

SanBio to announce the results of a Phase 2 STEMTRA trial regarding the use of regenerative cell medicine SB623 as a treatment for TBI at an annual scientific meeting of the American Association of Neurological Surgeons

Mountain View, Calif.—Mar. 6, 2019—The SanBio Group (SanBio Co., Ltd. and SanBio, Inc.), a scientific leader in regenerative medicine for neurological disorders, today announced its plan to make public the results of a global Phase 2 trial (Study of Modified Stem Cells in Traumatic Brain Injury, or "STEMTRA") conducted in the US and Japan regarding the use of regenerative cell medicine SB623 as a treatment for chronic motor deficit from traumatic brain injury (TBI). The Group plans to announce the results at an annual scientific meeting of the American Association of Neurological Surgeons, one of the world's preeminent neurosurgical conferences, scheduled to be held in San Diego, California, USA from April 13 through April 17, 2019, local time.

Enrollment of 61 patients for the STEMTRA was completed in April 2018, and in November 2018, the SanBio Group received favorable results from the trial; the primary endpoint was achieved, with the treatment group, who were administered SB623 cells, demonstrating a statistically significant improvement in motor function compared to the control group. In view of these results, the Group is aiming to submit an application for manufacture and marketing approval for its TBI program in Japan during the fiscal year ending January 31, 2020 (February 2019–January 2020) utilizing the conditional and term-limited authorization system for regenerative medicine products under the Revised Pharmaceutical Affairs Act of Japan.

The Group's presentation concerning the STEMTRA is currently scheduled to begin at 11:37 a.m. on April 16, 2019, Pacific Standard Time. For more information regarding this presentation, please follow the link below:

American Association of Neurological Surgeons: https://www.aans.org/Annual-Scientific-Meeting/2019/Online-Program/ProgramProposal?eventid=48888&itemid=PLENARY II

About SanBio, Inc. (SanBio)

SanBio is a regenerative medicine company headquartered in Tokyo and Mountain View, California, with cell-based products in various stages of research, development and clinical trials. Its proprietary cell-based product, SB623, is currently in a Phase 2b clinical trial for treatment of chronic motor impairments resulting from stroke, and in a Phase 2 clinical trial for treatment of motor impairment resulting from traumatic brain injury. More information about SanBio, Inc. is available at http://sanbio.com.

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