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SanBio Releases Analytical Results of Phase 2b Study in the U.S. Evaluating SB623, a Regenerative Cell Medicine for the Treatment of Patients with Chronic Ischemic Stroke

The SanBio Group (SanBio Co., Ltd. and its subsidiary SanBio Inc.) hereby announces that it had posted on ClinicalTrials.gov the analytical results of a Phase 2b clinical study in the U.S. evaluating SB623, a regenerative cell medicine for the treatment of patients with chronic ischemic stroke, in accordance with the regulations of the U.S. authorities (follow link below).

https://clinicaltrials.gov/ct2/show/results/NCT02448641?term=sanbio&draw=2&rank=1

On January 29, 2019, we announced that no statistically significant difference was found in the proportion of patients whose Fugl-Meyer Motor Scale (FMMS) score improved by 10 or more points over the baseline (the primary endpoint) between the treatment group and control group, and thus the trial did not meet the primary endpoint. The data posted on ClinicalTrials.gov provides more details of the study results. The SanBio Group is preparing to start clinical trials for the next SB623 program for the treatment of chronic ischemic stroke and chronic hemorrhagic stroke based on detailed analysis of the results of the Phase 2b study, including the data disclosed above. Regarding the SB623 program for the treatment of chronic traumatic brain injury in Japan, SanBio is preparing in earnest to file for marketing approval for regenerative medicine products in the fiscal year ending January 31, 2021 (February 2020 –January 2021).

The release of analytical results on ClinicalTrials.gov will have no impact on SanBio's earnings for the fiscal year ending January 31, 2021.

Note: ClinicalTrials.gov is a website run by the United States National Library of Medicine at the National Institutes of Health. Users of the service can search and view various information related to clinical trials.