December 9, 2025

Company name:	SanBio Co., Ltd. (Code: 4592 TSE Growth)
Name of representative:	Keita Mori, Representative Director and President
For inquiries, contact:	Yoshihiro Kakutani, Corporate Officer of Management Administration (Phone: 03-6264-3481)

SanBio Obtains Partial Change Approval for "AKUUGO® Suspension for Intracranial Implantation"

SanBio Co., Ltd. (head office: Tokyo, representative director & CEO: Keita Mori, the "Company") hereby announces that the Ministry of Health, Labour and Welfare (MHLW) has approved a partial change to the marketing authorization for the product "AKUUGO® suspension for intracranial implantation" (INN: vandefitemcel; hereafter, "AKUUGO®") and has revised the associated approval conditions.

Following the NHI price listing, the Company plans to launch AKUUGO®. AKUUGO® is the world's first regenerative therapy for the brain. It was granted conditional and time-limited approval in Japan in July 2024 — the first such approval in the world — as a treatment for chronic motor paralysis associated with traumatic brain injury.

【Explanation of Approval Conditions】

AKUUGO® received conditional and time-limited marketing authorization on July 31, 2024, with the following four conditions attached. Today, the MHLW approved a partial change lifting Condition ①, which had imposed restrictions on product shipment. Please note that AKUUGO® remains approved under the conditional and time-limited framework, and the Company continues to plan to obtain full approval within the seven-year period following the initial approval granted last year.

[Approval Conditions as Revised on December 8, 2025]
(Previous Conditions)

① Considering the limited manufacturing record for the Product, the Company shall promptly collect information on the Product's quality based on a pre-determined plan, and evaluate and report on the equivalence/homogeneity, in terms of quality, of the investigational product (clinical trials product) and the Product intended for commercial distribution. Based on the evaluation results, the Company shall apply for a partial change of approved matters. It shall not ship the Product until the partial change application has been approved.

② The Company must ensure that the Product is used in medical facilities fully equipped to handle emergencies, by physicians who possess sufficient knowledge and experience in the diagnosis and treatment of traumatic brain injury and stereotactic brain surgery techniques. The physicians must also have sufficient knowledge of the clinical trial results and adverse events of the Product.

③ Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must conduct post-marketing

evaluation of all cases where the Product is used.

④ Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must collect information on the biological characteristics reflecting the mechanisms of action of the Product and take necessary measures, such as improving its quality control strategy.

Future Outlook

Going forward, in line with our medium- to long-term growth strategy, we will advance business activities targeting traumatic brain injury in the U.S. market. Regarding our traumatic brain injury program, we have already reached agreement with the U.S. Food and Drug Administration (FDA) on the Phase 3 clinical trial design, and preparations for the clinical trial are scheduled to begin in the next fiscal year. In Japan, we also plan to initiate discussions with regulatory authorities regarding clinical trials for our stroke program in the next fiscal year. The Company aims to become a global leader in the field of regenerative medicine and will continue to strive to maximize corporate value.

We recognize that the impact of this matter on the current fiscal year’s business results is minimal.

December 9, 2025
SanBio Co., Ltd.

SanBio Obtains Partial Change Approval for "AKUUGO® Suspension for Intracranial Implantation"

SanBio Co., Ltd. (head office: Tokyo, representative director & CEO: Keita Mori, the "Company") hereby announces that the Ministry of Health, Labour and Welfare (MHLW) has approved a partial change to the marketing authorization for the product "AKUUGO® suspension for intracranial implantation" (INN: vandefitemcel; hereafter, "AKUUGO®") and has revised the associated approval conditions.

Following the NHI price listing, the Company plans to launch AKUUGO®. AKUUGO® is the world's first regenerative therapy for the brain. It was granted conditional and time-limited approval in Japan in July 2024 — the first such approval in the world — as a treatment for chronic motor paralysis associated with traumatic brain injury.

【Explanation of Approval Conditions】

AKUUGO® received conditional and time-limited marketing authorization on July 31, 2024, with the following four conditions attached. Today, the MHLW approved a partial change lifting Condition ①, which had imposed restrictions on product shipment. Please note that AKUUGO® remains approved under the conditional and time-limited framework, and the Company continues to plan to obtain full approval within the seven-year period following the initial approval granted last year.

[Approval Conditions as Revised on December 8, 2025]

(Previous Conditions)

① Considering the limited manufacturing record for the Product, the Company shall promptly collect information on the Product's quality based on a pre-determined plan, and evaluate and report on the equivalence/homogeneity, in terms of quality, of the investigational product (clinical trials product) and the Product intended for commercial distribution. Based on the evaluation results, the Company shall apply for a partial change of approved matters. It shall not ship the Product until the partial change application has been approved.

② The Company must ensure that the Product is used in medical facilities fully equipped to handle emergencies, by physicians who possess sufficient knowledge and experience in the diagnosis and treatment of traumatic brain injury and stereotactic brain surgery techniques. The physicians must also have sufficient knowledge of the clinical trial results and adverse events of the Product.

③ Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must conduct post-marketing evaluation of all cases where the Product is used.

④ Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must collect information on the biological characteristics reflecting the mechanisms of action of the Product and take necessary measures, such as improving its quality control strategy.

Future Outlook

Going forward, in line with our medium- to long-term growth strategy, we will advance business activities targeting traumatic brain injury in the U.S. market. Regarding our traumatic brain injury program, we have already reached agreement with the U.S. Food and Drug Administration (FDA) on the Phase 3 clinical trial design, and preparations for the clinical trial are scheduled to begin in the next fiscal year. In Japan, we also plan to initiate discussions with regulatory authorities regarding clinical trials for our stroke program in the next fiscal year. The Company aims to become a global leader in the field

About "AKUUGO® suspension for intracranial implantation"

AKUUGO® suspension for intracranial implantation(INN: vandefitemcel) is an allogeneic, human bone marrow–derived mesenchymal stem cell product manufactured by culturing and processing mesenchymal stromal cells derived from the bone marrow fluid of healthy adult donors. When transplanted into damaged neural tissue in the brain, it releases fibroblast growth factor-2 (FGF-2), a type of protein that is expected to stimulate the brain's inherent regenerative capacity by promoting the proliferation and differentiation of neural cells. Vandefitemcel (SB623) has been designated by Japan's Ministry of Health, Labour and Welfare (MHLW) as a regenerative medical product under the Sakigake Designation System. In the United States, it has been granted Regenerative Medicine Advanced Therapy (RMAT) designation by the U.S. Food and Drug Administration (FDA), and in Europe, it has been designated as an Advanced Therapy Medicinal Product (ATMP) by the European Medicines Agency (EMA).

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 deficit 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/

For more information, contact:
SanBio Co., Ltd.
Management Administration
Email: info@sanbio.com