February 6, 2025
SanBio Co., Ltd.

The Results of the Second Commercial Production Run to Meet the Approval Conditions for the Shipment of AKUUGO® Suspension for Intracranial Implantation

SanBio Co, Ltd. (Head office: Tokyo, Representative Director and President: Keita Mori) announced on December 6, 2024, that it had successfully secured the planned production yield for the second commercial production run of AKUUGO® Suspension for Intracranial Implantation (INN: vandefitemcel), conducted to meet the shipment conditions required for obtaining product approval. The Company has completed specification testing and characteristic analysis for the second manufacturing run and has confirmed its results.

The second manufacturing run cleared all specification requirements and was deemed compliant. The third manufacturing run has already commenced.

With the compliance of this manufacturing run, the company will run one more manufacturing compliant with necessary specifications and plans to file a partial change application and subsequently obtain approval for the partial change to meet the shipment conditions.

As a result, the anticipated timing for AKUUGO® to become eligible for shipment remains unchanged, with shipment expected to begin in the second quarter of the fiscal year ending January 31, 2026 (May–July 2025).

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/

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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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