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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.

June 20, 2024
SanBio Co., Ltd.

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

On June 12, 2024, SanBio Co., Ltd. (the "Company") provided an update on the progress toward obtaining marketing approval for the SB623 development program for chronic effects of traumatic brain injury in Japan. In the update, we notified that the Pharmaceutical Affairs and Food Sanitation Council's Subcommittee on Regenerative Medicine Products (the "Subcommittee") was scheduled to hold a meeting on June 19, and that the Subcommittee would deliberate on whether to grant the regenerative medicine "AKUUGO suspension for intracranial implantation," our pipeline product SB623, marketing approval.

In the meeting held yesterday, the Subcommittee concluded that it is possible to grant conditional and time-limited approval for "AKUUGO suspension for intracranial implantation" as a treatment for improvement of motor paralysis in the chronic phase associated with traumatic brain injury, subject to conditions and time limit for approval. Going forward, we expect to obtain official approval from the Ministry of Health, Labour and Welfare based on the results of the deliberations by the Committee

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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