



December 16, 2019

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**Additional Information Regarding Announcements on December 13, 2019 Concerning  
“Consolidated Financial Results for the Nine Months Ended October 31, 2019 [Japanese  
GAAP]” and “Decision to Terminate a Joint Development and License Agreement for  
Regenerative Cell Medicine SB623 for Chronic Stroke in North America”**

SanBio Co., Ltd. hereby announces the release (see attached document) of a “Message from Representative Director and President, Keita Mori, regarding disclosures made on December 13, 2019,” in order to provide additional information regarding the announcements on that date of “Consolidated Financial Results for the Nine Months Ended October 31, 2019 [Japanese GAAP]” and the “Decision to Terminate a Joint Development and License Agreement for Regenerative Cell Medicine SB623 for Chronic Stroke in North America.”

December 16, 2019  
SanBio Co., Ltd.

**Message from Representative Director and President,  
Keita Mori, regarding disclosures made on December 13, 2019**

SanBio Co., Ltd. (the “Company”) has received a number of inquiries regarding the Consolidated Financial Results for the Nine Months Ended October 31, 2019, released on December 13, 2019. I offer my sincere apologies for any concerns raised among the stakeholders who have provided the Company with generous support over the years, and below offer answers to the questions posed.

**1) Regarding change in timing of approval filing for regenerative cell medicine SB623 for chronic motor deficit from traumatic brain injury in Japan**

Previously, the Company aimed to file for manufacturing and marketing approval of SB623 for indication of chronic motor deficit from traumatic brain injury (TBI) during FY01/20. However, the Company now will aim to file for approval during FY01/21. We regret to convey this message concerning a timing change, having previously reiterated that preparations were under way with a view to filing during FY01/20.

The revised timing stems from changes to the schedule for preparing commercial production, in order to ensure stable supply once the product is on the market. The Company decided it would be best to allow plenty of time for these preparations, having determined that further work was needed to build a stable supply system capable of reliably delivering this much-awaited new drug to all patients.

**2) Regarding termination of joint development and license agreement with Sumitomo Dainippon Pharma for regenerative cell medicine SB623 for chronic motor deficit from ischemic stroke in North America**

On December 13, 2019, SanBio, Inc., SanBio’s subsidiary in the United States, and Sumitomo Dainippon Pharma Co., Ltd. had agreed to discontinue joint development of regenerative cell medicine SB623 for chronic motor deficit from ischemic stroke in North America, and to terminate the license agreement concluded between the two companies.

The Company has been asked whether or not termination of the agreement signifies an end to development of SB623. SanBio intends to continue development with an eye toward a future global rollout, based on comprehensive consideration of a number of factors including favorable clinical trial data from Phase 1/2a of the chronic motor deficit from ischemic stroke program and Phase 2 of the chronic motor deficit from TBI program, and the fact that no safety issues were observed in Phase 2b of the former program. With the termination of this agreement, all rights to SB623 as a treatment for chronic motor deficit from ischemic stroke in North America will return to the SanBio Group (SanBio and SanBio, Inc.). From among the many options available, including an alliance with a new partner, the Company will look to identify the approach to deliver this new drug to patients in the timeliest possible fashion. A new development schedule will be released once planning reaches a stage at which the Company can make a public announcement.

Finally, I again offer my sincere apologies for any concerns raised among the stakeholders who have provided the Company with generous support over the years.

The Company will first seek to launch SB623 as a treatment for chronic motor deficit from traumatic brain injury in Japan and North America, and build a foundation for the post-marketing production, logistics, commercial distribution, and appropriate use. In addition, we will pursue the development of SB623 for additional indications, such as ischemic stroke, cerebral hemorrhage, and ophthalmic diseases, and deliver the product to as many patients as possible in the shortest possible time.

It was my decision to allow plenty of time for laying the foundations needed for SanBio to fulfil its corporate social responsibility and become a company that delivers value to patients. Hereafter, the Group will make a concerted effort in this respect, and we ask for further support from stakeholders as we pursue this challenge.

SanBio Co., Ltd.  
Representative Director and President  
Keita Mori