

## ASX ANNOUNCEMENT

### Exopharm Shareholder Update

- Webinar 10:30am Wednesday 2 September at <https://exo.ph/Sept2020Webinar> open to all
- Exoria™ – a new product to measure and track EVs
- Exopharm's Fortrexo™ Coronavirus project taking shape
- Investments in EV medicines accelerating globally
- Naïve EV products advancing toward clinical studies
- Operations continue despite COVID-19 restrictions

**19 August 2020, Melbourne, Australia:** Exopharm Limited (ASX:EX1) is a clinical stage Australian company using exosomes (extracellular vesicles (EVs)) from cells to generate a new class of cell-free medicines. Exopharm is a leader in the manufacture and experimental clinical use of EV medicines.

Exopharm continues to expand its EV platform as well as developing two main types of EV products:

- NEVs (naïve EVs) from stem cells and platelets as a new class of regenerative medicine; and
- EEVs (engineered EVs) designed as specific medicines to treat conditions such as viral infection, cancer and neurological conditions.

#### Invitation for behind the scenes webinar

Shareholders and other interested people are invited to join a Webinar update on at 10:30am Friday 28 August May at <https://exo.pl/May2020>. Dr Karen Holden, Head of Translation and Dr Patrick James, Head of Product Development, will provide a look into some of the scientific developments at Exopharm in the last three months. There will be a Q&A session with Ian Dixon (CEO) and Chris Baldwin (CCO) at the end of the Webinar.

#### Exoria – potential product to measure and track EVs

Exopharm has expanded its technology portfolio with an invention that solves a problem faced by EV researchers – how to measure and track 'invisible' EVs in the laboratory and in animal studies.

Presently researchers use dyes that are expensive and work poorly with EVs. Exopharm recently developed a proprietary fluorescent dye for EVs called Exoria. Exoria attaches to EVs well, provides a bright signal, and is chemically stable in solution and in cells. The combination of these traits makes Exoria an extremely useful tool for tracking EVs *in vitro* and will allow researchers to quantify EVs during *in vitro* and *in vivo* experiments.

Exoria is currently undergoing testing at nine internationally recognized EV research laboratories in Europe, America, Asia and Australia. Feedback thus far has been very promising. "The data presented clearly demonstrate that Exoria can label all EVs, showing sub-populations that were not obvious when stained with traditional protein EV markers," said Dr Patrick James, Head of Product Development at Exopharm.

### Exopharm's Fortrexo coronavirus project taking shape

Exopharm has joined the battle against SARS-CoV-2 with its Fortrexo CoV research product that is under development in Melbourne.

While others are waiting for vaccines or treatments for ARDS, Exopharm's team has designed proprietary EEVs using the LOAD and EVPS technologies to tackle SARS-CoV-2 at the stage of cell infection and viron replication.

Fortrexo CoV has been designed and will soon be made and tested here in Melbourne. A patent application has also been lodged.

The Fortrexo CoV 'precision medicine' prototype combines two features – the EV is targeted specifically to cells that SARS-CoV-2 infects and delivers into them a set of antiviral agents designed to inhibit virus replication – breaking the coronavirus' lifecycle and potentially averting later consequences of infection such as ARDS.

The Fortrexo approach has many other potential applications including anti-viral, anti-inflammatory, neurology and tissue regeneration. "Fortrexo is also applicable to future Coronavirus pandemics and other viruses such as swine flu and Dengue," said Dr Karen Holden, Head of Translation at Exopharm.

### Investments in EV medicines accelerating globally

Since May 2020 there have been five additional major investments announced in EV companies: three have been billion-dollar development partnerships between EV companies and pharma companies, and two have been Series A funding rounds both in excess of \$30 million.

These transactions show that the EV medicine field is developing quickly and that the expectations about the value of EV assets and capabilities are rising as well. Chris Baldwin will be speaking along with other EV company leaders at the virtual Exosome TX meeting in November.

### Development progresses with Naïve EVs

#### PLEXOVAL I clinical study update

The second wave of COVID-19 cases in Melbourne and resulting tightening of restrictions has kept the autologous PLEXOVAL I study on hold.

