November 16, 2026
SanBio Co., Ltd.

Notice Regarding the First Administration of AKUUGO® Suspension for Intracranial Implantation at Okayama University Hospital

—Second Post-Marketing Administration—

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 Okayama University Hospital on October 27, 2026, marking the first use of AKUUGO® at the hospital. This is the second post-marketing administration of AKUUGO®, following the first at Hokkaido University Hospital on October 2, 2026. AKUUGO® was administered at Okayama University Hospital following the prescribed procedures, and the hospital will continue to carefully monitor the patient's postoperative progress.

Overview of the administration
- Medical institution: Okayama University Hospital
- Date of administration: Tuesday, October 27, 2026
- Indication: Chronic motor paralysis associated with traumatic brain injury
- Product: AKUUGO® Suspension for Intracranial Implantation

Dr. Shota Tanaka of Okayama University Hospital commented on the administration as follows:

"We are deeply moved to have been able to administer AKUUGO® at Okayama University Hospital. Treatment options for chronic motor paralysis associated with traumatic brain injury have been limited until now, so we believe it is of great significance that access to a new treatment is expanding for patients with this condition. Looking ahead to a future in which this treatment is widely available to the patients who need it, Okayama University Hospital is committed to contributing to its further development and adoption."

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 TBI[1]. 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 impairment[2], and an estimated 3.17 million people are living with long-term motor impairment secondary to TBI[3].

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

Management Administration, SanBio Co., Ltd.
Email: info@sanbio.com