June 3, 2026
SanBio Co,. Ltd.

Notice Regarding the Launch of AKUUGO®, a New Treatment Option for Chronic Motor Paralysis Following Traumatic Brain Injury

SanBio Co., Ltd. (head office: Tokyo, Japan; president & CEO: Keita Mori; hereinafter the "Company") hereby announces that on May 21 it has launched AKUUGO® Suspension for Intracranial Implantation (INN: vandefitemcel; "AKUUGO®"), a cell therapy product indicated for the improvement of chronic motor paralysis associated with traumatic brain injury ("TBI").

TBI is a condition in which strong external force applied to the head, such as from traffic accidents or falls, impairs brain function[1]. The symptoms and their severity are reported to vary depending on the location and extent of the injury[1, 2]. TBI is now recognized not merely as a transient injury, but as a chronic condition associated with functional impairment that can have long-term effects on physical function, cognitive function, and social life, representing a significant unmet medical need.

AKUUGO® is a cell therapy product for chronic motor paralysis associated with TBI and received conditional and time-limited approval in Japan in July 2024. The product is manufactured by culturing mesenchymal stem cells derived from the bone marrow of healthy donors and introducing the human Notch-1 intracellular domain gene to enhance neuroregenerative capacity. Following implantation into damaged neural tissue in the brain, factors such as FGF-2 (a type of protein) are released and are believed to enhance the intrinsic regenerative capacity of damaged neural cells while stimulating their proliferation and differentiation[3, 4].

Keita Mori, President & CEO of the Company, commented:
"Twenty-five years after our founding in California, we are truly pleased to provide a new treatment option to TBI patients in Japan. We view this achievement as a new starting point and will continue to execute our growth strategy focused on expanding into the U.S. market and developing additional indications, including ischemic stroke, with the goal of bringing hope and improving the lives of as many patients with TBI or ischemic stroke, and their families, as possible."

In addition, on the same day, SanBio has launched a Cell Therapy Telephone Consultation Service for patients and a dedicated website for healthcare professionals to promote the proper use of AKUUGO®. The Company will continue to develop an environment in which patients requiring AKUUGO® can access appropriate medical institutions, while also establishing systems to support proper use and facilitate the smooth adoption in clinical practice.

Establishment of a Cell Therapy Telephone Consultation Service (for Patients and Families)

For patients suffering from chronic motor paralysis associated with TBI, it has been noted that in some cases access to appropriate medical care may be difficult, including difficulty identifying medical institutions capable of providing cell therapy. In light of this situation, the Company has established a telephone consultation service to support patients who wish to receive or are considering treatment with AKUUGO® by helping them better understand cell therapy, the treatment process, and how to consult appropriate medical institutions. This consultation service is not intended to recommend any specific treatment, nor does it provide individual diagnoses, treatment recommendations, or determinations regarding eligibility for treatment with AKUUGO®. Rather, it is intended to provide patients with appropriate information to support consultations with medical institutions.

Cell Therapy Telephone Consultation Service

- Eligible Users: Patients and family members
- Toll-free number: 0120-653481
- Hours: 9:00 a.m.–6:00 p.m. weekdays (excluding weekends and holidays)
  * Please note that callers may experience difficulty getting through during busy periods, as only one phone

line is available.

Launch of a Dedicated Website for Healthcare Professionals

The Company has launched a dedicated website for healthcare professionals to provide information on AKUUGO® and support medical collaboration. As an information platform, the website primarily includes the following content. The Company has also established a Medical Information Center to respond to product information inquiries and other questions from healthcare professionals regarding AKUUGO®. Details, including the telephone number, are available on the website. Please note that access to the website is restricted to healthcare professionals and is not available to patients, family members, or the general public.

Website for Healthcare Professionals（https://akuugo.jp/）

- Basic information on AKUUGO® (clinical trial and other information materials)
- List of medical institutions administering AKUUGO® treatment
- Requirements for treatment facilities and e-learning content for institutions seeking designation as AKUUGO® treatment facilities
- Physician and cell preparation requirements related to administration of AKUUGO®

