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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.

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SanBio Co., Ltd.

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

On March 25, our regenerative medicine product, “AKUUGO suspension for intracranial implantation,” developed as SB623, was deliberated by the Pharmaceutical Affairs and Food Sanitation Council's Subcommittee on Regenerative Medicine Products (the “Subcommittee”). The Subcommittee concluded to continue the deliberation at a later date. Following the Subcommittee meeting, the Ministry of Health, Labour, and Welfare published a summary of the deliberations, as detailed below. We regret that SB623 did not receive acceptance for approval during the meeting, thus missing our goal of regulatory approval within March. The Subcommittee recognized the clinical significance of making SB623 available for medical use; therefore, we understand that the remaining focus for approval centers on quality-related issues. We plan to engage in further consultations with the regulatory authorities and to submit additional information such as additional data addressing quality.

Below is a reprint from the Ministry of Health, Labour, and Welfare website, titled “Summary of Deliberations on AKUUGO Suspension for Intracranial Implantation at the Pharmaceutical Affairs and Food Sanitation Council's Subcommittee on Regenerative Medicine Products”:

1. Main discussions and deliberation results
The Subcommittee acknowledged the progress made to date and the future direction.
(1) On clinical issues
Provided that comparability between the investigational product and this product for commercial use is confirmed, the product is expected to demonstrate some degree of efficacy. Considering the benefits, its safety is considered acceptable. Despite the current limited data on efficacy and safety, it is deemed significant to make this product available to clinical sites.
(2) On quality issues
With the current data, it is not possible to confirm comparability between the investigational product and this product for commercial use.

2. Future plans

If additional information such as additional data are submitted by the company, the PMDA will conduct a review of such data, and the Pharmaceutical Affairs and Food Sanitation Council will deliberate again on the approval or disapproval of the product.

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 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 Oakland, 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.

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