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

Tokyo, Japan and Mountain View Calif. – October 20, 2022 – On July 20, 2022, Japan's Ministry of Health, Labour, and Welfare (MHLW) announced plans to convene an August 3 meeting of the Regenerative Medicine and Biotechnology Subcommittee of the Pharmaceutical Affairs and Food Sanitation Council. On July 22, SanBio provided an update on the status of manufacturing and marketing approval for the SB623 chronic traumatic brain injury (TBI) program in Japan. We now take this opportunity to deliver a further update to continue conveying information in an appropriate and timely manner to the patients and family members as well as shareholders and investors who await the product's approval.

SB623 is undergoing review in the Sakigake Designation System for the treatment of traumatic brain injury. Measures required to respond to production-related review have become more apparent and will require more time than anticipated. As a result, we now believe that approval during the current fiscal year is unlikely. While the timing for approval is outside of the company's control, SanBio pledges to continue working diligently as one team to facilitate review, to ensure that not a day is wasted in bringing approval to reality in the next 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

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. SanBio 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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