Notice regarding completion of approval filing for Japan SB623 chronic TBI program

Tokyo, Japan and Mountain View, Calif. – March 7, 2022 - The SanBio Group (SanBio Co., Ltd. of Tokyo, Japan, SanBio, Inc. of Mountain View, California, US, and SanBio Asia Pte. Ltd. of Singapore) (TSE:4592), hereby announces the completion of an application filing today with Japan's Ministry of Health, Labour, and Welfare (MHLW) for manufacture and marketing approval as a regenerative medicine product for the investigational product SB623, as a treatment for chronic motor deficit from traumatic brain injury (TBI).

This application for approval is based on efficacy and safety results from the US-Japan global Phase 2 clinical trial (Study of Modified Stem Cells in Traumatic Brain Injury, or STEMTRA). STEMTRA is a randomized, double-blind, surgical sham-controlled trial evaluating the efficacy and safety of SB623 in patients with chronic motor deficits secondary to traumatic brain injury. In this study, SB623 met its primary endpoint, with patients treated with SB623 achieving statistically significant improvement in motor function compared with sham surgery. The trial also demonstrated that SB623 was generally safe and well tolerated.

The Japan SB623 chronic TBI program received designation for priority review from MHLW under the Sakigake Designation System, and the Company Group filed for approval within this framework, based on the comprehensive Sakigake evaluation consultations held through January 31, 2022. In addition to receiving the Sakigake designation, SB623 also was granted orphan regenerative medicine designation by the MHLW, and regenerative medicine advanced therapy (RMAT) designation by the US Food and Drug Administration (FDA).

The Company is pursuing manufacture and marketing approval for SB623 to offer a new treatment option as soon as possible to patients suffering from chronic impairment of TBI, an area of high unmet medical need.

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 pharmaceutical products originating in Japan for which exceptional effectiveness can be expected based on early-stage clinical trials. The aim is to shorten the overall review period from filing to approval to six months.

About Orphan Regenerative Medicine Designation

Based on Article 77, Paragraph 2 of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices, a regenerative medicine product is granted orphan designation if it is intended to treat a disease that affects fewer than 50,000 patients in Japan and satisfies the following criteria: (1) there is no appropriate alternative drug, medical device, regenerative medicine product, or treatment; (2) substantially higher levels of efficacy and safety are expected compared with existing drugs, medical devices, or regenerative medicine products; and (3) there is a theoretical rationale for using the regenerative medicine product in treating the target disease, and the development plan for the product is appropriate. If a regenerative medicine product is granted orphan designation, the developer in general can enjoy such benefits as priority review to ensure that the product can be used in clinical settings as soon as possible.

About SanBio

SanBio is engaged in the regenerative cell medicine business, spanning research, development, manufacture, and sales of regenerative cell medicines. SanBio targets patients with high unmet medical needs that cannot be addressed by existing medical treatments, mainly in diseases of the central nervous system. The Company is headquartered in Tokyo, Japan and has subsidiaries based in Mountain View, California, and Singapore. Additional information about SanBio Group is available at https://www.sanbio.com/en/.

Sources:

[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.

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