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Baxano Enrolls First Patient in Groundbreaking STRiDE Trial

-- Prospective, multi-center study designed to evaluate treatment of lumbar spinal stenosis with an iO-Flex® System enabled decompression --

San Jose, CA – September 12, 2011 – Baxano, Inc., a Silicon Valley based medical device company and manufacturer of the iO-Flex® System for spinal decompression surgery, announces enrollment of the first patient into its post-market STRiDE (Spondylolisthesis Treated with an iO-Flex® System enabled Decompression) trial. The study is designed to evaluate the effectiveness of the system in treating patients having moderate to severe lumbar spinal stenosis with stable grade I degenerative spondylolisthesis compared to the current standard of care.

Anthony Asher, M.D. National Principal investigator for the trial said, "The focus of all stakeholders in the medical system has shifted dramatically towards critical analyses of quality and cost in healthcare delivery. In that regard, innovative strategies and technologies primarily designed to improve the value of medical interventions are re-shaping the way we deliver care. In this clinical study, our objective is to compare the outcomes of patients treated with the Baxano iO-Flex® System to outcomes achieved in similar clinical conditions using much more invasive and expensive technologies. Based on preliminary analyses, we believe that the iO-Flex® System has the potential to revolutionize the care of patients with spinal disorders by allowing decompression of neural structures on par with more invasive techniques, thus saving costs and minimizing trauma to healthy tissues."

The landmark STRiDE trial will enroll 150 patients in up to 30 leading centers across the United States. The primary endpoint at 2 years is a responder analysis based on achievement of≥ 15 point change from baseline on the Oswestry Disability Index (ODI). In addition, change in multiple patient reported outcomes from baseline will be assessed at six months and annually out to 5 years. These outcomes will be compared to objective performance criteria established by the current standard of care.

Jed Vanichkachorn, MD, orthopedic spine surgeon at Tuckahoe Orthopaedics in Richmond, VA, performed the first clinical study case. "The iO-Flex® System is a breakthrough technology in the field of lumbar spinal decompression, which has allowed me for the first time to perform a minimally invasive facet sparing decompression for patients with spondylolisthesis and stenosis. I look forward to further evaluating this technology in the STRiDE study," said Dr. Vanichkachorn.

The FDA-cleared iO-Flex® System is the first minimally invasive set of flexible instruments designed to precisely target central, lateral recess and foraminal lumbar stenosis without disrupting spinal anatomy critical for maintaining spinal stability. It offers the only decompression alternative able to decompress up to four nerve roots on both sides of the spine through one small incision to minimize muscle trauma.

"The iO-Flex® System brings important new capabilities to spine surgeons to treat Lumbar Spinal Stenosis. This breakthrough technology continues our commitment to advancing patient care," said Tony Recupero, CEO, Baxano, Inc.

Baxano is also currently enrolling its first post-market study, “Evaluation of the Baxano iO-Flex® System for Decompressive Lumbar Surgery,” at 20 sites throughout the U.S. This study is designed to further showcase the effectiveness and economics of the system in treating patients with lumbar spinal stenosis. Enrollment is expected to be complete in early 2012.

For more information about Baxano, the iO-Flex® System or the company’s post-market clinical trials, please visit: www.baxano.com.

About Lumbar Spinal Stenosis

Lumbar Spinal Stenosis is a degenerative medical condition in which the spinal canal narrows and compresses the spinal cord and nerves in the lumbar area of the spine. Symptoms include pain, weakness, numbness and tingling in the lower back and legs.

Decompression surgery is a common procedure used to treat lumbar spinal stenosis by cutting away overgrown bone and tissue causing pressure on the spinal nerves. Approximately 325,000 surgical procedures involving decompression to treat lumbar stenosis are performed each year in the U.S.

About Baxano, Inc.

Baxano, Inc., based in San Jose, California, is a privately held company which was founded in 2005 with the vision to create flexible tools to provide precision lumbar decompression from the “inside out.” These important platform technologies will form the basis for future product offerings.

Baxano’s mission is to develop innovative tools that restore spine function, preserve healthy tissue, and enable a better quality of life for the patients we serve.

Along with our dedication to advanced technology development, Baxano is focused on providing exceptional value to patients, customers, investors and employees. For more information about Baxano and its products, please visit: www.baxano.com