June 27, 2016
SanBio Co., Ltd.

SanBio Presents Interim Results of Chronic Stroke Phase 1/2a Clinical Trial at International Society of Stem Cell Research Annual Meeting

Mountain View, Calif. —June 24, 2016 (June 25, 2016 Japan time)—SanBio, Inc., a scientific leader in regenerative medicine for neurological disorders, presented the 12-month interim results of a Phase 1/2a clinical trial for the treatment of chronic motor deficits secondary to stroke at the International Society of Stem Cell Research Meeting in San Francisco. Preliminary results suggest that SanBio's stem cell treatment, SB623, is generally safe and well-tolerated, and may have the ability to improve motor function in patients six months to five years following an ischemic stroke.

The trial was the first intracerebral stem cell transplant study for stroke in North America. It was an open-label, single-arm, dose escalation study of 18 patients with chronic motor deficits present for at least six months following an ischemic stroke. Patients received injections of SB623 cells—modified allogeneic mesenchymal stem cells derived from the bone marrow of healthy human adult donors—which promote recovery from injury when administered into neural tissue by triggering the brain's natural regenerative ability.

The data demonstrated statistically significant improvements in motor function based on the European Stroke Scale, National Institutes of Health Stroke Scale, the Fugl-Meyer total score and the Fugl-Meyer motor function total score for all sixteen patients who completed follow-up. SanBio's Chief Medical Officer and Head of Research, Dr. Damien Bates, commented that "This is a promising step in the right direction toward an effective treatment for the chronic effects of stroke."

The treatment was generally safe and well-tolerated by the trial participants. All patients reported minor treatment emergent adverse events (TEAEs), the most common of which was headache. No patients reported any serious side effects due to the stem cell treatment. Dr. Jerry Liu, Medical Director and Head of Clinical Development in North America at SanBio, added, "We are pleased and encouraged by these results and believe that these data suggest that chronic stroke patients tolerated the SB623 cell treatment at 12 months following the procedure."

SanBio has followed all patients for 24 months following the procedure, and these results will be reported later this year. Based on the encouraging results of this Phase 1/2a study, SanBio and its joint development partner in North America, Sumitomo Dainippon Pharma Co., Ltd., began a Phase 2b controlled clinical trial to further investigate SB623 for the treatment of chronic motor deficits secondary to ischemic stroke. SanBio also began a Phase 2 clinical trial of SB623 for traumatic brain injury in 2015.

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

# # #

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