May 20, 2026

Company name: SanBio Co., Ltd.
(Code: 4592 TSE Growth)
Name of Representative: Keita Mori, Representative Director and President
For inquiries, contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
(Phone: 03-6264-3481)

Notice Regarding NHI Price Listing of AKUUGO® Suspension for Intracranial Implantation

SanBio Co., Ltd. (head office: Tokyo, Japan; president & CEO: Keita Mori; hereinafter the "Company") hereby announces that AKUUGO® Suspension for Intracranial Implantation (INN: vandefitemcel; "AKUUGO®") was listed today on the National Health Insurance (NHI) drug price standard in Japan.

In the "Notice Concerning Chuikyo Approval of Proposed NHI Price for AKUUGO® and Revision of Consolidated Earnings Forecast for FY Ending Jan. 2027" dated May 13, 2026, the Company disclosed that the Central Social Insurance Medical Council (the "Chuikyo") had approved the proposed NHI price for AKUUGO®. With today's official publication in the Official Gazette, the final NHI price and reimbursement coverage under Japan's public health insurance system have now been formally confirmed.

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 5–6 mm 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 a transplantation 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

Outlook

Following this NHI price listing, the Company plans, as previously announced, to initially launch AKUUGO® primarily at medical institutions that participated in the product's clinical trials, while carefully establishing a coordinated healthcare framework encompassing patient care from administration through rehabilitation and proceeding with a phased market rollout. First shipments are expected to commence in the second half of the fiscal year (August 2026 to January 2027), as medical institutions will require a certain amount of time to complete internal procedures for the adoption of AKUUGO®. In addition, the Company intends to steadily and safely conduct the required post-marketing clinical trials and post-marketing surveillance during the seven-year conditional and time-limited approval period, with the aim of obtaining full approval.

As a next step after the NHI price listing, the Company will accelerate a project to expand AKUUGO®'s current indication for traumatic brain injury globally, including in the U.S., as well as into additional indications such as ischemic stroke. As the Company has already announced, the Company has reached an agreement with the U.S. Food and Drug Administration (FDA) on the design of a Phase 3 clinical trial for traumatic brain injury in the U.S. and is currently preparing to initiate the study. In Japan, discussions with the Pharmaceuticals and Medical Devices Agency (PMDA) regarding the ischemic stroke program are also planned, and preparations for the initiation of clinical trials are underway. Through these initiatives, SanBio aim to ensure its medium-to long-term growth opportunities.

End