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SanBio Announces Phase 2 STEMTRA Trial Using SB623 Cells for Treatment of Patients with Traumatic Brain Injury Met Primary Endpoint

The SanBio Group (SanBio Co., Ltd. and subsidiary SanBio Inc.; together, the "Company") announces today that the Phase 2 STEMTRA trial using SB623 cells for the treatment of patients with traumatic brain injury (TBI), met its primary endpoint.

This STEMTRA study showed that TBI patients with chronic motor deficits treated with SB623 cells demonstrated a statistically significant improvement in their motor function compared to the control group, based on the Fugl-Meyer Motor Scale (FMMS). The study met its primary endpoint, with SB623 patients achieving an average 8.7 point improvement from baseline in the FMMS, versus 2.4 in the control group, at 24 weeks. The safety data showed that SB623 was well tolerated and no new safety signals were identified.

"This global clinical trial, the largest stem cell study ever conducted for TBI, is especially exciting given the rigor of its randomized double-blind design and demonstration of significant improvement in motor function for many patients treated with SB623 cells," said Damien Bates MD, PhD, Chief Medical Officer and Head of Research at SanBio Group. "This is a significant milestone for regenerative medicine and for many patients suffering from persistent disabilities caused by TBI." Based on this study, SanBio Group aims to file for marketing approval in Japan in the fiscal year ending January 2020.

The outcome of this study is likely to have minimal impact on the earnings of SanBio Group for the current fiscal year. However, SanBio Group believes that it will improve the Company's earnings in the medium to long term.