November 15, 2024

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

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

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SanBio Co., Ltd.

The Results of the First 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 & CEO: Keita Mori) announced on July 31, 2024, that it had obtained conditional and time-limited approval for AKUUGO® suspension for intracranial implantation from the Ministry of Health, Labour and Welfare and that it planned to conduct about two commercial production runs to meet the shipment conditions required under this approval. We hereby provide the results of the first production run.

The first production run did not meet the specification standards. However, only one specification value was non-compliant, while all other specification values, including the yield—a key issue identified during the approval review process—were compliant. Moreover, the results of the characterization analysis were equivalent to those of the clinical trials product. We anticipated some non-conforming products due to batch-to-batch variability arising from the heterogeneity of cells, a critical raw material for AKUUGO®, and we consider the non-conformity of the first manufacturing lot to be within our expectations.

Regarding the outlook, since the manufacturing process has already been established and approved, we have commenced the second production run. After obtaining manufacturing results that conform to the specifications for the second time, we will file an application for a partial change and aim to obtain approval for the subsequent partial change.

As a result, the expected timeline for completing the two commercial production runs required to begin shipments of AKUUGO® has been delayed by a quarter, from the first quarter of the fiscal year ending January 2026 (February–April 2025) to the second quarter of the same fiscal year (May–July 2025).

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 Group (SanBio Co., Ltd. and SanBio, Inc.)

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 31th 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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