



January 25, 2024

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.



January 25, 2024  
SanBio Co., Ltd.

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

On December 14, 2023, SanBio Co., Ltd. (the “Company”) provided an update on the progress toward obtaining marketing approval of SB623 to treat chronic traumatic brain injury (TBI) in Japan, stating it aims to achieve approval by March 2024 and is actively engaged in the review process. Amidst this situation, the Ministry of Health, Labour and Welfare announced on January 22 that the Pharmaceutical Affairs and Food Sanitation Council's Subcommittee on Regenerative Medicine Products (the “Subcommittee”) would hold a meeting on February 5. However, our developmental product SB623, which is undergoing approval review as a treatment for TBI under the framework of the Sakigake Designation System, was not included in the agenda for this meeting. In response to this announcement, we understand that there may be patients, their families, shareholders, and investors who perceive that the Company has given up on obtaining approval. Therefore, we provide update on our current situation.

Although the timing of approval is outside of the Company’s control, we remain committed to achieving approval by March, given the ongoing review progress and the Subcommittee’s irregular meeting schedule. We are working unitedly as a company to bring you the news of the approval as soon as possible.

### **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.<sup>1</sup>

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

### **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.com](mailto:info@sanbio.com)