



October 2, 2025

Company name:	SanBio Co., Ltd. (Code: 4592 TSE Growth)
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**Notice Regarding Inclusion of AKUUGO® Suspension for Intracranial Implantation on the Committee Agenda**

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



October 2, 2025  
SanBio Co., Ltd.

## **Notice Regarding Inclusion of AKUUGO® Suspension for Intracranial Implantation on the Committee Agenda**

SanBio Co, Ltd. (Head office: Tokyo, Representative Director and President: Keita Mori) announced on June 25, 2025, that the Company had completed filing a partial change application of marketing approval of AKUUGO® Suspension for Intracranial Implantation (INN: vandefitemcel), and 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).

Today, the Ministry of Health, Labour and Welfare announced that the Pharmaceutical Affairs and the Subcommittee will hold a meeting on October 16, and we learned that the Subcommittee will deliberate, among others, on whether to grant a partial change application of marketing approval for the regenerative medicine “AKUUGO suspension for intracranial implantation”.

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 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.

**For more information, contact:**

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