SanBio Presents Interim Results of the First Intracerebral Stem Cell Transplant Study for Stroke in the United States

Preliminary Data Shared at American Congress of Rehabilitation Medicine Conference

Mountain View, CA – November 4, 2016 - Appearing at the world's largest conference for interdisciplinary rehabilitation research, experts from regenerative medicine leader SanBio, Inc., presented the 1-year interim results of the first intracerebral stem cell implant study for stroke in the United States.

In two separate presentations at the American Congress of Rehabilitation Medicine Conference, SanBio presented data suggesting that its stem cell treatment, SB623, was generally safe, was well-tolerated, and was associated with improved motor function in patients with chronic motor impairment following an ischemic stroke.

The clinical trial was a Phase 1/2a, open-label, single-arm dose escalation study of 18 patients with chronic motor deficits persisting six months to five years following an ischemic stroke. Through stereotactic surgery, patients received injections of SB623 cells, which are genetically modified allogeneic mesenchymal stem cells derived from the bone marrow of healthy adult donors.

The efficacy data was presented in a poster by Dr. Jerry Liu, SanBio's Head of Clinical Development in North America. "When SB623 cells were administered in patients who had previously suffered a stroke, we saw statistically significant improvement compared to baseline in motor function, and this improvement appears to be sustainable," said Dr. Liu. The improvements – summarized from all patients who completed follow up – were evaluated based on the European Stroke Scale, the National Institutes of Health Stroke Scale, the Fugl-Meyer total score, and the Fugl-Meyer motor function total score. "We are encouraged by this data," continued Liu, "and hope to provide an effective treatment for the millions of people living with impairments following a stroke."

The data also showed that the treatment was generally safe and well-tolerated by the trial participants, though all patients reported treatment emergent adverse events, the most common of which was procedure related headache. There were 6 serious adverse events (SAEs), with subdural hematoma, seizure, and pneumonia related or possibly related to the procedure. No SAEs were likely related to the stem cell treatment. Dr. Lawrence Wechsler from the University of Pittsburgh Medical Center reviewed the safety data in an oral presentation. "The data suggest that patients were able to tolerate SB623 cells at 12 months following procedure, and further demonstrates the potential for SB623 cells as a possible treatment option for patients with chronic impairments following a stroke," said Dr. Wechsler.

Based on the results of this Phase 1/2a study, SanBio and its joint development partner in the United States and Canada, Sumitomo Dainippon Pharma Co., Ltd., began a Phase 2b controlled clinical trial in 2015 in the United States to further investigate SB623 for the treatment

of chronic motor deficits following ischemic stroke. SanBio has also initiated a global Phase 2 clinical trial of SB623 for traumatic brain injury in the United States and Japan.

About SanBio, Inc.
SanBio is a regenerative medicine company located in Tokyo and Mountain View, California, with cell-based products in various stages of research, development, and clinical trial. 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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