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First Patient is Randomized in STEMTRA Trial For Traumatic Brain Injury

SanBio Inc., a subsidiary of SanBio Co., Ltd. ("the Company") announces today that the first patient is randomized in STEMTRA trial for traumatic brain injury in North America as attached.

Regarding the impact on the randomization of the first patient in STEMTRA trial, the Company makes no revision to "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.

First Patient is Randomized in STEMTRA Trial For Traumatic Brain Injury

Mountain View, Calif.—July 11, 2016—SanBio, Inc., a scientific leader in regenerative medicine for neurological disorders, today announced the randomization of the first patient in the STEMTRA Phase 2 clinical trial study for traumatic brain injury. The trial is enrolling patients in both the United States and Japan, and the first patient was randomized at Emory University Hospital in Atlanta, GA.

The STEMTRA "Stem cell therapy for traumatic brain injury" trial will examine the effects of SB623 stem cell treatment in patients with chronic motor deficits resulting from traumatic brain injury. SB623 cells, SanBio's proprietary product, are modified allogeneic mesenchymal stem cells, derived from the bone marrow of health human adult donors. When administered into neural tissue, SB623 cells appear to promote recovery from injury by triggering the brain's natural regenerative ability.

Traumatic brain injuries can be caused by a wide range of events, including car accidents, falls, firearm mishaps, and battlefield injuries. These events often result in permanent damage, including significant motor deficits; leaving more than 5.3 million people living with disabilities in the United States alone.

Damien Bates, Chief Medical Officer and Head of Research at SanBio, said, "This modified stem cell treatment has improved outcomes in patients with persistent limb weakness secondary to ischemic stroke—and our preclinical data suggest it may also help TBI patients. For people suffering from the often debilitating effects of TBI, this milestone brings us one step closer to proving whether it's an effective treatment option."

The STEMTRA trial follows a Phase 1/2a clinical trial in patients with chronic motor deficit secondary to ischemic stroke, which showed statistically significant improvements in motor function following implantation of the modified stem cells. The STEMTRA study will evaluate the efficacy, safety and tolerability of the SB623 cell treatment and administration process in patients with traumatic brain injuries. Patients must be at least 12 months post injury.

The study will be conducted across approximately 25 clinical trial sites throughout the United States and five sites in Japan. Total enrollment is expected to reach 52 patients.

About the STEMTRA Trial
The STEMTRA trial will evaluate the clinical efficacy and safety of intracranial administration of modified adult bone-marrow-derived stem cells for patients with chronic motor deficit from traumatic brain injury.

About SanBio Group
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. SanBio also began a Phase 2 clinical trial for treatment of motor impairment resulting from traumatic brain injury in late 2015. More information about SanBio, Inc. is available at http://san-bio.com.

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