

RoosterBio and Repligen Collaborate to Advance Scalable Exosome Bioprocessing

FREDERICK, MD, UNITED STATES, March 13, 2023 /EINPresswire.com/ -- RoosterBio Inc., a leading supplier of human mesenchymal stem/stromal cells (hMSCs), highly engineered media, development services, cell engineering, and advanced therapy bioprocess solutions, today announced that it has selected Repligen Corporation, a life sciences company focused on

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> Tim Kelly, Chief Executive Officer of RoosterBio

bioprocessing technology leadership, as a collaboration partner to advance scalable exosome bioprocessing.

RoosterBio's goal, in collaboration with Repligen, is to deliver solutions for manufacturing of exosomes using scalable and low shear technologies that enable costeffective commercialization of these advanced therapies.

There has been a growing demand in exosomes supply in recent years due to their emerging role as intercellular messengers and their therapeutic potential as targeted and natural drug delivery vehicles with high specificity and

efficiency. The complexity and fragility of the exosomes, scalability, yield, and purity of production processes are challenges to meeting demand. The combination of Rooster Bio's and Repligen's scalable platforms are being advanced to overcome those challenges.

RoosterBio is leveraging its well-established technology platform including hMSC cell banks and highly engineered bioprocess media to generate representative bulk exosome product in stirred tank bioreactors at 3L scale. Repligen's KrosFlo[®] TFDF and hollow fiber KrosFlo[®] TFF systems enable highly efficient and scalable, clarification and concentration steps to significantly improve potent exosome yields. Repligen also brings to the collaboration the ability to develop exosome affinity resins for product purification. The exosomes are being evaluated for quality, purity and potency utilizing RoosterBio's extensive panel of analytical characterization techniques.

The results to date of the RoosterBio/Repligen collaboration, which began in September 2022, clearly demonstrate at small scale the benefit of Repligen's integrated automated single-use platform for high recovery yield of functional hMSC exosomes during clarification and concentration steps.

The combination of RoosterBio off-the-shelf cell and media products, and analytical

characterization capabilities, along with Repligen filtration and purification technologies makes possible a manufacturing scale, cGMP compatible platform to help address increased global demand for exosomes.

"Exosomes are an emerging therapeutic modality that has the potential to create transformational impact on human health, while also posing a unique set of manufacturing and analytical characterization challenges. We are thrilled to partner with Repligen to accelerate our customers' path to the clinic and enable successful commercialization of innovative exosome therapies," said Tim Kelly, Chief Executive Officer of RoosterBio.

"We started this collaboration last year and the results to date are very encouraging. We believe that this joint collaborative effort will provide commercially and clinically viable scalable solutions for exosome manufacturing," said Vikas Gupta, VP & GM, Downstream Bioprocessing and Gene Therapy of Repligen.

Both companies will investigate extending these studies from laboratory scale to pilot and manufacturing scales, enabling the manufacturing, clarification, chromatography, and concentration of exosomes for even the largest advanced therapy indications.

About Repligen Corporation

Repligen Corporation is a global life sciences company that develops and commercializes highly innovative bioprocessing technologies and systems that increase efficiencies in the process of manufacturing biological drugs. We are inspiring advances in bioprocessing for the customers we serve; primarily biopharmaceutical drug developers and contract development and manufacturing organizations (CDMOs) worldwide. Our corporate headquarters are located in Waltham, Massachusetts, with additional administrative and manufacturing operations worldwide. The majority of our manufacturing sites are located within the U.S. (California, Massachusetts, New Jersey, and New York), and outside of the U.S., we have sites in Estonia, France, Germany, Ireland, the Netherlands, and Sweden.

About RoosterBio

RoosterBio accelerates human mesenchymal stem/stromal cell (hMSC) and extracellular vesicle (EV) product and process development to fuel the rapid implementation 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 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 client success and creating a world where safe and effective regenerative medicines are rapidly developed and widely available on a global scale.

www.roosterbio.com LinkedIn: RoosterBio

Media Contact RoosterBio, Inc. +1 301-200-5366 email us here Visit us on social media: Facebook Twitter LinkedIn Other

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