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Publication of STEMTRA Phase 2 Interim Analysis for SB623 in *Neurology*®

SanBio Co., Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori) hereby announces that the interim analysis from the SB623 Phase 2 clinical "STEM cell therapy for TRAumatic brain injury" (STEMTRA) trial that the SanBio Group (SanBio Co., Ltd. and its subsidiary SanBio, Inc.) conducted was published in the leading journal, *Neurology*®, the medical journal of the American Academy of Neurology. Please see the attached document for details.

The impact of the newly published analytical results on earnings for the current fiscal year (ending January 2021) is expected to be marginal, but the Company thinks the new findings will contribute to enhancing its performance in the medium to long term.

SanBio Announces Publication of STEMTRA Phase 2 Interim Analysis for SB623 in *Neurology*

Publication Affirms SanBio's Approach to Treating Chronic Traumatic Brain Injury Patients

Tokyo, Japan and Mountain View, Calif. - Jan. 5, 2021 - The SanBio Group (SanBio Co., Ltd. and its subsidiary SanBio, Inc.) (TSE:4592) a scientific leader in regenerative medicine for neurological disorders, today announced that the interim analysis from the Company's SB623 Phase 2 clinical "STEM cell therapy for TRAumatic brain injury" (STEMTRA) trial was published in the January 4, 2021 online issue of *Neurology*®, the medical journal of the American Academy of Neurology. The full manuscript, entitled "Cell Therapy for Chronic TBI: Interim Analysis of the Randomized Controlled STEMTRA Trial" can be accessed here.
(https://n.neurology.org/content/early/2021/01/04/WNL.0000000000011450)

STEMTRA was a Phase 2, randomized, double-blind, surgical sham-controlled, global trial evaluating the efficacy and safety of SB623 compared to sham surgery in patients with stable chronic neurological motor deficits secondary to traumatic brain injury (TBI). The study achieved its primary efficacy endpoint of significant improvement from baseline of Fugl-Meyer Motor Scale (FMMS) score at six months for SB623-treated patients. Secondary efficacy endpoints improved from baseline but were not statistically significant versus control. In the six-month, pre-specified interim analysis, treatment with SB623 cells appeared to be safe and well-tolerated. In the trial, patients were followed for efficacy and safety for up to twelve months.

"Until recently, chronic brain dysfunction was considered to be a difficult field for drug development. It is good news for this field that several start-up companies are attempting to develop new therapeutics with emergent new modalities including regenerative medicine and cell therapy. The publication of the interim analysis results of the STEMTRA trial in *Neurology* is a significant step going forward. The study data presented here show improvement in motor dysfunction associated with chronic traumatic brain injury. We are excited about the possibility of regenerative medicine and cell therapy for patients with a TBI," said Nobuhito Saito, MD, PhD, a professor of neurosurgery at the University of Tokyo.

"Traumatic brain injury is one of the leading causes of death and disability worldwide, and the treatment of long-term motor deficits secondary to TBI remains a major unmet medical need," added Masahito Kawabori MD, PhD, Specially Appointed Associate Professor, Department of Neurosurgery, Hokkaido University Hospital, Sapporo, Japan, lead author and an investigator in the STEMTRA trial. "We are encouraged by the positive data from the study in which the procedure and treatment were well-tolerated, and that patients implanted with SB623 experienced significant improvement in their motor status. Importantly, we believe publication of the STEMTRA interim results underscores the potential for cell therapy to improve the mobility for chronic TBI patients."

Bijan Nejadnik, Chief Medical Officer and Head of Research, SanBio Group, concluded, "Publication of our STEMTRA data in *Neurology* further validates our efforts to raise awareness and improve the lives of patients suffering from the long-term complications of TBI. I would like to personally thank the patients who participated in the study, our clinical trial investigators, and the authors of the manuscript for their contributions to this important work."

About the STEM cell therapy for TRAumatic brain injury (STEMTRA) Trial

STEMTRA was a 12-month, Phase 2, randomized, double-blind, surgical sham-controlled, global trial evaluating the efficacy and safety of SB623 compared to sham surgery in patients with stable chronic neurological motor deficits secondary to TBI (https://clinicaltrials.gov identifier: NCT02416492). In this study, SB623 cells were implanted directly around the site of brain injury. The primary endpoint was mean change from baseline in FMMS score at six months to measure changes in motor impairment.

To be eligible for this trial, patients (ages 18-75) must have been at least 12 months post-TBI and had a Glasgow Outcome Scale extended (GOS-E) score of 3-6 (e.g., moderate or severe disability). Patients must also have been able to undergo all planned neurological assessments and had no seizures in the prior three months. The STEMTRA trial treated 61 patients from 27 sites in the U.S., Japan and Ukraine.

In this study, SB623 met its primary endpoint, with patients treated with SB623 achieving an average 8.3-point improvement from baseline in the FMMS, versus 2.3-points in the control group, at 6 months ($p=0.040$). Of patients treated with SB623, 18 (39.1%) reached a 10 or more point improvement of FMMS compared to one control patient (6.7%; $p=0.039$). No new safety signals were identified, and the most commonly reported adverse event was headaches.

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/

Sources and data on file.

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