February 27, 2023

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Research Paper Awarded Hirakawa Prize from Japan Society of Neurotraumatology

SanBio Co., Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori) hereby announces that Masahito Kawabori, MD, PhD, of the Department of Neurosurgery, Hokkaido University Graduate School of Medicine, the lead author of a paper discussing the interim analysis of the Phase 2 STEMTRA trial on SB623 for the indication of traumatic brain injury (TBI), has been awarded the Hirakawa Prize from the Japan Society of Neurotraumatology on February 25, 2023. Please refer to the attachment for details.

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SanBio Co., Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori) hereby announces that Masahito Kawabori, MD, PhD, of the Department of Neurosurgery, Hokkaido University Graduate School of Medicine, the lead author of a paper discussing the interim analysis of the Phase 2 STEMTRA trial on SB623 for the indication of traumatic brain injury (TBI), has been awarded the Hirakawa Prize from the Japan Society of Neurotraumatology (JSNT).

The JSNT created the Hirakawa Prize to enhance research and clinical practice on neurological trauma in Japan, so that the country could play a world-leading role in the field, as advocated by the late Dr. Kimiyoshi Hirakawa, Tokyo Medical and Dental University emeritus professor. Every year, the JSNT awards the prize for an outstanding paper on neurotrauma. This year it chose “Cell Therapy for Chronic TBI: Interim Analysis of the Randomized Controlled STEMTRA Trial”[1], which was published in Neurology®, the medical journal of the American Academy of Neurology. Masahito Kawabori, MD, PhD, of the Department of Neurosurgery, Hokkaido University Graduate School of Medicine, the lead author of the paper, received the award.

Dr. Kawabori, the lead author of the award-winning paper and principal investigator of the STEMTRA trial at Hokkaido University, commented: “I think this award is testimony to the high regard the research is held in and acknowledges its significance in the search for cell therapies for a major unmet medical need—motor dysfunction in the chronic phase of traumatic brain injury. I am very pleased to have been able to contribute to the advancement of medicine in the fields of traumatic brain injury and cell therapy. I hope we can become a world leader in these fields in the future.”

About SB623

SB623 (INN: vandefitemcel) is a human (allogeneic) bone marrow-derived modified mesenchymal stem cell that is produced by modifying and culturing mesenchymal stem cells derived from the bone marrow aspirate of healthy adults. Implantation of SB623 cells into injured nerve tissues in the brain is expected to trigger the brain’s natural regenerative ability

to restore lost functions. SB623 is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from traumatic brain injury and ischemic stroke.

About Traumatic Brain Injury

Traumatic brain injury (TBI) is one of the leading causes 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.[2]

Overall, TBI and long-term motor deficits secondary to TBI significantly impair a person's self-care, employability, and quality of life, and are major burdens on healthcare systems worldwide. In the United States, approximately 43% of surviving hospitalized persons with TBI experience long-term disabilities,[3] and it is estimated that 3.17 million people are living with long-term disabilities secondary to TBI.[4]

About the STEMTRA Trial

STEMTRA was a 48-week, randomized, double-blind, surgical sham-controlled, global Phase 2 trial evaluating the efficacy and safety of SB623 in patients with chronic motor deficits secondary to traumatic brain injury. In this study, SB623 was implanted directly around the site of brain injury. The primary endpoint was mean change from baseline in Fugl-Meyer Motor Scale (FMMS) score at 24 weeks to measure changes in motor impairment. 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 point in the control group, at 24 weeks (p=0.040). The safety data showed that SB623 was well tolerated.

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/

<References>

1 Publication of STEMTRA Phase 2 Interim Analysis for SB623 in Neurology®
https://ssl4.eir-parts.net/doc/4592/tdnet/1916941/00.pdf

2 James SL, et al. “Global, regional, and national burden of traumatic brain injury and spinal cord injury, 1990- 2016: a systematic analysis for the Global Burden of Disease Study 2016.” Lancet Neurol 2019;18:56-87.
3 Selassie AW, et al. “Incidence of long-term disability following traumatic brain injury hospitalization, U.S.”, 2003. J Head Trauma Rehabil 2008;23:123-31
4 Zaloshnja E, Miller T, Langlois JA, Selassie AW. “Prevalence of long-term disability from traumatic brain injury in the civilian population of the United States, 2005.” J Head Trauma Rehabil. 2008 Nov-Dec;23(6):394-400.

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