NEWS

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Sentien Biotechnologies-Led Team Awarded $2.4M Contract from the U.S. Department of Defense and the Medical Technology Enterprise Consortium

Award will fund potency assay development for regenerative medicine cell-based products

LEXINGTON, MA, October 8, 2020 – Sentien Biotechnologies, Inc., a clinical-stage biotechnology company developing novel approaches to cell therapy, has been awarded a $2.4 million contract from the Medical Technology Enterprise Consortium (MTEC). The funds will be used to support the development of a potency assay for mesenchymal stromal cells (MSCs) in regenerative medicine products.

Sentien has partnered with RoosterBio, Inc., a developer of MSCs and bioprocess media, and GenCure, a cell therapy-focused contract development and manufacturing organization (CDMO). Together, this team will develop a potency assay framework using MSCs, spanning large-scale biomanufacturing, in vitro assay development and in vivo biomarker analytics.

The award was granted by the U.S. Army Medical Research & Development Command (USAMRDC) in collaboration with the Medical Technology Enterprise Consortium (MTEC), a 501(c)(3) biomedical technology consortium working in partnership with the Department of Defense (DoD).

The Defense Health Agency has identified a need for quality management in the biomanufacturing of regenerative medicine-based products. For cell therapy products, the potency assay is the most robust quality metric, representing the biological ability of a product to effect a clinical outcome. Developing a potency assay is a complex challenge, requiring significant characterization of process parameters and quality attributes throughout the preclinical and clinical development stages.

This work will take an integrated, cross-functional approach to potency assay development. First, biomanufacturing process parameters and quality attributes will be evaluated during the expansion of MSCs derived from different tissue sources. Second, the resulting cell banks

will be analyzed using Sentien's ex-vivo bioreactor platform to assess the immunomodulatory effects of the MSCs and generate putative potency markers. Finally, the putative potency markers will be matched against clinical trial samples from subjects with systemic inflammatory conditions who have been treated with SBI-101, Sentien's lead product.

SBI-101 is a combination biologic product, in which MSCs reside on the exterior of hollow fibers, while blood flows through the interior. The unique design of SBI-101 enables real-time sampling of both MSC-secreted factors (pharmacokinetics) and their effect on patient blood (pharmacodynamics), which will provide particular value for this project. The ultimate goal of the project is to develop a broadly applicable potency assay framework that members of the regenerative medicine community can leverage for their particular biomanufacturing process, product and indication of interest.

"Sentien is grateful to MTEC and the DoD for recognizing the potential impact of our proposal and awarding the funds to undertake this work. We have an opportunity to add real value to the regenerative medicine community by developing this potency assay framework which spans R&D, biomanufacturing and clinical translation," said Chris Gemmiti, Senior Vice President of Operations at Sentien. "This award demonstrates external recognition of how our proprietary microreactor platform can offer unique insights into MSC biology. This is very timely as the interest in MSCs has been increasingly heightened in the context of COVID-19 trials," said Rita Bárcia, Vice President of R&D at Sentien. "We are very excited to be partnering with RoosterBio and GenCure on this project," added Sentien CEO, Brian Miller. "We believe this team of collaborators, with complementary technologies and skills, will together produce a valuable, widely applicable deliverable."

"We are very much looking forward to this collaboration to provide our platform solutions and expertise in MSC manufacturing in support of this project," said RoosterBio CEO, Margot Connor. "The development of a MSC potency assay framework is really the cornerstone of a successful regenerative medicine product thus we are grateful for the opportunity to contribute to this team effort."

Becky Cap, Chief Operating Officer for GenCure, a subsidiary of BioBridge Global, commented, "GenCure values creative approaches to solving difficult problems, and the Sentien team has developed some highly innovative approaches to treatment with SBI-101. With this project, they are finding ways to leverage that innovation to address more fundamental questions about potency and the impact of tissue source on both potency and therapeutic benefit. We are honored to be part of this project."

About Sentien Biotechnologies

Sentien Biotechnologies, Inc. is a privately-held, clinical-stage company developing novel ex-vivo cell therapy applications to treat conditions caused by systemic, immune-mediated inflammation. Sentien's lead product, SBI-101, integrates allogeneic mesenchymal stromal cells (MSCs) within an extracorporeal, hollow-fiber device. By immobilizing MSCs within a blood-filtration device, SBI-101 enables controlled, dynamic, and sustained delivery of MSC-secreted factors to the patient's blood, without the need for direct injection of the MSCs themselves.

SBI-101 has been evaluated in a Phase 1b/2a study in subjects with dialysis-requiring acute kidney injury (AKI-D). An initial readout from the study provides preliminary evidence of anti-inflammatory and wound healing effects consistent with the SBI-101 therapeutic hypothesis. Building on this data, SBI-101 is being investigated in COVID-19 patients suffering from severe systemic inflammation.

Sentien's technology can be applied to additional systemic inflammatory indications in both acute and chronic diseases, focusing on complex conditions where single-factor agents have not been effective. For more information, please visit www.sentienbiotech.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 stem 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, accelerating the road to discovery in Regenerative Medicine. www.roosterbio.com

About GenCure

GenCure, a subsidiary of San Antonio-based nonprofit BioBridge Global, is focused on enabling the development of cell-based therapies by providing access to source materials, cGMP biomanufacturing experience and clinical research support. Learn more at gencurebiomanufacturing.org.

About Medical Technology Enterprise Consortium

MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transactional Agreement with the U.S. Army Medical Research and Materiel Command. To find out more about MTEC, visit www.mtec-sc.org.

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