End

Reference Information

Product overview

Brand name	AKUUGO® Suspension for Intracranial Implantation
INN	Vandefitemcel
Indication	Improvement of chronic motor paralysis associated with traumatic brain injury
NHI price	72,716,528 yen
Dosage and administration	In adults, implant 300μL of a cell preparation containing 5 x 10^6 viable human (allogeneic) bone marrow-derived mesenchymal stem cells into the peri-lesional area of the damaged brain tissue by stereotactic surgery using the dedicated administration device set. Through three implantation trajectories extending from a single burr hole in the skull to the peri-lesional area, administer 100μL of the cell suspension per trajectory at five sites spaced 5–6mm apart, starting from the deepest point, with 20μL administered at each site. The infusion rate should be approximately 10μL/min. Perform the following procedures during implantation. 1. Prior to surgery, attach the guide-and-stop assembly and the stylet-equipped inserter of the dedicated administration device set to the invasive neurosurgical head fixation device. 2. Thaw the intracerebral implantation cell product and wash it using the dedicated preparation solution. Prepare the product with the dedicated preparation solution to achieve an implantation concentration of 1.67 x 10^6 cells/100μL, thereby creating the cell suspension. After cleansing the microsyringe fitted with the administration cannula of the dedicated administration device set using the dedicated preparation solution, load the cell suspension into the microsyringe.
Summary of efficacy evaluation	International Phase 2 clinical trial (TBI-01 study: the U.S., Japan, and Ukraine) Multicenter, randomized, double-blind, sham surgery-controlled study in which subjects were randomized in a 3:1 ratio to the product group or the sham surgery group (product group: 2.5 x 10^6 cell group, 5.0 x 10^6 cell group, and 10.0 x 10^6 cell group). Study results Efficacy: For the primary endpoint, the change from baseline in FMMS at Week 24 was 8.3 ± 10.6 in the pooled SB623 group (n = 46) across all dose cohorts, compared with 2.3 ± 4.7 in the sham surgery group (n = 15), with a statistically significant difference observed between the groups (mean ± standard deviation; p = 0.0401).
Date of marketing approval	July 31, 2024

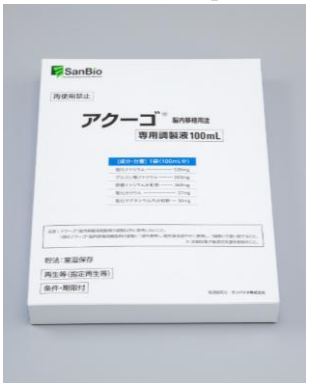
Product image

Vial containing cell suspension

Dry shipper

Hard case for transportation

Dedicated preparation solution 100mL
(single-unit package)



Dedicated preparation solution 100mL
(commercial package)

Dedicated delivery device set

Dedicated delivery device set
(commercial package)

About Traumatic Brain Injury (TBI)

TBI is one of the leading causes of death and disability worldwide. In 2016, the estimated number of new TBI cases globally was 27 million, while the estimated number of people living with chronic disabilities resulting from TBI was 55.5 million[5]. TBI and the long-term motor impairment resulting from it can severely compromise patients' independence, employment, and quality of life (QOL), while also imposing a substantial burden on healthcare systems from both social and economic perspectives. In the U.S., approximately 43% of patients hospitalized for TBI who survive experience long-term motor impairment[6], and an estimated 3.17 million people are living with persistent motor impairment resulting from TBI.[7]

About AKUUGO® Suspension for Intracranial Implantation

AKUUGO® is an allogeneic human bone marrow-derived modified mesenchymal stem cell product (INN: vandefitemcel) manufactured by processing and culturing mesenchymal stem cells derived from the bone marrow of healthy adult donors. When implanted into damaged neural tissue in the brain, the product is believed to release FGF-2 (a type of protein), enhancing the intrinsic regenerative capacity of damaged neural cells while stimulating their proliferation and differentiation. Vandefitemcel (SB623) was designated as a regenerative medicine product under Japan's Sakigake Designation System by the Ministry of Health, Labour and Welfare (MHLW) and received conditional and time-limited marketing approval on July 31, 2024. In the U.S., vandefitemcel has received Regenerative Medicine Advanced Therapy (RMAT) designation from the U.S. Food and Drug Administration (FDA). In Europe, it has been designated as an Advanced Therapy Medicinal Product (ATMP) by the European Medicines Agency (EMA).

About SanBio

Founded in California, U.S., in 2001 with the vision of becoming a global leader in regenerative medicine, SanBio is engaged in the R&D, manufacturing, and commercialization of regenerative medicine products. The Company focuses primarily on central nervous system disorders, where existing medical treatments and pharmaceuticals are unable to adequately address significant unmet medical needs, and is advancing R&D and commercialization efforts in these fields. For more information about the SanBio Group, which is headquartered in Tokyo and has a subsidiary in California, please visit https://www.sanbio.com/en/.

<References>

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