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First Patient is Enrolled in Global STEMTRA Trial for Traumatic Brain Injury in Japan

Mountain View, Calif. and Tokyo – October 26, 2016 – SanBio Co., Ltd., a scientific leader in regenerative medicine for neurological disorders, today announced that the first patient in Japan was enrolled in the STEMTRA Phase 2 clinical trial study of regenerative cell medicine SB623 for patients affected by traumatic brain injury. STEMTRA is the world's first global Phase 2 clinical trial of allogeneic stem cell medicine for traumatic brain injury.

The STEMTRA trial is designed to study the safety, efficacy and tolerability of SB623 in patients with chronic motor impairments persisting at least twelve months following traumatic brain injury. It is being conducted across approximately 30 clinical trial sites in the United States and Japan. The first patient was enrolled in July, 2016, in the United States, and total enrollment is expected to reach 52 patients.

Traumatic brain injury, or TBI, can result from a variety of causes, including car accidents, falls, combat-related incidents and sports injuries, leaving many survivors with life-long motor deficits. Currently there are no approved medicines for the treatment of persistent TBI-related motor disability. There are more than 5.3 million people living with disabilities resulting from traumatic brain injury in the United States alone. The trial is designed to demonstrate the efficacy and safety required to address this area of high unmet medical need.

Damien Bates, Chief Medical Officer and Head of Research at SanBio, said, "This is an important milestone for SanBio. We've demonstrated that we can work with regulators to obtain approval for, and rapidly launch, a landmark clinical study for regenerative medicine in Japan."

Japan grants marketing approval for regenerative medicines earlier than any other country, due to an amendment to the Pharmaceutical Affairs Law in 2014. This amendment introduced a conditional and term-limited Accelerated Approval system for regenerative medicine products, and established Japan as a world leader in this field. SanBio intends to utilize Japan's Accelerated Approval system upon the completion of the STEMTRA study to market SB623 in Japan prior to the rest of the world.

Keita Mori, CEO of SanBio, said, "since 2014, Japan has provided the most dynamic regulatory framework in the regenerative medicine field. We are pursuing early product approvals in Japan, and we will rapidly bring new treatments to patients around the world."

Regarding the impact on the full-year financial results forecast, the Company makes no revision to its "Consolidated Financial Results Forecast for the Fiscal Year Ending January 31, 2017 (February 1, 2016 to January 31, 2017)" in "Consolidated Financial Results for the Fiscal Year Ended January 31, 2016 [Japanese GAAP]", which was released on March 16, 2016.

About regenerative cell medicine

SanBio's regenerative cell medicine, SB623, is comprised of modified allogeneic mesenchymal stem cells, which are derived from bone marrow stromal cells isolated from healthy adult donors. When administered into neural tissue, SB623 cells promote recovery from injury by triggering the brain's natural regenerative ability. SanBio recently completed a U.S.-based Phase 1/2a clinical trial for SB623 in patients with chronic motor impairments six months to five years following an ischemic stroke. The results suggested the medicine's potential to improve motor function following a stroke. Based on these results, a Phase 2b randomized double blind clinical trial of 156 subjects began enrollment in December 2015 for the stroke indication.

About SanBio Ltd. and SanBio Inc. (together, the "Group")

The Group is engaged in research, development, manufacture and marketing of regenerative cell medicines. The Phase 2b trial of the unique regenerative cell medicine SB623 for stroke was launched in December 2015 in the U.S., and the Phase 2 clinical trial for traumatic brain injury was launched in October 2015. The Group has headquarters in Tokyo, and its primary base for research and development is in the San Francisco Bay Area of the U.S. More information about SanBio Inc. is available at www.sanbio.com.

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