March 13, 2018

Company name: SanBio Co., Ltd.

Representative: Keita Mori, Representative Director and President
(TSE Mothers Code: 4592)

Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
(TEL: +81-3-6264-3481)

Update on Development Progress of Regenerative Cell Medicine SB623

The SanBio Group (SanBio Co., Ltd. and subsidiary SanBio Inc.) has updated part of its February 21, 2018 release "Development Progress of Regenerative Cell Medicine SB623". Updated sections are underlined below.

In the SB623 development program targeting chronic motor deficit from ischemic stroke, a Phase 2b clinical trial jointly conducted with Sumitomo Dainippon Pharma Co., Ltd., is under way in the U.S., and enrollment of all 163 patients was completed in December 2017. The results of the trial are due in July 2019 following a 12-month follow-up period. In Japan, on February 14, 2018, SanBio and Teijin Limited terminated their licensing agreement, which previously had out-licensed to Teijin development and marketing of SB623 for stroke in Japan. Concurrently, SanBio initiated its own SB623 development program for chronic deficit from ischemic stroke in Japan with the objective to deliver a product in Japan earlier than in any other market in the world.

In a separate global development program targeting chronic motor deficit from traumatic brain injury (TBI), which SanBio is developing independently in Japan and the U.S., a Phase 2 clinical trial is under way; and as of today, 52 targeted patients have been enrolled (100% enrollment versus plan). Upon enrolling several more pre-registered patients, the Phase 2 clinical trial enrollment will be completed. SanBio plans to utilize the conditional and time-limited marketing authorization system for regenerative medicine products under the Revised Pharmaceutical Affairs Act of Japan to begin sales for its TBI indication before its other SB623 development programs. Specifically, SanBio plans to publish clinical trial results for its Phase 2 TBI study by the end of the fiscal year ending January 2019 and file for approval in the fiscal year ending January 2020.

＜Overview of development progress of SB623＞

Indication	Region	Progress to date	Schedule
Chronic motor deficit from ischemic stroke	US, Canada	Completed patient enrollment for Phase 2b, double-blind study (163 patients) in December 2017	Results to be published by July 2019 after 12-month follow-up period
	Japan	Terminated licensing agreement with Teijin in February 2018	Began preparations for starting own development program in February 2018. Aim to deliver a product in Japan earlier than in any other market in the world.
Chronic motor deficit from traumatic brain injury	Global (US & Japan)	In patient enrollment for Phase 2, double-blind study, 52 targeted patients have been enrolled (100% enrollment versus plan) as of March 13, 2018. To be completed after enrolling several more pre-registered patients.	Results to be published in the fiscal year ending January 2019, after six-month follow-up period following completion of patient enrollment. (Japan) Aim to file for approval in the fiscal year ending January 2020 assuming utilization of Japan's conditional and time-limited marketing authorization system for commercialization.