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Development Progress of Regenerative Cell Medicine SB623

The SanBio Group (SanBio Co., Ltd. and subsidiary SanBio Inc.) has been developing the regenerative cell medicine SB623—a proprietary new treatment for central nervous system (CNS) disorders—in Japan and the U.S., with a goal of commercializing therapeutic products. An overview of the current state of progress of the development programs is provided below.

In the SB623 development program targeting chronic 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 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 stroke in Japan with the objective to deliver a product to the market in Japan earlier than in any other country in the world.

In a separate development program targeting chronic traumatic brain injury, which SanBio is developing independently in Japan and the U.S., a Phase 2 clinical trial is underway; and as of today, 43 out of 52 patients (82%) have been enrolled. SanBio plans to utilize Japan's conditional and time-limited authorization system for regenerative medicine products to begin sales as early as possible after the Phase 2 study is completed.

＜Overview of development progress of SB623＞

Indication	Region	Progress to date	Schedule
Chronic stroke	US, Canada	Completed patient enrollment for Phase 2b, double-blind study (163 patients) in December 2017	Results to be published in 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 to the market in Japan earlier than in any other region in the world.
Chronic traumatic brain injury	Global (US & Japan)	Patient enrollment for Phase 2, double-blind study under way. 43 out of target 52 (82%) patients enrolled as of February 21, 2018.	Results to be published after six-month follow-up period following completion of patient enrollment. (Japan) Aim to utilize Japan's conditional and time-limited authorization system for commercialization.