June 25, 2025

Company name:	SanBio Co., Ltd. (Code: 4592 TSE Growth)
Name of representative:	Keita Mori, Representative Director and President
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Notice Regarding Revision of Expected Approval Timing for Partial Changes to AKUUGO® Suspension for Intracranial Implantation

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

June 25, 2025
SanBio Co., Ltd.

Notice Regarding Revision of Expected Approval Timing for Partial Changes to AKUUGO® Suspension for Intracranial Implantation

SanBio Co, Ltd. (Head office: Tokyo, Representative Director and President: Keita Mori) announced on June 12, 2025, that the Company had completed filing a partial change application of marketing approval of AKUUGO® Suspension for Intracranial Implantation (INN: vandefitemcel), and expected shipments of AKUUGO® to commence in the second quarter of the fiscal year ending January 31, 2026 (May–July 2025).

As a result of submitting the application, the Company now has greater visibility into the process leading to approval. Going forward, the application will be reviewed by the regulatory authorities and the committee, with approval expected in the second half of the fiscal year ending January 2026 (August2025–January 2026). Following reimbursement pricing approval, AKUUGO® is planned to be launched.

This matter will have only a minimal impact on the financial performance of the current fiscal year.

About "AKUUGO® suspension for intracranial implantation"

AKUUGO® suspension for intracranial implantation (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. 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.

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 31 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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