



University Hospitals Case Medical Center Randomizes the First Patient in ACTIsSIMA Trial for Chronic Stroke

Mountain View, Calif. —March 10, 2016— [SanBio, Inc.](#), announced today the randomization of the first enrolled patient in the [ACTIsSIMA](#) Phase 2b clinical trial being conducted in the United States.

Ischemic strokes account for approximately 87 percent of all strokes in the United States and occur when there is an obstruction in a blood vessel supplying oxygen to the brain. With approximately 800,000 cases occurring in the United States every year, stroke is the leading cause of acquired disability in the United States. Although existing drug treatments for stroke focus on prevention or acute care, there are no medical treatments currently available for people living with the debilitating effects of stroke, months or even years after the stroke occurred.

The ACTIsSIMA trial will examine the safety and efficacy of SB623 cells in patients who have experienced an ischemic stroke in the previous six months to five years and exhibit chronic motor impairments. SB623 cells are modified allogeneic mesenchymal stem cells, derived from bone marrow stromal cells isolated from healthy donors. When administered into neural tissue, SB623 cell therapy is designed to promote recovery from injury by potentially triggering the brain's natural regenerative ability.

Damien Bates, M.D., Chief Medical Officer & Head of Research at SanBio, said, "Our previous trial suggested there was potential for SB623 to improve outcomes for patients with lasting motor deficits following an ischemic stroke. Randomization of the first subject marks an exciting step toward further evaluating this treatment as a promising new option for patients."

SanBio is working closely with Sunovion Pharmaceuticals, Inc., a wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., on the conduct of the clinical trial. SanBio and Sumitomo Dainippon Pharma have entered into a joint development and license agreement for exclusive marketing rights in North America for SB623 for chronic stroke.

The ACTIsSIMA trial will include approximately 60 clinical trial sites throughout the United States, and total enrollment is expected to reach 156 patients.

About the ACTIsSIMA Trial

The ACTIsSIMA trial will examine the efficacy of SB623, modified adult bone-marrow-derived stem cells, when administered to patients with chronic motor deficit secondary to ischemic stroke. A secondary purpose is to evaluate the safety of SB623 in these patients.

About SanBio, Inc. (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 beginning Stage 2b clinical trials for treatment of chronic stroke. SanBio also began Stage 2 clinical trials

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for treatment of traumatic brain injury in 2015. More information about SanBio, Inc. is available at www.san-bio.com.

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