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Idea & Innovation

AWARD - Bioscience: SanBio creates better odds for stroke recovery

Bioscience Winner

Premium content from Silicon Valley / San Jose Business Journal by N. Sheree Saunders

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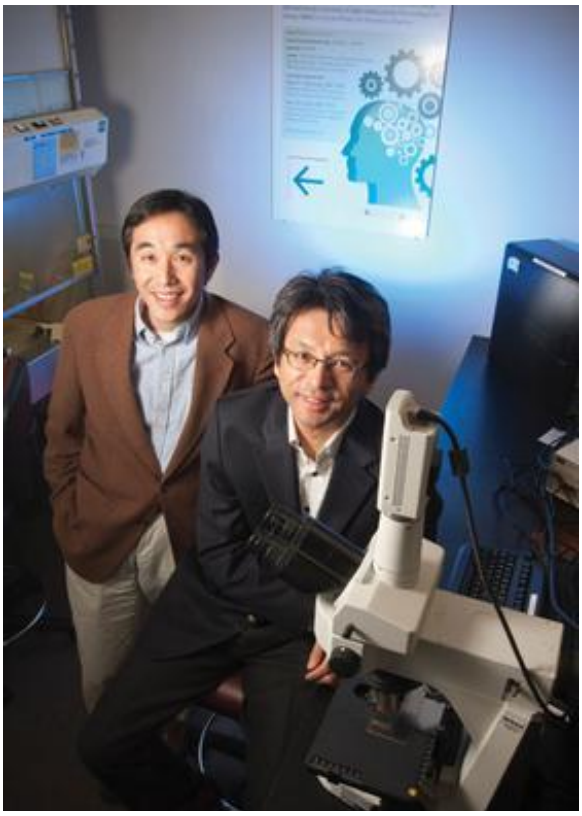
A Mountain View-based biotech company could change how stroke patients are medically treated.

SanBio Inc. recently received approval from the **U.S. Food and Drug Administration** to test a regenerative cell therapy on patients who have become disabled as a result of ischemic stroke, or strokes caused by blocked blood vessels in the brain. This is the only clinical trial in the United States currently testing the regenerative potential of cell therapy in the brain, according to company officials.

The company had treated its first four patients as of January and intends to treat one to two patients a month throughout 2012 until it reaches 18.

CEO Keita Mori said the therapy could mean a significant breakthrough in treatment for chronic stroke patients, a population without many therapeutic options. Strokes are the leading cause of serious, long-term handicaps in the United States and according to the **American Heart Association**, Americans will pay about $73.7 billion a year for stroke related medical costs and disability.



Vicki Thompson

Toru Kawanishi (left) and Keita Mori, co-CEOs of SanBio, are testing a cell therapy that could provide patients help up to three years after a stroke occurs.

To date, the sole FDA-approved stroke therapy, tissue plasminogen activator (tPA), a protein that helps break down blood clots, must be administered within hours of the onset of stroke symptoms. However, many people who experience stroke symptoms don't get help that quickly, and because of this, less than 10 percent of patients who have suffered from a stroke qualify for TPA treatment.

But SanBio's SB623 therapy, created from genetically manipulated bone marrow stem cells, is administered to damaged tissue and can be used on patients who have suffered a stroke up to three years prior to treatment.

Casey Case, vice president of research at SanBio, said SanBio has spent much of its 10 years developing the product.

After experiencing success with preclinical models — in animal studies, treatment with SB623 brought measurable improvements in the use of limbs — last summer, the company cleared the regulatory hurdles required to initiate human testing. In September, SanBio announced that a patient at **Stanford Medical Center** had become the first person to be treated with SB623.

SanBio plans to monitor patients for two years, using this phase of the trial to focus on safety. Once this phase is completed, Case said SanBio will ask the FDA for permission to do another clinical trial 10 times larger, with a focus on efficacy. Ultimately, the company hopes to be able to make the treatment available to the public for treatment of stroke, spinal cord injury and Parkinson's disease, within six years. Other products in the company's pipeline include a treatment for multiple sclerosis and spinal cord injury, and a treatment of muscular dystrophy and trauma.

"We're trying to find new therapies for completely unmet medical needs," Case said. "It's very satisfying to talk to people who have had a stroke, and ... have no other alternatives (for treatment), and be able to help them."

SanBio
Location: Mountain View
Co-CEOs: Toru Kawanishi and Keita Mori
Founded: 2001
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