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SanBio Co., Ltd.

Positive Results of Key Development Product SB623 for Chronic Effects of Traumatic Brain Injury, including Sustained Motor Function Improvement up to 48 weeks, published in Neurology

SanBio Co., Ltd. (head office: Chuo-ku, Tokyo, representative director & CEO: Keita Mori) hereby provides notice that a paper providing more detailed data supporting results of the previously conducted Phase 2 randomized, double-blind, comparative multicenter clinical trial conducted from 2016 to 2019 of the key development product SB623 for chronic motor paralysis associated with traumatic brain injury (the "STEMTRA trial"), specifically data indicating sustained motor function improvement up to 48 weeks and improved movement in daily activities, was published in the online edition of *Neurology*, the journal of the American Academy of Neurology.

Please see the full paper titled, "Mesenchymal Stromal Cell Implants for Chronic motor paralysis after Traumatic Brain Injury: Post-hoc Analysis of a Randomized Trial," here. https://www.neurology.org/doi/10.1212/WNL.0000000000209797

This paper is a follow-up to an article titled "Cell Therapy for Chronic TBI: Interim Analysis of the Randomized Controlled STEMTRA Trial," also published in Neurology in 2021. https://n.neurology.org/content/early/2021/01/04/WNL.0000000000011450

In STEMTRA study, 63 eligible patients were randomized 1:1:1 to the SB623 low-dose group (2.5×10^6 units), SB623 medium-dose group (5.0×10^6 units) and SB623 high-dose group (10.0×10^6 units) or sham surgery group. 46 patients received SB623 and 15 patients underwent sham surgery as the control group.

The treatment group demonstrated a statistically significant improvement in motor function as measured by the change in Fugl-Meyer Motor Scale (FMMS) score from baseline at 24 weeks, the primary endpoint of the trial, compared with the control group (8.3 points [1.4] in the treatment group vs 2.3 points [2.5] in the control group, p-value=0.04). Improvement from baseline in FMMS at 48 weeks was not significantly different in the SB623-treated group overall compared with sham-operated controls, but there was significant improvement in the medium-dose group (5.0×10^6 units group) (10.5 points [1.8] in the SB623 medium-dose group and 4.1 points [1 .8], p-value=0.02). The results of the Action Research Arm Test (ARAT), walking speed, and Neuro-QOL Upper and Lower Extremity Function T-scores indicated a correlation between SB623 transplantation and improvements in motor function and movement in daily activities at 48 weeks. In addition, SB623 was well tolerated, consistent with previous results, and no new safety concerns were identified.

About SB623

SB623 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. The transplantation of AKUUGO® into damaged nerve tissues in the brain is expected to trigger the release of FGF-2 (a type of protein) and other substances, which in turn will promote the natural regenerative ability of damaged nerve cells and induce proliferation and differentiation of nerve cells. In Japan, SB623 was designated as a regenerative medicine product under the Sakigake Expedited Review System by the Ministry of Health, Labour and Welfare, and we obtained conditional and time-limited approval for our mainstay product AKUUGO® for the indication of improving chronic Motor Paralysis resulting from traumatic brain injury in July 2024. SB623 has been granted regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Association, and the Advanced Therapy Medicinal Product classification from the European Medicines Agency.

About SanBio Group (SanBio Co., Ltd. and SanBio, Inc.)

SanBio is engaged in the regenerative cell business—we research, develop, manufacture, and sell regenerative cell medicines. In July 2024, under the Sakigake Designation Program, we obtained conditional and time-limited approval for our mainstay product AKUUGO® for the indication of improving chronic Motor Paralysis resulting from traumatic brain injury. Going forward, we will continue focusing our R&D efforts on central nervous system disorders with significant unmet medical needs that cannot be addressed by existing medicine or drugs. The Company is headquartered in Tokyo, Japan and Oakland, California, and additional information about SanBio Group is available at https://sanbio.com/en/

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