



June 12, 2025  
SanBio Co., Ltd.

## **Notice of Completion of Application for Partial Change Approval of AKUUGO® Suspension for Intracranial Implantation**

SanBio Co, Ltd. (Head office: Tokyo, Representative Director and President: Keita Mori) announced on May 29, 2025, that the third manufacturing run of AKUUGO® Suspension for Intracranial Implantation (INN: vandefitemcel), cleared all specification requirements and was deemed compliant as well, regarding the three production runs required for the release of shipments.

Accordingly, we hereby announce that today we have completed filing a partial change application of marketing approval of AKUUGO®. If the application is approved, one of the conditions will be revised, allowing the product to become eligible for shipment. While the judgment depends on the regulatory authorities, we continue to expect shipments of AKUUGO® to commence in the second quarter of the fiscal year ending January 31, 2026 (May–July 2025), in line with our previous projections.

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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