SanBio publishes interim 12-month Phase 1/2a clinical trial results in the peer-reviewed medical journal, Stroke

Mountain View, Calif. —June 2, 2016—SanBio, Inc., a scientific leader in regenerative medicine for neurological disorders, today announced the publication of an important paper in Stroke, a leading peer-reviewed journal from the American Heart Association. The paper, titled “Clinical Outcomes of Transplanted Modified Bone Marrow-Derived Mesenchymal Stem Cells in Stroke: A Phase 1/2a Study,” presents the 12-month interim follow-up data from a two-year clinical trial of its SB623 stem cell treatment in patients with chronic motor deficits from ischemic stroke. These data suggest the cell treatment was both well-tolerated and effective in promoting functional recovery in those living with motor impairments six months to five years following their stroke.

Said Dr. Damien Bates, Chief Medical Officer and Head of Research at SanBio, “This was the first intracerebral stem cell treatment study for stroke in North America, and we are excited that Stroke has chosen to share the findings of this significant development in stroke research. The clinical data suggest that patients not only tolerated the SB623 cell treatment, but that they also experienced significant improvement in motor function post treatment. These results are encouraging for both the medical community working toward a treatment for chronic motor deficits from stroke and all patients suffering from the long-term effects of stroke.”

The trial was an open-label, single-arm dose escalation study of 18 patients. Patients had chronic motor deficits more than six months following their initial stroke. The group was split into three cohorts that each received different SB623 cell doses.

SB623 cells, SanBio’s proprietary product, are modified allogeneic mesenchymal stem cells, derived from the bone marrow of healthy human adult donors. When administered into neural tissue, SB623 cells promote recovery from injury by triggering the brain’s natural regenerative ability.

The 12-month interim data from the Phase 1/2a Study demonstrated that the treatment met the majority of its efficacy endpoints; overall, for the 16 patients who completed follow up, there were statistically significant improvements in motor function according to the European Stroke Scale, National Institutes of Health Stroke Scale, the Fugl-Meyer total score and the Fugl-Meyer motor function total score.

The treatment was also 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.

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

###

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