SanBio announces SB623 regenerative cell therapy for traumatic brain injury has received Ministry of Health, Labour and Welfare (MHLW) Sakigake designation

Tokyo, Japan—Apr. 8, 2019—The SanBio Group (SanBio Co., Ltd. and SanBio, Inc.), a scientific leader in regenerative medicine for neurological disorders, announced today that SB623, a regenerative cell therapy that the Group is developing globally for the treatment of chronic motor deficit resulting from traumatic brain injury (TBI), has received the Sakigake Designation for innovative medical products from the Ministry of Health, Labour, and Welfare (MHLW) of Japan.

The Sakigake Designation System was unveiled in June 2014 as part of the "Strategy of SAKIGAKE" by an MHLW project team to lead the world in the practical application of innovative medical products. It is a scheme for rapid authorization of innovative pharmaceutical products initially developed in Japan for which exceptional effectiveness can be expected based on preclinical results and early-stage clinical trials. The Sakigake Designation System targets regenerative medicines that treat serious diseases which urgently require innovative therapies.

SanBio's proprietary regenerative cell medicine SB623, which has been granted the Sakigake Designation, is made from modified and cultured adult bone marrow-derived mesenchymal stem cells that undergo temporary genetic modification. Implantation of SB623 cells into injured nerve tissue in the brain is expected to trigger the brain's natural regenerative ability to recover lost motor functions.

The SanBio Group has been conducting a global Phase 2 clinical trial of SB623 in Japan and the US by ourselves, targeting chronic motor deficit resulting from TBI. Enrollment of 61 patients was completed in April 2018, and in November 2018, the 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. Based on these results, the Group is aiming to submit an application for manufacturing and marketing approval for its TBI program in Japan during the fiscal year ending January 31, 2020 (February 2019–January 2020), using the conditional and term-limited authorization system for regenerative medicine products under the Revised Pharmaceutical Affairs Act of Japan.

Following the Sakigake Designation of SB623, SanBio will receive priority consultation and review by the Pharmaceuticals and Medical Devices Agency (PMDA) regarding manufacturing and marketing approval. The SanBio Group will take advantage of the designation to apply for approval in Japan.

SanBio Medical Director and Head of Development / Japan, Takehiko Kaneko, commented: "We are delighted that the TBI program for SB623 has received the Sakigake Designation. Conducting the clinical trials made us realize how excited health professionals and patients in Japan are about SB623. We are deeply grateful to everyone who helped us receive the designation and reaffirm our commitment to delivering SB623 to patients as soon as possible."

For more information, please follow the link below:

MHLW release: Product Designation under the SAKIGAKE Designation System: 11 pharmaceutical products have been newly designated to accelerate development of groundbreaking products in Japan
https://www.mhlw.go.jp/stf/newpage_04339.html

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 impairments resulting from traumatic brain injury. More information about SanBio, Inc. is available at http://sanbio.com.

# # #

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