April 6, 2016

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)

Clinical trial involving regenerative cell treatment for patients with traumatic brain injury permitted in Japan

Mountain View, Calif. and Chuo-ku, Tokyo—April 6, 2016—SanBio, Inc., a scientific leader in regenerative medicine for neurological disorders and the United States subsidiary of SanBio Co., Ltd., announced today that they are now able to conduct the world's first global Phase 2 clinical trial for chronic traumatic brain injury with allogeneic stem cells in Japan. The 30-day review period of Clinical Trial Notification of the regenerative cell therapy SB623 (hereinafter "this medicine") for traumatic brain injury in Japan, which was submitted to Pharmaceuticals and Medical Devices Agency (PMDA) as of March 7, 2016, has passed without further concern.

The STEMTRA "Stem cell therapy for traumatic brain injury" trial will study the safety and efficacy of SB623 cell therapy in treating patients with chronic motor impairments following a traumatic brain injury. Enrollment began in the United States in October 2015 and, going forward, will include clinical trial sites and patients in Japan. The trial will enroll 52 subjects, and the inclusion of Japanese patients is expected to accelerate overall enrollment.

Damien Bates, Chief Medical Officer and Head of Research at SanBio, said, "SanBio's regenerative cell medicine, SB623, has improved outcomes in patients with persistent motor deficits due to ischemic stroke, and our preclinical data suggest it may also help TBI patients. This is the first global Phase 2 clinical trial for TBI with allogeneic stem cells, and the approval to conduct the trial in Japan, as well as in the United States, brings us one step closer to determining SB623's efficacy for treating those who suffer from the effects of traumatic brain injury."

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.

Traumatic brain injuries can result from a variety of causes, including car accidents, falls, occupational hazards and sports injuries. The injury can lead to lifelong motor deficits, and there are currently no approved medicines for the treatment of persistent motor disability from traumatic brain injury. Therefore, this is an area of high unmet medical need.

Although the cause of the brain injury differs from ischemic stroke, the clinical manifestation of motor deficits is similar. As the mechanism of action and proposed route of administration are similar to the Phase 1/2a clinical study in stroke, it is anticipated that the results of this traumatic brain injury clinical trial will be similarly efficacious.

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. We will proceed with the clinical development of SB623 as soon as possible, so that we can contribute to patients suffering from ongoing disability."

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 the conditional and term-limited Accelerated Approval system for regenerative medicine products has started. Two regenerative medicine products have already gained marketing approval under this new system, and the government-led industrialization of regenerative medicine productshas gradually been realized.

SanBio has begun the preparation of clinical trial facilities in Japan and expects early commencement of the clinical trial in 2016. They aim to market this medicine in Japan ahead of the world by taking full advantage of the Accelerated Approval system.

As announced in the news release on March 31, 2016 "Notice Concerning Borrowing of Funds," SanBio concluded a contract with Mizuho Bank, Ltd. for borrowings based on a commitment line of credit. Through these borrowings and a portion of funds procured from the stock listing in April 2015, SanBio plans to cover the research and development expenses related to the program for treatment of chronic motor deficits secondary to traumatic brain injury using the SB623 cell product in Japan.

Highlights of the loan include:

- A borrowing limit of 1.0 billion Yen from Mizuho Bank, Ltd.
- Contract period through April 1, 2016 to March 31, 2025
- An applied annual interest of Mizuho TIBOR 1.2%

About regenerative cell medicine

The regenerative cell medicine with which SanBio deals is a stem cell based product that is expected to trigger/promote the regeneration process of physical functions lost by diseases or accidents.

About SanBio Co., Ltd. and SanBio, Inc. (hereinafter referred to as "the Group")

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

Media contact:
Meredith Gallagher
(612) 455-1724
Meredith.Gallagher@padillacrt.com

###