



March 29, 2019

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 Announces to give an encore presentation on the results of a Phase 2  
STEMTRA trial regarding the use of regenerative cell medicine SB623 as a treatment  
for TBI at the 14th Korea–Japan Joint Conference on Surgery for Cerebral Stroke**

SanBio Co., Ltd. announces today that SanBio to give an encore presentation on the results of a Phase 2 STEMTRA trial regarding the use of regenerative cell medicine SB623 as a treatment for TBI at the 14th Korea–Japan Joint Conference on Surgery for Cerebral Stroke as attached.



## **SanBio to give an encore presentation on the results of a Phase 2 STEMTRA trial regarding the use of regenerative cell medicine SB623 as a treatment for TBI at the 14<sup>th</sup> Korea–Japan Joint Conference on Surgery for Cerebral Stroke**

**Tokyo, Japan—Mar. 29, 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 the 14<sup>th</sup> Korea–Japan Joint Conference on Surgery for Cerebral Stroke, scheduled to be held in Sapporo, Hokkaido from April 26 to 28, 2019, Japan Standard 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; primary endpoints were 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 results announcement is an encore of the STEMTRA trial results presentation the Group plans to give at an annual scientific meeting of the American Association of Neurological Surgeons scheduled to be held in San Diego, California, USA, with the presentation starting at 11:37 a.m. on April 16, 2019, local time <sup>(Note 1)</sup>.

The encore presentation will be delivered during Symposium III scheduled for 10:30 a.m. to noon on April 27, 2019, Japan Standard Time. For more information regarding the presentation, please follow the link below:

**The 14<sup>th</sup> Japan–Korea Joint Conference on Surgery for Cerebral Stroke:**  
<http://www2.convention.co.jp/kjic2018/index.html>

(Note 1) Please refer to the March 6, 2019 release entitled “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.”

### **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](mailto:info@sanbio.jp)