Press release
23 November 2022

Sartorius BIA Separations and Exopharm sign joint research agreement to develop integrated technology for large-scale exosome production

- *Partnership will address technical challenges of large-scale, high-efficiency purification of therapeutic exosomes for non-viral drug delivery*
- *Programme combines novel technologies and expertise - LEAP exosome purification technology from Exopharm and BIA's CIM monoliths*

Melbourne, Australia and Ajdovščina, Slovenia, 23 November 2022: Sartorius BIA Separations (BIA), a leading bio-chromatography company, now part of the international life science group Sartorius, and Exopharm Ltd. (ASX:EX1), a company at the forefront of transformative medicines using exosomes, or extracellular vesicles (EVs), today announced they had entered into a formal collaboration. The two companies have signed a Material Transfer Agreement and associated collaborative programme that aims to exploit the synergy of Exopharm's patented LEAP technology together with BIA's unique CIM (Convective Interaction Media) monolith chromatography for improved large-scale therapeutic exosome production and commercialisation.

BIA and Exopharm recognise the demand for a large-scale, high-efficiency purification technology that overcomes critical issues associated with the production of clinical-quality exosomes as delivery vehicles for gene-based therapeutics. To meet this demand, the new collaboration will utilise novel and innovative technologies alongside subject matter expertise provided by both Companies.

As part of the programme, BIA's CIM monolith chromatography columns have been selected as an optimal carrier for Exopharm's LEAP ligands. BIA's CIM monolith chromatography columns enable high-throughput, capacity and resolution separation in combination with high stability and controlled exposure of the bioprocess material. Selected to work synergistically, Exopharm's LEAP ligands are able to 'gently pull out' exosomes with a high degree of efficiency and could provide a powerful solution for large-scale and high-efficiency purification of therapeutic exosomes.

Genetic medicines, such as mRNA, require a drug-delivery chassis, and exosomes are emerging as an effective, non-viral chassis for additive gene therapy, CRISPR gene editing, etc. RNA can be loaded into exosomes to make therapeutic products that could one-day address many medical problems. Exosomes have advantages over alternative nanoparticle delivery technologies – being non-toxic, efficient at delivering RNA cargoes into cells and able to do so without eliciting an immune response. Immune and cytotoxic responses to lipid nanoparticle-encapsulated mRNA have been a major concern in early clinical studies[1]. Furthermore, exosomes can be engineered to provide specific delivery as well as repeated dosing.

Initial research efforts between BIA and Exopharm will focus on the assessment and validation of the addition of LEAP ligand chemistry to CIM monolithic columns, with the expectation that this will improve both specificity and purified exosome purity relative to BIA CIM ion exchange columns. In addition, BIA also aims to determine the optimal immobilisation density of LEAP ligands for high-throughput, large scale production of purified exosomes.

BIA and Exopharm expect to have the results from this testing programme early in CY ’23, after which plans could potentially be made for commercialisation.

Dr Aleš Strancar, co-founder and managing director of BIA, said “BIA sees the potential in exosomes for new and innovative therapeutic applications and understands that purification of exosomes has held back their adoption as a non-viral drug-delivery technology. We believe that BIA’s CIM monolith technology and Exopharm’s exosome-specific LEAP ligands can work synergistically together to enhance specificity, efficiency and capacity of industrial exosome purification processes. This work with Exopharm has the potential to be a game-changer in the emerging exosome field.”

Dr Ian Dixon, founder and CEO of Exopharm, commented “BIA’s CIM columns are ideally suited as the carrier of Exopharm’s LEAP ligands as they are already used in the industry for large-scale and efficient bioprocessing. The combination of LEAP ligands, together with CIM monolithic columns for large scale exosome purification will be tested over the next few months, after which we can begin to explore how best to bring this exciting new technology into applications.”

Exopharm’s LEAP technology is subject to US Patent 11,202,805 B2 and its utility for purifying exosomes has already been demonstrated when the LEAP ligand chemistry is immobilised on other substrates (resins) in affinity chromatography columns.

To learn more about Sartorius BIA Separations’ services and technology for therapeutic vectors, visit www.biaseparations.com. For information on Exopharm, visit www.exopharm.com.

1 Rohner et al 2022 https://doi.org/10.1038/s41587-022-01491-z

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Notes to Editors

Exopharm’s lab facilities

For high resolution images, please contact Zyme Communications

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About Sartorius BIA Separations: www.biaseparations.com

Sartorius BIA Separations is the leading developer of monolith technology and the exclusive producer of CIM® (convective interaction media) chromatographic columns for the production, purification, and analysis of large biomolecules. The Company's multi-use research, production, and training facility is headquartered in Ajdovščina, Slovenia, with sales and distribution offices located internationally. Sartorius BIA Separations' ongoing mission is to develop and produce CIM® monolithic columns of the highest quality and provide superior research and method development services for our customers. In addition, the Company now offers the highly versatile PATfix™ HPLC system for producing analytical gradient separations.

About Exopharm: www.exopharm.com

Exopharm (ASX:EX1) is a leader in advancing Genetic Medicines and other exosome-based medicines using exosomes or extracellular vesicles (EVs) as a chassis for improved and non-viral drug-delivery.

Exopharm (ASX:EX1) is pursuing a product pipeline-driven platform strategy. Exosomes can be loaded with a variety of active pharmaceutical ingredients (APIs) and can be targeted to selected cell-types and tissue types, improving the safety-profile of the APIs and providing better treatments. Exosomes can be used to deliver small molecule drugs, mRNA, DNA and other types of APIs. Exosomes are an alternative means of drug-delivery inside the body, alongside technologies such as lipid nanoparticles (LNP), cell-penetrating peptides, viral vectors and liposomes.

Exopharm's exosome technologies solve important needs for the success of exosome medicines – LEAP manufacturing technology, LOAD API loading technologies and EVPS tropism technologies. Exosome-based medicines could improve the treatment of many chronic or inherited medical conditions.

Exopharm is making its proprietary technologies available to pharmaceutical and biotechnology companies that want to harness exosome-delivery for their own products.

In addition, Exopharm is using its technology platform to enable its own product development programs - each aimed at delivering a transformative medicine for an unmet medical need.

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.