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Addition of a Cerebral Hemorrhage Program for SB623 Regenerative Cell Medicine

At a meeting held today, the Board of Directors of SanBio Co., Ltd. (hereinafter, the "Company") resolved to add a program for treatment of chronic motor deficit from cerebral hemorrhage as a new indication for SB623, a regenerative cell medicine developed by the Group. (Hereinafter, the "Group" refers to two companies, SanBio Co., Ltd., and SanBio, Inc.)

1. Details of the Decision

As part of its mission to introduce new therapeutic drugs for the central nervous system, the Group is moving forward with the development of programs for chronic motor deficit from traumatic brain injury (TBI) and chronic motor deficit from ischemic stroke, centering on the United States and Japan. Regarding the program for treatment of chronic motor deficit from TBI, positive results were announced on November 1, 2018, with respect to a Phase 2 clinical trial, namely that "Patients administered SB623 demonstrated a statistically significant improvement in their motor function compared to the control group, confirming that the study has met its primary endpoint." Regarding the program targeting chronic motor deficit from ischemic stroke, the Company expects to announce results of a Phase 2b clinical trial in the first half of the fiscal year ending January 31, 2020 (from February 1, 2019 to July 31, 2019).

Given the positive results of the program targeting chronic motor deficit from TBI mentioned above, the Group has reevaluated the scope of indications for SB623. Consequently, the Company has decided to initiate a program for treatment of chronic motor deficit from cerebral hemorrhage, which is similar to TBI, as a new indication for SB623. The Company is considering Japan and the United States as development regions for this program.

Ischemic stroke is caused by the blockage of blood vessels, whereas cerebral hemorrhage results from ruptured blood vessels. Both can result in hemiplegia, sensory impairment, or memory impairment. Currently, no definitive therapy exists.

As of today, the Company expects to commence clinical trials for this program from Phase 2 or Phase 3. However, the development details and timing are not yet decided. The Company will provided these as soon as they become available.

2. Outlook

This decision does not affect the Company's consolidated operating performance for the fiscal year ending January 31, 2019.