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SanBio begins clinical trial of regenerative cell medicine for patients with traumatic brain injury in Japan

SanBio Co., Ltd., a scientific leader in regenerative medicine for neurological disorders, announced today that it has begun a Phase 2 clinical trial of regenerative cell medicine SB623 (hereinafter "this medicine") for patients affected by traumatic brain injury in Japan.

SanBio Inc., a subsidiary of the Company, had previously announced the world's first global Phase 2 clinical trial for chronic traumatic brain injury with allogeneic stem cells, with patient enrollments already begun in the United States. The STEMTRA ("Stem cell therapy for traumatic brain injury") trial is designed to study the safety and efficacy of SB623 cell therapy in treating patients with chronic motor impairments following traumatic brain injury. The trial will enroll 52 subjects, and SanBio today announced that Japanese patients will be included in this trial.

SB623 cells are modified allogeneic mesenchymal stem cells, 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 US-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. The STEMTRA trial extends the evaluation of SB623 to patients afflicted by TBI.

Traumatic brain injuries can result from a variety of causes, including car accidents, falls, combat incidents and sports injuries. TBI can result in lifelong motor deficits, and there are currently no approved medicines for the treatment of persistent TBI-related motor disability. Therefore, this is an area of high unmet medical need. There are more than 5.3 million people living with disabilities resulting from traumatic brain injuries in the United States alone.

Takehiko Kaneko, head of Clinical Development in Japan at SanBio, said, "I'm very glad that SB623 can advance to a clinical development phase in Japan following the clinical trial in the United States. Both doctors and patients involved in preparation for this trial showed strong support and high expectations. I am grateful for the early and enthusiastic support. We will proceed with the clinical development of SB623 and confirm its safety and efficacy, so that we can bring help to patients suffering from ongoing disability as soon as possible."

Japan grants marketing approval for regenerative medicines earlier than any other country in the world, due to an amendment to the Pharmaceutical Affairs Law in 2014. This amendment defined regenerative medicine products as a new category in addition to conventional drugs and medical devices, and established a conditional and term-limited Accelerated Approval system for regenerative medicine products. Two regenerative medicine products have already secured marketing approval under this new system, which has begun to establish Japan's position as a world leader in regenerative medicine.

SanBio Inc., was established in 2001 in California, and since then has continued the development of proprietary regenerative cell medicines. Last year the Company determined to expand the development team both in the United States and Japan, and began full-scale clinical-stage development in Japan. The Company aims to accelerate the completion of the global Phase 2 clinical trial for traumatic brain injuries, and also to market SB623 in Japan prior to the rest of the world by taking full advantage of Japan's Accelerated Approval system.

The STEMTRA study will be conducted across approximately 25 clinical trial sites in the United States and five sites in Japan. Total enrollment is expected to reach 52 patients. The first patient was enrolled in the United States in July, 2016. The STEMTRA study will evaluate the efficacy, safety and tolerability of SB623 cell treatment and its administration process.

Regarding the impact on the full-year financial results forecast, 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.

About regenerative cell medicine

SanBio's regenerative cell medicine, SB623, is a stem cell based product that is designed to promote the regeneration of physical functions lost by diseases or accidents.

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 the main 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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