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SanBio Inc. begins recruiting patients to test regenerative treatment for Traumatic Brain Injury

SanBio Inc. (hereafter “the Company”), a subsidiary of SanBio Co., Ltd., announces today that the Company begins recruiting patients to test regenerative treatment for Traumatic Brain Injury as attached.



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Evaluates potential for patients struggling with chronic motor deficits 12-36 months post injury

Mountain View, Calif. — October 5, 2015 — [SanBio Inc.](#), a scientific leader in regenerative medicine for neurological disorders, announced today that it has opened patient recruitment for its Phase 2 clinical trial study to evaluate the clinical efficacy and safety of its proprietary cell therapy following traumatic brain injury (TBI).

In the United States alone, more than 5.3 million people live with disabilities caused by TBI – with approximately 1.5 million people suffering from such an injury each year. The effects can be devastating, often requiring long-term rehabilitation and care to overcome severe neurological deficits, including cognitive and motor-function impairment.

The [STEMTRA](#) “Stem cell therapy for traumatic brain injury” trial will examine the effects of SanBio’s regenerative therapy using SB623 cells (genetically modified adult bone-marrow-derived stem cells), specifically in patients with chronic motor deficits resulting from focal traumatic brain injury.

Damien Bates, Chief Medical Officer and Head of Research at SanBio, said, “Focal traumatic brain injuries occur in association with the more typical diffuse injuries seen in TBI patients, and can be caused by a wide range of events such as car accidents, falls, firearm mishaps, and battlefield injuries. These events often result in permanent damage, leaving a patient with significant motor deficits. Our hope is that SB623 will prove to be a safe and effective treatment option for these patients.”

The Phase 2 clinical 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 SB623 cells. The Phase 2 study will further evaluate the efficacy and safety of the treatment, as well as the safety and tolerability of the administration process. Patients must be between 12 - 36 months post injury.

The study will be conducted across approximately 20 clinical trial sites throughout the United States. 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 SB623, modified adult bone-marrow-derived stem cells, for patients with chronic motor deficit from traumatic brain injury.

About SanBio

SanBio is a regenerative medicine company with cell-based products in various stages of research, development and clinical trials. Its proprietary cell-based product, SB623, is already in Stage 2 clinical trials for treatment of chronic stroke, and is expected to begin Stage 2 clinical trials for treatment of traumatic brain injury later in 2015. Based in Tokyo, the company also has a United States headquarters in the San Francisco Bay Area.

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