December 16, 2019
SanBio Co., Ltd.

Q&A Regarding Announcements on December 13, 2019 Concerning "Consolidated Financial Results for the Nine Months Ended October 31, 2019" and "Decision to Terminate a Joint Development and License Agreement for Regenerative Cell Medicine SB623 for Chronic Stroke in North America,"

	Question	Answer
1	Could you explain when you decided on the change in timing of approval filing, and the reasons for the announcement made on December 13?	Until very recently, SanBio had intended to file for approval during the current fiscal year, but we determined that the company has a responsibility to take plenty of time in preparing for commercial production in order to ensure stable supply once the product launches, and decided to publicize this decision along with consolidated financial results for the nine months ended October 31, 2019.
2	Will the change in timing of approval filing also affect the launch timing?	The change in timing of approval filing will indeed affect the launch timing as well.
3	How do you think the change in timing of approval filing will affect the timing of actual approval?	SB623 has Sakigake designation, and judging by other companies' experiences, SanBio should receive notice of the authorities' decision around six months after filing. The next step is MHLW drug price listing, and then launch. As the party looking to receive approval, though, SanBio refrains from commenting further on this subject.
4	Was the change in timing of approval filing influenced at all by results from the Phase 2 clinical trial for the chronic motor deficit from traumatic brain injury program and the Phase 2b trial for the chronic motor deficit from ischemic stroke program?	Results from clinical trials had no bearing on the decision, which was made solely in the interests of building a stable supply system.
5	Could you provide any further information about work to build a stable supply system?	SanBio has experience in manufacturing investigational drugs and also possesses technologies for mass production, but decided it was necessary to further strengthen company infrastructure to ensure continuous supply of the product. Strengthening infrastructure includes putting various control systems in place and also training manufacturing personnel, but as business knowhow is involved, the company refrains from commenting any further on this subject.
6	Do you expect the change in timing of approval filing to affect global Phase 3 trials being conducted in the US and Europe?	At this juncture, we do not envision any impact of note.
7	Please explain the reasons for terminating the license agreement with Sumitomo Dainippon Pharma.	It came to our attention that Sumitomo Dainippon Pharma had reviewed its overall strategy and determined to discontinue development of SB623, based on results published in January 2019 from a Phase 2b trial evaluating SB623 as a treatment for chronic motor deficit from ischemic stroke. Discussions followed, and the two companies reached an amicable decision to terminate the agreement.
8	Approximately when do you expect to publish detailed results from the Phase 2b trial for the chronic motor deficit from ischemic stroke program?	At this juncture, SanBio does not plan to present the results at any academic symposium or equivalent forum. In fact, the company intends for the detailed results to remain undisclosed.
9	Could you explain how you intend to raise funds for future development activities?	SanBio plans to use cash on hand to fund the chronic motor deficit from traumatic brain injury program through to approval filing and subsequent approval. With respect to development funding for the chronic motor deficit from ischemic stroke program, the company plans to consider its options upon review of the funding situation at the time. If necessary, SanBio would look at project financing, bank borrowings, grants, or outlicensing in preference to equity financing.