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Sartorius partners with RoosterBio to advance cell and gene therapy manufacturing

The life science company Sartorius signed a strategic collaboration with RoosterBio Inc., a leading supplier of human mesenchymal stem/stromal cell (hMSC) working cell banks, highly engineered media and hMSC bioprocess systems. The collaboration aims to advance the scale-up of hMSC manufacturing for regenerative medicine by leveraging the best-in-class solutions of both companies to significantly reduce process development efforts, industrialize the supply chain and accelerate the development and commercialization of groundbreaking cell-based regenerative cures.

RoosterBio and Sartorius will create a set of GMP-compatible, customer-centric protocols using RoosterBio's hMSC and media systems, alongside Sartorius's single use manufacturing technologies, process control software and cell analysis tools of hMSC final product manufacturing. Cell expansion will be rapidly optimized using Sartorius's benchtop Ambr® system and MODDE® design of experiment software allowing the technical team to compare cultures in identically sized, multi-parallel bioreactors to gain process information and optimized conditions in a short timeline. Sartorius's scalable Biostat STR® production bioreactors will then be used to scale up to 50L as part of this collaboration, with the system benefitting from scalability to 2000L. Sartorius equipment will also be leveraged to develop post-harvest processing methods with the kSep® system as well as process and quality analytics. This joint effort will simplify multiple steps in therapeutic development by providing robust, streamlined, end-to-end platform technologies and protocols that can be implemented for rapid scale up of manufacturing processes, allowing product developers to significantly speed up their development timelines.

"Taking hMSC manufacturing to the thousand-liter scale is critical in meeting product dose requirements in commercial manufacturing," said RoosterBio CEO Margot Connor. "For truly robust and standardized production in the field, a highly controlled manufacturing strategy is needed, with the implementation of automation, process monitoring and control to increase batch scale, consistency and efficiency. This collaboration is well-positioned to accomplish the clinical scale requirements of regenerative medicine product developers while laying foundation for true commercial scale manufacturing."

"With the combination of technologies and tools of RoosterBio and Sartorius we support our customers to develop stem cells and therapies faster, better and more cost-efficient. Scalability is key in commercial manufacturing and this cooperation will help to meet the requirements of our customers even better", said Hugo de Wit, Head of Advanced Therapies at Sartorius.

Both companies aim to use the data from this collaboration to provide co-learning and development opportunities to support the growing cell and gene therapy industry.

About 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 2019, the company earned sales revenue of some 1.83 billion euros. At the end of 2019, more than 9,000 people were employed at the Group's approximately 60 manufacturing and sales sites, serving customers around the globe. Visit www.sartorius.com

About RoosterBio, Inc.

RoosterBio, Inc. is a privately held cell manufacturing platform technology company focused on accelerating the development of a sustainable Regenerative Medicine industry, one customer at a time. RoosterBio's products are high-volume, affordable, and well-characterized adult human mesenchymal stem/stromal cells (hMSCs) paired with highly engineered media systems. RoosterBio has simplified and standardized how living cells are purchased, expanded, and used in development, leading to marked time and costs savings for customers. RoosterBio's innovative products are ushering in a new era of productivity and standardization into the field. Visit www.roosterbio.com.

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