#### PLEXOVAL II clinical study update

Building on our experience from the autologous PLEXOVAL I, Exopharm's clinical focus has advanced to the allogeneic (off-the-shelf) PLEXOVAL II study – unmatched NEVs from platelets testing for safety and signs of efficacy.

PLEXOVAL II is being managed in Melbourne by an outsourced clinical trials unit and stands to provide important evidence in the field of NEVs, validating Exopharm's manufacturing process scale and quality. Commencement is subject to Human Research Ethics Committee (HREC) approval, which is presently under review. We expect that PLEXOVAL II could be completed in CY 2020.

### Ocular animal studies update

COVID-19 restrictions have impeded final reporting of this first exploratory ocular animal study being conducted by expert researchers in Melbourne as previously announced. Dosing occurred in late CY 2019 with the scale-up of the LEAP purification technology. NEVs were sourced from stem cells and we've established the product formulation and stability.

This first ocular study demonstrated the manufacturing process, product sterility and safety and provided valuable study design insights. "No signs of retinal or ocular pathology were observed in the test animals. Increased dosing would now be permissible to explore the therapeutic-window of the NEVs in ocular disease models. Taken together, the results of this study provide an early milestone on the pathway for ocular EV drug development," said Dr Angus Tester, Head of Product Evaluation, who is planning further studies of NEVs that could commence after COVID-19 restrictions.

### Operations continue despite COVID-19 restrictions

The COVID-19 pandemic has illustrated the importance of developing and commercialising innovative medicines against new threats. Exopharm has been working hard over the past months to design EVs for fast response to viral infections.

Due to the nature of its work, Exopharm is exempt from the Stage 4 business closure restrictions and has maintained continuity of its work, with the exception of the PLEXOVAL I study as previously reported. During the COVID-19 situation Exopharm has implemented policies and procedures to protect the team including regular testing of lab staff to protect against non-symptomatic transmission. There have been no reductions in staff or work-levels.

At Exopharm COVID-19 influenced our work in a variety of ways including:

<b>Impact of COVID-19</b>	<b>Exopharm Response</b>
Halt of autologous PLEXOVAL I study (as previously reported)	Acceleration of allogeneic PLEXOVAL II study design and conduct Accelerate internal proof-of-concept work with EEVs
Reduced access to shared research facilities	Accelerated transfer of our staff to our new site at Baker Institute – access has been open
Interruption of suppliers	Focus on activities fully within Exopharm's control
Reduced international travel for commercial and other meetings	Increased videoconferencing

### **Glossary**

ARDS	Acute respiratory distress syndrome
Dengue	A mosquito-borne virus causing approximately 60 million infections worldwide
Fortrexo	An Exopharm product in early stage in vitro testing designed for the interruption of viral replication in infected cells – including COV, RSV and Dengue

In vitro	In vitro means studies performed with microorganisms, cells, or biological molecules outside their normal biological context.
In vivo	In vivo means studies performed with animals their normal biological context.
Plexaris	Exopharm's platelet-derived extracellular vesicle medicine currently in human safety trials.
SARS-COV	Coronavirus, a family of viruses responsible for the variant causing COVID-19
Viron	A viral particle

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

### ***Company and Media Enquiries:***

Dr Ian Dixon, MBA  
 Founder and Managing Director  
 P: +61 (0)3 9111 0026 [ian.dixon@exopharm.com](mailto:ian.dixon@exopharm.com)

Rudi Michelson  
 Monsoon Communications  
 Tel: +61 (0)411 402 737  
[rudim@monsoon.com.au](mailto:rudim@monsoon.com.au)

*Join our mailing list to receive updates:*

<http://exo.ph/ExoMails>

[www.exopharm.com](http://www.exopharm.com)

P: +61 (0)3 9111 0026

### **ABOUT EXOPHARM**

Exopharm Limited (ASX:EX1) is a clinical-stage Australian regenerative medicine company developing therapeutic exosome products as regenerative medicines and precision medicines.

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.