



December 22, 2022

SanBio Co., Ltd.

Presentation of Phase 2 STEMTRA Trial Results at
The 14th World Congress on Brain Injury

SanBio Co., Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori) hereby announces that the final analysis of SB623 Phase 2 STEMTRA trial has been selected as an oral presentation abstract for the 14th World Congress on Brain Injury hosted by the International Brain Injury Association. This is a global academic conference where experts in brain injury field gather from all over the world. The conference takes place once in every two to three years and it has been three years since the last conference took place in Toronto, Canada 2019.

The presentation abstract is as following,

Title : Final analysis of the double-blind, randomized, surgical sham-controlled, Phase 2 STEMTRA Trial: 1-year safety and efficacy outcomes in patients with chronic motor deficits secondary to traumatic brain injury

Presenter : Dr. Alan H. Weintraub
Craig Hospital
Rocky Mountain Regional Brain Injury System
Associate Clinical Professor University of Colorado School of Medicine

Content : Analysis on Efficacy & Safety Data of 48 Weeks STEMTRA Trial

Date : March 29th, 2023 – April 1st, 2023

Location : The Convention Centre Dublin, Dublin, Ireland

For more information, please visit <https://braininjurycongress.org/>

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.¹

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,² and it is estimated that 3.17 million people are living with long-term disabilities secondary to TBI.³

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 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>

¹James 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.

² 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

³ 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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