ShiftBio Partners with RoosterBio to Accelerate Development of a Novel Genetically Engineered Exosome, SBI-102

RoosterBio's MSC-derived exosome bioprocess technology platform enables accelerated development of ShiftBio's lead therapeutic candidate.

FREDERICK, MARYLAND, UNITED STATES, April 26, 2022 /EINPresswire.com/ -- ShiftBio, a leader in the development of innovative exosome platform technologies, announced today a strategic partnership with RoosterBio Inc., a leading supplier of human mesenchymal stem/stromal cells (MSCs), highly engineered media, and bioprocess development services. This partnership will accelerate ShiftBio's therapeutic candidates, starting with SBI-102 (Stem cell-derived exosomes expressing a therapeutic ligand), into the clinic.

> We are thrilled to partner with ShiftBio, a global innovator in the field of exosomes, to advance their pipeline of transformative therapeutics, starting with SBI-102."
>
> *Tim Kelly, CEO of RoosterBio*

Through this partnership, RoosterBio will develop a cGMP manufacturing process designed to meet the needs for Phase I/II clinical trials, with the ability to scale as needed for Phase III and commercial production. RoosterBio will design and execute all process development studies, leveraging its industry-leading cell and media product portfolio. The manufacturing process will feature genetic engineering of MSCs to express the therapeutic ligand, expansion of stable pools, production of gene-modified exosomes in stirred-tank bioreactors at an initial scale of 50-200L, downstream purification to achieve desired quality attributes, and finally formulation and filling of the drug product. The resulting product will be extensively characterized via state-of-the-art analytical methods to ensure identity, purity, potency, and safety of the engineered SBI-102 exosomes. These processes are built on RoosterBio's scalable "off the shelf" cell and media product platforms, which come with strong regulatory support packages, including FDA-

approved type II master files.

“We are thrilled to partner with ShiftBio, a global innovator in the field of exosomes, to advance their pipeline of transformative therapeutics, starting with SBI-102,” stated Tim Kelly, CEO of RoosterBio. “This program brings together all of RoosterBio’s unique capabilities: our cGMP MSC banks, proprietary media for genetic engineering, cell expansion, and exosome collection, as well as our deep and broad expertise in bioprocess development services. The opportunity to forge a true collaboration and create this kind of impact to accelerate advanced therapies to patients is what drives our entire organization.”

ShiftBio created the Maxisome platform technology that maximizes the expression of therapeutic proteins on the exosome surface, enhancing the overall therapeutic impact, as demonstrated in SBI-102. Their exosome platform technologies also include InProDel and Fusosome, which can make "undruggable" therapeutic macromolecules "druggable." Based on their innovative platform technologies, nine pipelines will offer a "second chance" to patients without treatment options. ShiftBio strives to solve unmet medical needs with their platform technology-based exosome medicines.

"We have established a novel platform technology for exosome modifications that can address rare diseases and cancers. Especially, our lead candidate SBI-102 shows promising applications in untreatable disease indications. Finding an appropriate partner with expertise that can convert our knowledge into processes and products suitable for clinical trials was one of our company's most important early decisions. RoosterBio has a proven track record coupled with the right products and processes to move our programs forward. Leveraging RoosterBio's process development services will enable us to save significant time and expense. As a result of the partnership, we have already made substantial progress towards our first IND," stated Gi-hoon Nam, Co-Founder of ShiftBio.

About ShiftBio
ShiftBio is harnessing the power of exosomes, naturally occurring nano-sized extracellular vesicles, to create new medicines. We will offer a "Second Chance" to patients without treatment options through our proprietary exosome platform technologies. Our pipelines are focused on treating rare diseases and cancer. We have a strong desire to solve unmet medical needs with our platform technology-based exosome medicines. ShiftBio is bringing the paradigm shift to the next therapeutic modality, exosome.

https://www.shiftbio.net/
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About RoosterBio
RoosterBio accelerates human mesenchymal stem/stromal cell (hMSC) and exosome product

and process development to fuel the rapid commercialization of scalable regenerative cures. Our high-quality hMSCs, bioprocess media, genetic engineering tools, and exosome 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 II drug master files, and cGMP products, we have enabled therapy developers to traverse their path to clinical translation in under 1 year. RoosterBio is driven by 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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