June 14, 2023

Company name: SanBio Co., Ltd.
Representative: Keita Mori, Representative Director and President
(TSE Growth Code: 4592)
Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
(TEL. +81-3-6264-3481)

Further Update on Status of Manufacturing and Marketing Approval for SB623 Chronic Traumatic Brain Injury (TBI) Program in Japan

SanBio Co., Ltd. hereby provides an update on this matter as per the attached document.

The impact of this matter on the consolidated earnings forecast for the fiscal year ending January 2024 is expected to be marginal and is factored into company earnings forecasts already

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Further Update on Status of Manufacturing and Marketing Approval for SB623 Chronic Traumatic Brain Injury (TBI) Program in Japan

At the result briefing for the fiscal year ended January 2023 held on March 17, 2023, SanBio Co., Ltd. (the "Company") announced that it was working to resolve the issue of production yield, to bring yield back to the level at the time of application filing toward obtaining marketing approval of SB623 to treat chronic traumatic brain injury (TBI) in Japan during the current fiscal year ending January 2024. The Company announced that whether the issue is resolved should be known by June 2023 and will be reported at the result briefing for the first quarter of the fiscal year ending January 2024. The Company hereby provides a progress update, to ensure timely disclosure to concerned patients, their families, as well as shareholders and investors who await the approval of SB623.

SB623 is under review in the Sakigake Designation System for approval as a treatment for chronic effects associated with TBI. Toward obtaining approval, the Company is currently focused on resolving the issue related to the production yield and responding to production-related review. Although we have yet to fully recover the production yield obtained at the time of application filing, additional data from the latest production run has led to measures that could resolve the yield-related issue. A production run with implemented measures is currently underway, and results are expected in August. Although the timing of approval is outside of the Company's control, by resolving the yield-related issue and responding to production-related review in a timely manner, presently the Company's goal remains to obtain approval during the current fiscal year.

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.[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 the Sakigake Designation System

The Sakigake Designation System was unveiled in June 2014 as part of the Sakigake package strategy devised by an MHLW project team looking to lead the world in the practical application of innovative medical products. It is a scheme for priority review and rapid authorization of innovative products including pharmaceuticals, medical devices, in-vitro diagnostics and regenerative medicines originating in Japan for which exceptional effectiveness can be expected based on early-stage clinical trials.

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 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.

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.

For more information, contact:

SanBio Co., Ltd.
Management Administration
Email: info@sanbio.jp