Presentation of STEMTRA Phase 2 Trial Results at the 44th Annual Meeting of the Japan Society of Neurotraumatology

Tokyo, Japan and Mountain View, Calif. - Mar. 1, 2021 - The SanBio Group (SanBio Co., Ltd. and its subsidiary SanBio, Inc.) (TSE:4592), hereby announce that Masahito Kawabori, Specially Appointed Associate Professor of the Department of Neurosurgery and Neuronal Cell Therapy, Hokkaido University Hospital presented the results of the global Phase 2 clinical trial of SB623 targeting chronic effects associated with traumatic brain injury (STEMTRA study) during Symposium 3, Brain Protection and Regenerative Medicine, of the 44th Annual Meeting of the Japan Society of Neurotraumatology commenced on the day of this release (February 26–27, 2021) in Takamatsu, Kagawa Prefecture.

Presentation date: Friday, February 26, 2021
Session: Symposium 3, Brain Protection and Regenerative Medicine
Keynote speech: Clinical trial results of intracranial administration of mesenchymal stem cells (SB623) to patients suffering from chronic effects associated with traumatic brain injury (STEMTRA study)

For the detailed program of the academic conference, please visit the following website for the 44th Annual Meeting of Japan Society of Neurotraumatology (Japanese only):
http://neurotrauma44.umin.ne.jp/index.html

STEMTRA study was a randomized, double-blind, surgical sham-controlled, global Phase 2 trial to evaluate the efficacy and safety of SB623 in patients with chronic motor deficit resulting from traumatic brain injury. The primary endpoint of the study was met, with patients who received SB623 demonstrating statistically significant improvement in motor functions compared to the control group patients who received sham surgery. Further, interim analysis based on data obtained six months after the administration of SB623 or sham surgery indicated that SB623 was highly safe and well-tolerated. The Group, based on the study results, aims to apply for manufacture and marketing approval for SB623 as a regenerative medicine product by utilizing Japan's conditional and time-limited approval system for regenerative medicine products.

The interim analysis results of the trial were published in the online issue of Neurology®, the medical journal of the American Academy of Neurology (Note 1).

Note 1: Please see the Company's press release dated January 5, 2021, "Publication of STEMTRA Phase 2 Interim Analysis for SB623 in *Neurology*®."

About Traumatic Brain Injury

Traumatic brain injury (TBI) is a leading cause of death and disability worldwide. The estimated global incidence of acute TBI during 2016 was 27 million cases, and the estimated global prevalence of chronic impairment secondary to TBI was 55.5 million cases. Overall, TBI and long-term motor deficits secondary to TBI significantly impair patients' self-care, employability, and quality of life, and are major burdens on healthcare systems worldwide. In the United States, approximately 43% of surviving hospitalized patients with TBI experience long-term motor deficits, with 5.3 million people estimated to live with long-term motor deficits secondary to TBI.

About SB623

SB623 is a proprietary, cell-based investigational product made from allogeneic modified and cultured adult bone marrow-derived mesenchymal stem cells (MSCs) that undergo temporary genetic modification. Implantation of SB623 cells into injured nerve tissue in the brain is expected to trigger the brain's natural regenerative ability to recover lost motor functions.

SanBio is preparing to file a Biologics License Application with the Pharmaceuticals and Medical Devices Agency in Japan for SB623 for the treatment of chronic motor deficits resulting from traumatic brain injury, while also making progress in its global development program. Further, the Company is working toward commencing clinical trials of SB623 for stroke in Japan. SB623 has been granted Sakigake designation for innovative medical products from the Ministry of Health, Labour, and Welfare of Japan, Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Association, and the Advanced Therapy Medicinal Product classification from the European Medicines Agency.

About SanBio Group (SanBio Co., Ltd. and SanBio, Inc.)

SanBio Group is engaged in the regenerative cell medicine business, spanning research, development, manufacture, and sales of regenerative cell medicines. The Company's propriety regenerative cell medicine product, SB623, is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from traumatic brain injury and stroke. The Company is headquartered in Tokyo, Japan and Mountain View, California, and additional information about SanBio Group is available at https://sanbio.com/en/

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