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Publication of Results of Cell Implantation Location Analysis from Phase 2 Clinical Trial of Vandefitemcel (SB623) in TBI Patients (STEMTRA Trial) in Neurotrauma Reports

SanBio Co., Ltd. hereby provides on this matter as per the attached document.

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Publication of Results of Cell Implantation Location Analysis from Phase 2 Clinical Trial of Vandefitemcel (SB623) in TBI Patients (STEMTRA Trial) in Neurotrauma Reports

SanBio Co., Ltd. (Head office: Tokyo, Representative Director and President: Keita Mori) hereby announces that a research paper on the interim analysis results of the Phase 2 clinical trial of the Company's key development product SB623—human bone marrow-derived modified mesenchymal stem cells—was published in the online edition of *Neurotrauma Reports*, a U.S. journal specializing in traumatic brain injury ("TBI") on January 30, 2025.

The article, titled "Relationship Between Location of Cell Transplantation and Recovery for Intracerebral Stem Cell Transplantation for Chronic Traumatic Brain Injury: Post-hoc Analysis of STEMTRA Trial," is available via the following link.
https://www.liebertpub.com/toc/neur/6/1

Highlights

- The brain injuries responsible for motor paralysis were classified into two groups: the cortex group and the deep white matter (DWM) group.
- The study found that the correlation between the distance from the injury to the implantation site and treatment efficacy varied depending on the injury location. In the cortex group, shorter distances were associated with greater efficacy, while in the DWM group, shorter distances were linked to lower efficacy.

Dr. Masahito Kawabori, Department of Neurosurgery, Hokkaido University Graduate School of Medicine, who led the analysis gave the following comments:
"TBI-01 study suggested the potential for cellular therapeutics in treating TBI. However, the optimal location for cell transplantation remains not clear due to variations in transplanted lesions between patients. Although a larger cohort is necessary to clarify the research question, we came to the conclusion that the optimal location can be inferred based on the pattern of the brain injury site of the patient. Further data accumulation with more cases in the future will provide more detailed results on the site of administration and efficacy, which can be expected to lead to improved outcomes of cell therapy."

Shinya Hirata, Head of Research and Development, gave the following comments on the implications of the research findings for the Group's business:
"In the Guidance on Conditional and Time-Limited Approval for Regenerative Medicine and the Establishment of Post-Marketing Efficacy Evaluation Plans*, the Ministry of Health, Labour and Welfare ("MHLW") states that, unlike many conventional treatments using small-molecule drugs or biopharmaceuticals, regenerative medicine products—especially those involving surgical procedures—require careful evaluation of surgical methods. MHLW also emphasizes the need to properly inform healthcare providers about surgical techniques and key

considerations based on clinical trial results. It further underscores the importance of continuously collecting and reviewing data on surgical procedures even after obtaining marketing approval and providing updated information to healthcare professionals as new insights emerge. The latest findings on the relationship between implantation location and treatment efficacy are crucial for making AKUUGO® Suspension for Intracranial Implantation available in clinical settings and promoting its proper use. SanBio, through its ongoing research and development of vandefitemcel (SB623), which requires surgical administration, will continue to collect and review post-marketing data on surgical procedures to ensure the product's appropriate use.

**Guidance on Conditional and Time-Limited Approval for Regenerative Medicine and the Establishment of Post-Marketing Efficacy Evaluation Plans (Overview)* ①
URL: https://www.mhlw.go.jp/content/11120000/001232415.pdf

About Vandefitemcel (SB623)

Vandefitemcel (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 implantation 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, vandefitemcel (SB623) was designated as a regenerative medicine product under the Sakigake Expedited Review System by the Ministry of Health, Labour and Welfare. At a meeting held in June 2024, the Pharmaceutical Affairs Council's Subcommittee on Regenerative Medicine Products determined that it was possible to grant vandefitemcel (SB623), "AKUUGO® suspension for intracranial implantation," conditional and time-limited approval for the improvement of chronic motor deficit in the chronic phase of traumatic brain injury. Vandefitemcel (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 the STEM cell therapy for TRAumatic brain injury (STEMTRA) Trial

STEMTRA was a 12-month, Phase 2, randomized, double-blind, surgical sham-controlled, global trial evaluating the efficacy and safety of SB623 compared to sham surgery in patients with stable chronic neurological motor paralysis secondary to TBI. 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 SanBio

SanBio was founded in California, the US in 2001 with the vision of becoming a global leader in the field of regenerative medicine, and is engaged in the regenerative cell business—we research, develop, manufacture, and sell regenerative cell medicines. On July 31st 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 associated with 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/

[Disclaimer]

This document may contain forward-looking statements such as forecasts, outlooks, goals, and plans related to SanBio Group (SanBio Co., Ltd. and SanBio, Inc.). These statements are based on information available to the Company at the time of preparation of this document, including forecasts and other projections. In addition, certain assumptions (hypotheses) are used in making these statements. These statements or assumptions are subjective and may prove to be incorrect in the future or may not be realized in the future. There are several uncertainties and risks that could cause this to happen. Please refer to our financial statements and annual reports for additional information on these matters. The forward-looking statements in this document speak only as of the date of this document (or as otherwise indicated therein), as described above, and we have no obligation or policy to update such information from time to time to keep it current.

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