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SanBio Receives $20 Million Grant from CIRM for Stroke Clinical Trial

SanBio Group (SanBio Co., Ltd., and its subsidiary, SanBio Inc.), a scientific leader in regenerative medicine for neurological disorders, today announced it has been awarded a $20 million grant from the California Institute of Regenerative Medicine (CIRM) in support of its Phase 2b clinical trial for the treatment of chronic stroke (ACTIsSIMA), jointly sponsored with Sunovion Pharmaceuticals Inc.

CIRM is an agency of the State of California formed to accelerate the progress of regenerative medicine through a highly competitive grant program. Prospective grants are evaluated by an independent panel of the nation's top experts in regenerative medicine, as well as medical authorities on neurological disorders. The evaluation of this stroke program received CIRM's highest ranking "1".

"We welcome CIRM's support for this next phase of our clinical development," said Dr. Damien Bates, Chief Medical Officer and Head of Research at SanBio. "But equally, we appreciate this strong vote of confidence by the premier institution supporting regenerative medicine in the United States. Research and clinical development to date suggests that SB623 is a potential breakthrough in addressing the unmet medical need of chronic motor deficit in stroke patients."

Stroke is the leading cause of acquired disability in the United States. Many patients suffer from permanent loss of function. After the first six months, the possibility for further recovery through traditional therapies is minimal. Sufferers from stroke disability impose a significant burden on the health care system.

"Today the CIRM Board approved two very different methods, using different kinds of stem cells, to address this need," says Dr. Maria Millan, interim CEO and President of the agency. "By funding "multiple shots on goal" we believe that we have a better chance of finding a way to repair the damage caused by stroke and give people a better quality of life."

About SB623 and ACTIsSIMA

The ACTIsSIMA (Allogeneic Cell Therapy for Ischemic Stroke to Improve Motor Abilities) clinical trial studies the safety and efficacy of SanBio's proprietary cell-based product, SB623, in patients with chronic motor impairments resulting from ischemic stroke. Enrollment for the ACTIsSIMA study is expected to be complete in March 2018. Patients will be monitored for 12 months, with results reported in 2019. This trial follows its Phase 1/2a study, the results of which were reported in the journal *Stroke* last year.[1]

About SanBio, Inc. (SanBio)

SanBio is a regenerative medicine company headquartered in Tokyo, Japan, and Mountain View, California, with cell-based products in various stages of research, development, and clinical trials. Its proprietary cell-based product, SB623, is currently in a Phase 2b clinical trial for treatment of chronic motor impairments resulting from stroke with its joint development partner, Sumitomo Dainippon Pharma Co., Ltd., in the United States and Canada. SanBio is also implementing a global Phase 2 clinical trial in the United States and Japan using SB623 for treatment of motor impairment resulting from traumatic brain injury. More information about SanBio, Inc. is available at http://sanbio.com.

About California Institute of Regenerative Medicine (CIRM)

CIRM was created by the people of California to accelerate stem cell treatments to patients with unmet medical needs, and acts with a sense of urgency to succeed in that mission.

To meet this challenge, a team of highly-trained and experienced professionals actively partners with both academia and industry in a hands-on, entrepreneurial environment to fast track the development of today's most promising stem cell technologies.

With $3 billion in funding and approximately 300 active stem cell programs in its portfolio, CIRM is the world's largest institution dedicated to helping people by bringing the future of cellular medicine closer to reality. For more information go to www.cirm.ca.gov

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[1] Steinberg GK, et al., Clinical Outcomes of Transplanted Modified Bone Marrow-Derived Mesenchymal Stem Cells in Stroke: A Phase 1/2a Study. Stroke. 2016 Jul;47(7):1817-24