knowledge, based on the limitations outlined below.

“The results of the BioMAP testing will help Exopharm plan its next studies with additional insights and confidence. After that, further human clinical trials are the next step,” says Dr Dixon.

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

Further details

Eurofins (www.eurofinsdiscoveryservices.com) is an international company, employing more than 600 researchers in seven operational sites worldwide, that offers outsourced testing services to support clients in their drug discovery programs.

Eurofins’ BioMAP Phenotypic Profiling and Screening Service provides an unbiased, target-agnostic and data-driven approach to understanding a medicine’s impact on human disease models and translational biomarkers.

Validated with clinically approved drugs and known test agents, the BioMAP platform is powered by human primary cell-based disease systems, a reference database of more than 4,500 compounds, data analytics, and expert interpretation to provide clients with actionable insights.

Exopharm provided Eurofins with both Plexaris (exosomes from platelets) and Cevaris (exosomes from adult stem cells) material for testing under a paid-for-services contract. All of the intellectual property arising from the test results is owned by Exopharm.

In Exopharm's testing, the BioMAP phenotypic results include:

Plexaris

- Plexaris was active modulating cell adhesion molecules, MHC class II receptors and protease inhibitor biomarkers associated with inflammatory, immunomodulatory and tissue remodelling activities. *Plexaris was not cytotoxic and did not cause antiproliferative effects at the concentrations tested.*

Cevaris

- Cevaris was active modulating multiple types of protein biomarkers including cytokines, chemokines, cell adhesion molecules, MHC class II receptors, extracellular proteins, proteases and inhibitors associated with inflammatory, immunomodulatory and tissue remodelling activities. *Cevaris was not cytotoxic and did not cause antiproliferative effects at the concentrations tested*

These results identified a number of potential mechanisms of action and biological pathways for Plexaris and Cevaris that will be verified in planned non-clinical studies. Understanding how a medicine works is important in many ways. Understanding mechanism of actions and biological pathways of products can identify medical indications likely to be a good match (and avoid medical indications where the match is limited).

Importantly, comparison of the screening profiles of both Plexaris and Cevaris against the database of 4,500 other medicines did not produce a significant match, suggesting that both Plexaris and Cevaris have different and distinct activities to comparison existing drugs. This is a valuable finding, pointing to exosomes as an unique and potentially new class of medicine, with potential application unmet by existing medicines.

Limitations of the BioMAP testing include:

- The results of the BioMAP 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 BioMAP testing does not replace specific toxicology testing and is not sufficient to permit a human trial with the experimental products
- The BioMAP testing results have not been reviewed by external ethics committee or regulatory agency

Glossary

Cytotoxic	Toxic to cells
Antiproliferative	Prevents cells from undergoing cell division
Biological pathways	The series of interactions among molecules within or on a cell that leads to a certain change in a cell.
Mechanism of action	The biochemical process (pathway) by which a drug produces its effect

Exosome	Membrane bound extracellular vesicles produced by cells
Phenotypic	Observable characteristics of cells resulting from the cell's interaction with medicines (<i>in the context of this testing</i>)
Platelets	Also called thrombocytes, are derived from megakaryocytes and are present in blood
Adult stem cells	Undifferentiated cells found in adult body
Non-clinical	Other than clinical
Clinical testing	Human clinical testing
Toxicology	Understanding the harmful effects that chemicals and substances can have on cells, tissue, organs and people

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.