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SanBio Co., Ltd.

Additional analytical results of the US-based Phase 2b clinical trial of regenerative cell medicine SB623 for the treatment of chronic motor deficit from ischemic stroke, and review of plans to initiate clinical trials for the ischemic stroke and hemorrhagic stroke programs in Japan based on these results

SanBio Co., Ltd. (headquarters: Chuo-ku, Tokyo, Representative Director and President: Keita Mori, hereafter "SanBio") hereby announces that it has obtained new analytical results from the Phase 2b clinical trial (the "trial") of SB623 for the treatment of chronic motor deficit resulting from ischemic stroke the SanBio Group (SanBio Co., Ltd. and its subsidiary SanBio, Inc.) conducted in the US. It also announces that based on the newly obtained results, it has updated its development plans, including in regard to late-stage clinical trials for the ischemic stroke and hemorrhagic stroke programs of SB623 in Japan.

The trial evaluated efficacy and safety of SB623 in 163 patients suffering from chronic motor dysfunction from ischemic stroke. On January 29, 2019, SanBio announced that the trial did not meet its primary endpoint, as it failed to demonstrate statistical significance in the difference in the proportion of patients whose Fugl-Meyer Motor Scale (FMMS) score improved by 10 or more points from the baseline (primary endpoint) between the treatment group that received SB623 and the control group. Since then, the SanBio Group had continued to work on additional analysis of the trial data, and results of the additional analysis are as follows.

In conducting the additional analysis, from the perspective of minimal clinically important difference (MCID, or the minimal change in scores or other metrics that could be interpreted to mean the change in a patient is clinically meaningful) and based on the results of the Phase 2 clinical trial of SB623 for the treatment of chronic motor deficit from traumatic brain injury (TBI; STEMTRA trial), the company reevaluated trial data using composite FMMS. Of the total 163 patients enrolled in the trial, the company specifically looked at 77 patients who had infarct areas smaller than a certain size (47% of all patients enrolled in this trial). The SanBio Group evaluated the proportion of patients that met one or more of the following FMMS score improvement criteria 24 weeks after treatment: ≥6-point improvement on FMMS score for upper extremity, ≥4-point improvement on FMMS score for lower extremity, and ≥9-point improvement on FMMS total score (all from the baseline). Of the 51 patients in the treatment group that received SB623, improvement was seen in 49%, versus in 19% of 26 patients in the control group that received sham surgery, the difference between the two groups being statistically significant (p-value of 0.02). SanBio Group thinks that even compared to the primary endpoint—the proportion of patients whose FMMS score improved by 10 or more points over the baseline six months after treatment—the endpoint using composite FMMS can adequately explain clinical significance of the treatment efficacy.

Based on the above results, the SanBio Group has begun preparations for the next late-stage clinical trials in the ischemic stroke and hemorrhagic stroke programs of SB623). Specific designs of the clinical trials and the contents of development for those two programs will be announced promptly upon being finalized. To maximize the value of SB623 at an early stage by selecting areas to focus the Group's management resources on, the SanBio Group plans to prioritize the development of the ischemic stroke and hemorrhagic stroke programs in Japan at the same time as it prepares to file for approval of SB623 for the treatment of chronic motor deficit resulting from TBI in Japan by the end of the current fiscal year (ending January 2021). The Group, however, postponed the global Phase 3 clinical trial for the TBI program of SB623 it had planned to commence

this fiscal year to the next or subsequent fiscal years.

Many patients suffering from the chronic effects of ischemic stroke are said to be regularly taking drugs to prevent recurrence. However, because there is no drug that can fundamentally cure motor dysfunction, there is high unmet need for therapeutic drugs to restore motor functions for patients in the chronic phase of stroke. The SanBio Group aims to contribute to improving the lives of these patients, as well as of their family members, suffering from motor impairment and difficulties it causes in carrying out their daily lives through SB623.

About SB623

SB623 is an allogeneic mesenchymal stem cell produced by modifying and culturing bone marrow derived from healthy donors. Implantation of SB623 cells into nerve tissues is expected to promote regeneration of damaged nerve cells. Because SB623 is made from allogeneic cells, large-scale production is possible and there is no need for complex cell processing required for treatments using autologous cells, e.g., cell preparation for each patient at medical institutions. Hence, pharmaceutical products made from allogeneic cells, such as SB623, can be provided to many patients in uniform quality.

About SanBio Co., Ltd. and SanBio, Inc.

SanBio Group is engaged in the regenerative cell medicine business, spanning research, development, manufacture, and sales of regenerative cell medicines. The Company's propriety regenerative cell medicine product, SB623, is currently being investigated for the treatment of several conditions including chronic neurological motor deficit resulting from traumatic brain injury and ischemic stroke. The Company is headquartered in Tokyo, Japan and Mountain View, California, and additional information about SanBio Group is available at https://sanbio.com.

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