

September 25, 2024

Company name: SanBio Co., Ltd.

Representative: Keita Mori, Representative

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Notice Concerning Today's Meeting of the Pharmaceutical Affairs Council

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



September 25, 2024 SanBio Co., Ltd.

Notice Concerning Today's Meeting of the Pharmaceutical Affairs Council

SanBio Co., Ltd. (head office: Tokyo, representative director & CEO: Keita Mori) hereby announces that today the Fourth Meeting of the Pharmaceutical Affairs Council for FY2024 was held at the Ministry of Health, Labour and Welfare. During the meeting, a report was made on the results of deliberations by the Subcommittee on "AKUUGO® suspension for intracranial implantation", which was approved by the Pharmaceutical Affairs Council's Subcommittee on Regenerative Medicine Products and obtained conditional and time-limited marketing approval on July 31, 2024. We announce that no special discussion was held on the contents of this report.

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/

For more information, contact:

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Management Administration
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