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Notice Regarding the First Post-Marketing Administration of AKUUGO® Suspension for Intracranial Implantation

Please see the attached press release for details regarding the above matter.

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SanBio Co., Ltd.

Notice Regarding the First Post-Marketing Administration of AKUUGO® Suspension for Intracranial Implantation

SanBio Co., Ltd. (head office: Tokyo, Japan; Representative Director and President: Keita Mori; hereinafter “SanBio”) hereby announces that AKUUGO® Suspension for Intracranial Implantation (INN: vandefitemcel; “AKUUGO®”), a cell therapy indicated for the improvement of chronic motor paralysis associated with traumatic brain injury, was administered to a patient at Hokkaido University Hospital for the first time since its launch.

This marks the first use of AKUUGO® in clinical practice following its manufacturing and marketing approval in July 2024 and its launch in May 2026.

Overview of the administration

- Medical institution: Hokkaido University Hospital
- Date of administration: Friday, October 2, 2026
- Indication: Chronic motor paralysis associated with traumatic brain injury
- Product: AKUUGO® Suspension for Intracranial Implantation

AKUUGO® was administered at Hokkaido University Hospital following the prescribed procedures. The hospital will continue to carefully monitor the patient’s postoperative progress.

Comment from Keita Mori, Representative Director and President

We find it deeply meaningful that AKUUGO® has been administered to its first commercial patient at Hokkaido University Hospital. After obtaining manufacturing and marketing approval in July 2024 and launching the product in May 2026, we have now seen AKUUGO® used to treat a patient in actual clinical practice, which marks an important milestone for SanBio.

We extend our heartfelt gratitude to the medical professionals at Hokkaido University Hospital and other institutions, as well as everyone else involved, for their dedicated efforts in making this administration possible. SanBio will continue its efforts to promote the proper use and ensure the stable supply of AKUUGO®, so that it can be made available as an appropriate treatment option to the patients who need it.

About traumatic brain injury

Traumatic brain injury (TBI) is one of the leading causes of death and disability worldwide. In 2016, there were an estimated 27 million new cases of acute TBI and an estimated 55.5 million people living with chronic disability secondary to TBI¹. TBI and the long-term motor impairment secondary to TBI significantly affect patients’ independence, employment, and quality of life (QOL), placing a heavy burden on healthcare systems in many countries from both social and economic perspectives. In the U.S., approximately 43% of surviving patients hospitalized for TBI experience long-term motor impairment², and an estimated 3.17 million people are living with long-term motor impairment secondary to TBI³.

About AKUUGO® Suspension for Intracranial Implantation

AKUUGO® Suspension for Intracranial Implantation is an allogeneic, human bone marrow-derived modified mesenchymal stem cell product (INN: vandefitemcel) produced by processing and culturing mesenchymal stromal cells derived from the bone marrow aspirate of healthy adults. When implanted into damaged neural tissue in the brain, it releases FGF-2 (a type of protein), which is suggested to stimulate the innate regenerative capacity of damaged neurons and promote their proliferation and differentiation. Vandefitemcel (SB623) was designated as a regenerative medicine product under the SAKIGAKE Designation System by Japan’s Ministry

of Health, Labour and Welfare, and obtained conditional and time-limited manufacturing and marketing approval on July 31, 2024. In the U.S., it has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA), and in Europe, it has received Advanced Therapy Medicinal Product (ATMP) classification from the European Medicines Agency (EMA).

About SanBio

Founded in California, U.S., in 2001 with the vision of becoming a global leader in the field of regenerative medicine, SanBio is engaged in the research, development, manufacture, and sale of regenerative medicine products. SanBio focuses its research, development, and commercialization efforts primarily on central nervous system disorders with high unmet medical needs that cannot be addressed by existing medical treatments or pharmaceuticals. Further information about the SanBio Group, headquartered in Tokyo with a subsidiary in California, is available at <https://www.sanbio.com/en/>.

<References>

- ^{1.} James SL, et al. Global, regional, and national burden of traumatic brain injury and spinal cord injury, 1990-2016: a systematic analysis for the Global Burden of Disease Study 2016. *Lancet Neurol.* 2019; 18: 56-87.
- ^{2.} Selassie AW, et al. Incidence of long-term disability following traumatic brain injury hospitalization, U.S., 2003. *J Head Trauma Rehabil.* 2008; 23: 123-31.
- ^{3.} Zaloshnja E, Miller T, Langlois JA, Selassie AW. Prevalence of long-term disability from traumatic brain injury in the civilian population of the United States, 2005. *J Head Trauma Rehabil.* 2008 Nov-Dec; 23(6): 394-400.

For inquiries regarding this matter

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