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SanBio and Sunovion begin Patient Recruitment for Phase 2b Trial to Test Regenerative Treatment for Chronic Stroke in North America

SanBio Co., Ltd. (hereafter “the Company”) announces today that SanBio and Sunovion begin patient recruitment for Phase 2b trial to test regenerative treatment for Chronic Stroke in North America as attached.



SanBio and Sunovion begin Patient Recruitment for Phase 2b Trial to Test Regenerative Treatment for Chronic Stroke in North America

Studying patients impaired six months to five years following ischemic stroke

Mountain View, Calif. — December 21, 2015 — [SanBio, Inc.](#), a scientific leader in regenerative medicine for neurological disorders, announced today that it has initiated patient recruitment for a Phase 2b clinical trial to further test the safety and efficacy of its proprietary cell therapy. 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. Earlier clinical trial results suggested the therapy's potential to improve motor function following an ischemic stroke. 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.

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 strokes occurring in the United States every year, stroke is the leading cause of acquired disability in the United States. Therapies for acute stroke generally do not result in meaningful improvement beyond the first six months following a stroke.

The [ACTIsSIMA](#) "Allogeneic Cell Therapy for Ischemic Stroke to Improve Motor Abilities" 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 still suffer from 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 triggering the brain's natural regenerative ability.

Damien Bates, M.D., Chief Medical Officer & Head of Research at SanBio, said, "While 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. We are optimistic that SB623 may provide a new treatment option for these patients."

"This collaboration represents our shared commitment to patients with serious conditions where no effective drugs exist for whom regenerative therapies may offer a truly innovative therapeutic approach," said Antony Loebel, M.D., Executive Vice President and Chief Medical Officer, Sunovion Pharmaceuticals Inc., and Head of Global Clinical Development for Sumitomo Dainippon Pharma Group.

The [ACTIsSIMA](#) Phase 2b clinical trial follows a Phase 1/2a clinical trial in which the SB623 cell treatment suggested improvements in motor function. The Phase 2b clinical trial will further evaluate the safety and efficacy of SB623 treatment. There are expected to be 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 is expected to begin Stage 2 clinical trials for treatment of traumatic brain injury later in 2015. More information about SanBio, Inc. is available at www.san-bio.com.

About Sunovion Pharmaceuticals Inc. (Sunovion)

Sunovion is a leading pharmaceutical company dedicated to discovering, developing and commercializing therapeutic products that advance the science of medicine in the Psychiatry, Neurology and Respiratory disease areas to improve the lives of patients and their families. Sunovion, an indirect, wholly owned subsidiary of Sumitomo Dainippon Pharma Co., Ltd., is headquartered in Marlborough, Mass. More information about Sunovion Pharmaceuticals Inc. is available at www.sunovion.com.

About Sumitomo Dainippon Pharma Co., Ltd. (Sumitomo Dainippon Pharma)

Sumitomo Dainippon Pharma is a top-ten listed pharmaceutical company in Japan. Sumitomo Dainippon Pharma aims to produce innovative pharmaceutical products in the Psychiatry & Neurology area and the Oncology area, which have been designated as the company's therapeutic focus areas. Sumitomo Dainippon Pharma was formed by the 2005 merger of Dainippon Pharmaceutical Co., Ltd., and Sumitomo Pharmaceuticals Co., Ltd. Today, Sumitomo Dainippon Pharma has about 7,000 employees worldwide. Additional information about Sumitomo Dainippon Pharma is available through its corporate website at www.ds-pharma.com.

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