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Company name: SanBio Co., Ltd.
Representative: Keita Mori, Representative Director and President
(TSE Mothers Code: 4592)
Contact: Yoshihiro Kakutani, Corporate Officer of Management Administration
(TEL. +81-3-6264-3481)

SanBio announced the results of the Phase 2 STEMTRA trial of SB623 as a treatment for chronic motor deficit from traumatic brain injury, at 2019 World Federation of Neurosurgical Societies Special World Congress

SanBio Company Limited hereby announces that SanBio announced the results of the Phase 2 STEMTRA trial of SB623 as a treatment for chronic motor deficit from traumatic brain injury, at 2019 World Federation of Neurosurgical Societies Special World Congress as attached.

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Mountain View, Calif.—September 13, 2019—The SanBio Group (SanBio Co., Ltd. and SanBio, Inc.), a scientific leader in regenerative medicine for neurological disorders, today announced that results from the US–Japan global Phase 2 trial (Study of Modified Stem Cells in Traumatic Brain Injury, or STEMTRA) of SB623 as a treatment for chronic motor deficit from traumatic brain injury (TBI) were presented at the 2019 World Federation of Neurosurgical Societies Special World Congress (hereafter the Congress) held in Beijing, China from September 9 to September 12, 2019, local time.

The Congress is held every two years by the World Federation of Neurosurgical Societies (WFNS: the world's largest neurosurgical organization, comprised of 130 member societies including five continental associations), and serves as a forum for the release of groundbreaking research results in the neurosurgical field. SanBio was invited to the Congress to present results from STEMTRA, a randomized, double-blind trial evaluating the efficacy of SB623 in patients with chronic motor deficits secondary to TBI. Even on a global basis, STEMTRA is one of only a few studies in this field to achieve its primary endpoint, with the treatment group demonstrating a statistically significant improvement in motor function compared to the control group.

In presenting the results, SanBio's president, Keita Mori, said, "We found the Congress to be an excellent opportunity to enhance worldwide recognition of SB623, for which we have global aspirations. We regard China as a particularly promising market, and hope there will be further opportunities of this kind."

In its TBI program in Japan, SanBio plans to use the STEMTRA trial results to apply for manufacturing and marketing approval for SB623 as a regenerative medicine product during the fiscal year ending January 31, 2020 (February 2019–January 2020), using the nation's conditional and term-limited authorization system for regenerative medicine products.

SanBio gave a presentation on the STEMTRA trial results at the annual scientific meeting of American Association of Neurological Surgeons held in San Diego, California, USA in April 2019. For further details of the presentation, please refer to the press release, "SanBio to announce the results of a Phase 2 STEMTRA trial regarding the use of SB623 as a treatment for TBI at AANS," dated March 6, 2019.

About SanBio Group (SanBio Co., Ltd. and SanBio, Inc.)
SanBio Group 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. More information about SanBio Group is available at https://sanbio.com.

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For more information, contact:
SanBio Co., Ltd.
Management Administration
info@sanbio.jp