June 27 2024

Company name: SanBio Co., Ltd.
Representative: Keita Mori, Representative Director and President
(TSE Growth Code: 4592)
Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
(TEL. +81-3-6264-3481)

Further Update on Regarding Reports on "AKUUGO Suspension for Intracranial Implantation"

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

June 27, 2024
SanBio Co., Ltd.

Further Update on
Regarding Reports on "AKUUGO® Suspension for Intracranial Implantation"

Following our announcement on June 20th last week, entitled "Regarding Reports on 'AKUUGO® Suspension for Intracranial Implantation'", we have received numerous inquiries from patients, members of the press, investors and others. Below, we summarize these inquiries and provide our responses.

Q1: Why was AKUUGO® suspension for intracranial implantation (hereinafter, "AKUUGO®") approved in June, following its initial deferment in March?
A1. We have submitted additional data after March deliberation, namely data from property analysis separate from specification testing for AKUUGO®. The reviewing authority granted approval after evaluating this data. Moving forward, in addition to conducting about two production runs and performing specification testing, we plan to conduct characteristic analysis similar to the additional data analysis, results of which were submitted after the March deliberation. We will be able to ship the product after obtaining approval for partial changes to the terms of approval (hereinafter, "partial change approval").

Q2. This approval is considered unusual. In what respect are the approval conditions unusual?
A2. The unusual aspect of this approval is the condition attached to shipment, namely, approval condition (1) below. We recognize that conditions (2) through (4) are typically seen in conditional and time-limited approvals.

1. Considering the limited manufacturing record for the Product, the Company shall promptly collect information on the Product's quality based on a pre-determined plan, and evaluate and report on the equivalence/homogeneity, in terms of quality, of the investigational product (clinical trials product) and the Product intended for commercial distribution. Based on the evaluation results, the Company shall apply for a partial change of approved matters. It shall not ship the Product until the partial change application has been approved.
2. The Company must ensure that the Product is used in medical facilities fully equipped to handle emergencies, by physicians who possess sufficient knowledge and experience in the diagnosis and treatment of traumatic brain injury and stereotactic brain surgery techniques. The physicians must also have sufficient knowledge of the clinical trial results and adverse events of the Product.
3. Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must conduct post-marketing evaluation of all cases where the Product is used.
4. Until the Company re-applies for marketing approval for the Product prior to the expiration of the conditional and time-limited approval, the Company must collect information on the biological characteristics reflecting the mechanisms of action of the Product and take

necessary measures, such as improving its quality control strategy.

Q3. You have stated you will make preparations in anticipation of shipments and sales of AKUUGO® becoming possible in the first quarter of the fiscal year ending January 2026 (February to April 2025). Specifically, what are you doing to prepare for this?
A3. Going forward, we plan to promptly run around two rounds of commercial production to build inventories in preparation for launch, gauging the equivalence/homogeneity between the commercial product and the investigational product (hereinafter, "the product's equivalence/homogeneity") during the process. Based on the results, we plan to apply for inclusion in the NHI drug price listing and seek approval for partial changes to the terms of approval. Once the condition for shipment is met, it also will be possible to market product manufactured in the production runs prior to obtaining partial change approval.

Q4. In order to verify equivalence/homogeneity, is it necessary to submit additional data which could prove extremely difficult and time-consuming?
A4. Regarding equivalence/homogeneity, it has been determined that there would be no problem in granting the current conditional and time-limited approval upon evaluation of the additional data submitted after the March deliberation. Going forward, in light of "the limited manufacturing record for the product" as noted in the aforementioned Condition (1) of the approval, we will run two or so rounds of commercial production to accumulate inventories in preparation for launch, as stated in A1 above.

Q5. Will shipping and sales of AKUUGO not be possible until after the seven-year manufacturing and marketing approval period?
A5. Under the current conditional and time-limited approval, we expect the shipment and sale of AKUUGO® to be possible in the first quarter of the fiscal year ending January 2026 (February to April 2025). The seven-year manufacturing and marketing approval period is a period for conducting post-marketing surveillance trial in order to obtain full approval. The product can be sold during this period provided that post-marketing surveillance trial and a treatment outcome study are carried out on all patients receiving the product, in accordance with approval condition (3).

Q6. Is the post-marketing surveillance trial conducted to obtain full approval designed to demonstrate equivalence/homogeneity?
A6. We are aiming for full approval of AKUUGO® in accordance with the Ministry of Health, Labour and Welfare's "conditional and time-limited approval" for regenerative medicine products. Post-marketing surveillance trial will be conducted to obtain full approval under this framework, and no clinical trials will be conducted to confirm the equivalence/homogeneity of inventories accumulated prior to the application for partial change approval.

For more information, contact:
SanBio Co., Ltd.
Management Administration
Email: info@sanbio.com