February 1, 2019
SanBio Co., Ltd.

# Q&A concerning the January 29, 2019 press release "SanBio Announces Topline Results from a Phase 2b Study in the U.S. Evaluating SB623, a Regenerative Cell Medicine for the Treatment of Patients with Chronic Stroke"

| | Questions | Answers |
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| 1 | What were the results of the Phase 2b clinical trial of SB623 regenerative cell medicine for chronic motor deficit from ischemic stroke? | The topline results indicated that SB623 was not able to meet the primary endpoint regarding efficacy. On the other hand, the trial did not observe any safety issues. We are currently analyzing the data in detail and will make related announcements through future academic conferences and other forums. Dates for these announcements have not yet been determined. |
| 2 | What was this trial's primary endpoint? | The trial's primary endpoint was determined using the Fugl-Meyer Motor Scale (FMMS). For this analysis, we separated patients into a treatment group and control group and calculated the proportion of patients in each group that improved by 10 or more points over the baseline, verifying any statistically significant changes. |
| 3 | Please fill us in on the particulars of the data obtained from this trial. | We are currently analyzing the data in detail and plan to make related announcements through future academic conferences and other forums. Dates for these announcements have not yet been determined. |
| 4 | What are your future development plans for the SB623 program for the treatment of chronic motor deficit from ischemic stroke in Japan? | As mentioned in the January 29, 2019 press release, "Topline Analytic Results of a Phase 2b Clinical Trial in the US of SB623 Regenerative Cell Medicine for Chronic Motor Deficit from Ischemic Stroke," we will reevaluate development methods and timetables for the SB623 program for the treatment of chronic motor deficit from ischemic stroke in Japan. We will then provide information regarding development plans when we announce updated business plans. We aim to release these, at the latest, by the end of March 2019, at which time we plan to hold our earnings briefing session for the fiscal year ended January 31, 2019. |
| 5 | What is your agenda concerning future development for the SB623 program for the treatment of chronic motor deficit from ischemic stroke? | We will decide on future development plans after detailed analysis and evaluation of trial data and thorough consultation with Sumitomo Dainippon Pharma Co., Ltd. |
| 6 | What impact will the results of this trial have on the SB623 program for the treatment of chronic motor deficit from traumatic brain injury (TBI)? | We do not believe that the results of this trial have any impact on clinical trial results related to the SB623 program for the treatment of chronic motor deficit from TBI. As before, we aim to obtain approval for SB623 in the US and Japan as quickly as possible. Furthermore, we still plan to apply for approval in Japan during the fiscal year ending January 31, 2020 (February 2019–January 2020). |
| 7 | What impact will the results of this trial have on the SB623 program for the treatment of chronic motor deficit from cerebral hemorrhage? | We will release information regarding the chronic motor deficit from cerebral hemorrhage program when we announce our revised business plans. |
| 8 | Will the results of this trial have any impact on joint initiatives with the Hitachi Chemical Group, with which you have contracted to handle your manufacturing? | Our joint initiatives with the Hitachi Chemical Group are related to the manufacture of regenerative cell medicine SB623. These initiatives, along with product launch plans for each development, are proceeding as scheduled, and this clinical trial's results have no impact on them. |

| | Questions | Answers |
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| 9 | Please tell us about SanBio's future development and business plans. | SB623 received favorable results in the Phase 2 trial (STEMTRA trial) for the treatment of chronic motor deficit from TBI, and we plan to continue related development, aiming for the earliest possible approval in the US and Japan. We are currently revising development methods and timetables for other indications. At the latest, we aim to release information regarding our revised development and business plans for the fiscal year ending January 31, 2020 and onward by the end of March 2019, when we plan to hold our earnings briefing session for the fiscal year ended January 31, 2019. |
| 10 | In the press release, "Topline Analytic Results of a Phase 2b Clinical Trial in the US of SB623 Regenerative Cell Medicine for Chronic Motor Deficit from Ischemic Stroke," dated January 29, 2019, you mentioned that you were reviewing necessary funds for development. Could you tell us what this means? | As of October 31, 2018, we had about 12.0 billion yen in cash and deposits on hand. "Reviewing necessary funds" refers to our intention to reevaluate how we allocate our funds as we revise our future development and business plans. |