December 6 2024
SanBio Co., Ltd.

The Yield Results of the Second Commercial Production Run for AKUUGO® Suspension for Intracranial Implantation

SanBio Co., Ltd. (head office: Tokyo, representative director & CEO: Keita Mori), announced in a press release dated November 15, 2024, the results of the first commercial production run for AKUUGO® suspension for intracranial implantation, as well as the commencement of the second commercial production run. We hereby inform you that the second production run has now been completed and the yield results have been confirmed.

We successfully obtained the expected yield from the second commercial production run. If all standards are met in specification testing and characteristic analysis, the second production run will be deemed compliant with the required specifications. It will take several months to obtain the results of the specification tests and characteristic analysis.

Our previous outlook remains unchanged. Once compliant production results are obtained from two commercial production runs, we will apply for partial changes to the terms of approval and work toward securing the approval. The expected timeline for the start of shipments remains the second quarter (May–July 2025) of the fiscal year ending January 31, 2026.

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 implantation 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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For more information, contact:
SanBio Co., Ltd.
Management Administration
Email: info@sanbio.com