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Sartorius collaborates with RoosterBio to advance downstream purification processes for the manufacture of exosomes

The life science group Sartorius extended a strategic collaboration partnership agreement with RoosterBio Inc. (RoosterBio) to address purification challenges and establish scalable downstream manufacturing processes for exosome-based therapies. Through this collaboration, Sartorius and RoosterBio will provide best-in-class solutions and expertise for a human mesenchymal stem/stromal cell (hMSC) - based exosome production platform that delivers industry-leading yield, purity, and potency. Additionally, this collaboration will focus on the development of comprehensive analytical techniques for the characterization of exosomes and the entire spectrum of extracellular vesicles (EVs) to establish quantitative strategies for quality control of exosome purification intermediates and final drug product. Collaboration between Sartorius and RoosterBio in the field of Cell and Gene therapy has existed for almost two years for the industrialization of cell-based regenerative cures. It now will take a step further to commercialize the Exosome production and purification process using our technologies.

Sartorius and RoosterBio will develop scalable platform purification processes using Sartorius' comprehensive toolbox of solutions to maximize exosome productivity while maintaining therapeutic attributes. Sartorius's Biostat STR® manufacturing bioreactor platform, process analytical technologies (PAT) toolbox, along with RoosterBio's hMSC banks, RoosterNourish™ hMSC cell growth medium, and RoosterCollect™ EV production medium will be used for upstream manufacture of exosomes at large scale. For the development of downstream purification methods, Sartorius's scalable filtration equipment, Sartoflow® Smart and Sartoflow® Advanced will be leveraged for clarification, concentration, and formulation of exosomes in combination with column chromatography unit operations. Sartorius' analytical platforms, including PATfix® HPLC, Virus Counter®, and Incucyte®, will be utilized for automated real-time process analysis and evaluation of purification process efficiency. This collaborative development effort, conducted in RoosterBio's state-of-the-art process development laboratories in Frederick, MD, will simplify multi-step therapeutic development processes by providing robust, end-to-end platform technologies and protocols that researchers can easily adopt to accelerate development timelines and incorporate a scalable platform approach into their manufacturing processes.

"Sartorius, a leading solutions provider is delighted to enter into a collaboration with RoosterBio to develop a robust process for Exosome production. With advanced and innovative Sartorius downstream technologies for both chromatography and filtration along with state-of-the-art analytical tools, we would work with RoosterBio team for process development for this emerging modality," said Michaela Pischke,

Head of the Business Area Separation Technologies at Sartorius. “Together we merge our technologies, RoosterBio’s Clinical MSC & EV solution portfolio and Sartorius’ regulatory-compliant bioprocess manufacturing solutions, and industry expertise to deliver the bundled solutions for enabling fast-track early drug development and robust, cost-effective, scalable manufacturing process for Exosomes.”

“We are delighted to continue our highly impactful partnership with Sartorius, as this collaboration builds upon our previous process development initiative to establish scalable stirred tank bioreactor expansion processes for hMSCs,” said Tim Kelly, Ph.D., CEO of RoosterBio. “Exosomes offer extremely high utility as a new therapeutic modality with the potential to address unmet medical needs. The cell and gene therapy industry will greatly benefit from access to robust, scalable, end-to-end solutions for the production and characterization of native and engineered exosome therapeutics. By combining our industry-leading MSC and exosome technology platform with Sartorius’ best-in-class bioprocess solutions and expertise, we will deliver transformational value to advance the clinical development of this new class of therapies to patients around the world.”

Sartorius and RoosterBio will leverage the data from this collaboration to provide application notes, technology presentations, and other guidance materials designed to address the most significant challenges faced by the biomanufacturing industry.

A profile of Sartorius

The Sartorius Group is a leading international partner of life science research and the biopharmaceutical industry. With innovative laboratory instruments and consumables, the Group’s Lab Products & Services Division concentrates on serving the needs of laboratories performing research and quality control at pharma and biopharma companies and those of academic research institutes. The Bioprocess Solutions Division, with its broad product portfolio focusing on single-use solutions, helps customers to manufacture biotech medications and vaccines safely and efficiently. The Group has been annually growing by double digits on average and has been regularly expanding its portfolio by acquisitions of complementary technologies. In fiscal 2021, the company earned sales revenue of some 3.45 billion euros. At the end of 2021, nearly 14,000 people were employed at the Group’s approximately 60 manufacturing and sales sites, serving customers around the globe.

About RoosterBio Inc.

RoosterBio accelerates human mesenchymal stem/stromal cell (hMSC) and extracellular vesicle (EV) product and process development to fuel the rapid commercialization of scalable advanced therapies. Our high-quality hMSCs, bioprocess media, genetic engineering tools, and EV production solutions are paired with expert bioprocessing knowledge to progress therapeutic developers from concept to first-in-human testing and commercial manufacturing at reduced cost and increased productivity. With optimized, scalable processes, Type 2 Drug Master Files, and cGMP products, we have enabled therapeutic programs to traverse their path to clinical translation in under 1 year. RoosterBio is driven by the client’s success and creating a world where safe and effective regenerative medicines are rapidly developed and widely available on a global scale.

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