June 10, 2013

Mountain View, California

SanBio Announces FDA Clearance for the Initiation of a Phase I/2a Clinical Trial Testing Their Cell Therapy Product, SB623, in Patients with Traumatic Brain Injury

MOUNTAIN VIEW, Calif., June 10, 2013 /PRNewswire/ -- SanBio Inc., a California-based regenerative medicine company, announced today that the U.S. Food and Drug Administration has approved their Investigational New Drug application (IND) for the use of SB623, a novel allogeneic stem cell therapy product, in patients suffering from traumatic brain injuries (TBI's). This approval allows the company to proceed with a Phase 1/2a clinical trial testing the safety and feasibility of the therapy. The clinical trial is expected to be carried out at several major hospitals in the United States.

"This is the second clinical program for SanBio," said Keita Mori, SanBio's Chief Executive Officer, "we see this as a clear validation of our development program and a significant broadening of the therapeutic application of our lead product SB623 for the treatment of unaddressed chronic neurological deficits."

"We measure the responses of TBI patients to physical therapy every day. Progress is often painfully slow and incremental," said Dr. Daniel Lu, Principal Investigator, Neuroplasticity and Repair Laboratory and Director, Neuromotor Recovery Research Center, University of California, Los Angeles, "If this new cell therapy approach improves outcomes it could have a dramatic positive effect on many lives."

About Traumatic Brain Injury: According to the Center for Disease Control and Prevention, more the 1.7 million people in the United States sustain a traumatic brain injury each year, resulting in approximately 50,000 deaths and 275,000 hospitalizations. Many of these more severely injured patients suffer permanent disabilities, including loss of motor function and cognitive impairment. Other than physical rehabilitation there is no effective therapy. Direct medical costs and indirect costs such as lost productivity of TBI totaled an estimated $76.5 billion in the United States in 2000.

About SB623: SB623 is a proprietary cell therapy product consisting of cells derived from genetically modified bone marrow stromal cells obtained from healthy adult donors. SB623 is administered adjacent to the damaged area of the brain. SB623 functions by producing factors that aid the regenerative process.

About SanBio: SanBio is a privately held San Francisco Bay Area biotechnology company focused on the discovery and development of new regenerative cell therapy products.

For more information: www.san-bio.com

Contacts:
Keita Mori, CEO
SanBio Inc.
231 S. Whisman Road
Mountain View, CA 94041
650-625-8965 x 11
Keita.mori@san-bio.com