Hanger completes enrollment of WalkAide INSTRIDE clinical trial

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AUSTIN, Texas, May 2, 2012 /PRNewswire/ -- Hanger Orthopedic Group, Inc. (NYSE: HGR) today announced the completion of enrollment in its pivotal INSTRIDE investigational device exemption (IDE) clinical trial studying the effectiveness of its WalkAide System in the rehabilitation of stroke survivors. With 496 patients enrolled at 30 institutions in the United States, the INSTRIDE trial is the largest, randomized, controlled study of a walking device ever conducted in stroke rehabilitation.

"We are pleased to reach this significant milestone on schedule and exactly two years to the day of enrollment of our first patient," said Hanger CEO Thomas F. Kirk, Ph.D. "We greatly appreciate the dedicated efforts of our physician investigators and their research staff. We are one step closer to bringing the WalkAide technology to those who need it most."

Addressing a frequent consequence of hemiplegia from stroke known as "foot drop", the purpose of the INSTRIDE trial is to compare the use of the WalkAide, a functional electrical stimulation (FES) device, with the standard of care ankle-foot orthosis (AFO), a rigid plastic brace designed to stabilize a paralyzed or weakened foot in a functional position. Primary outcome measures include ambulation (more specifically to gait velocity) and activities of daily living, with the main study endpoint as the comparison of success between the two devices at six months. The results of the INSTRIDE trial will form the basis for submission in 2013 to the Centers for Medicare and Medicaid Services (CMS) for national coverage of the WalkAide.

"The INSTRIDE clinical trial is a one-of-a-kind endeavor that could facilitate reimbursement of this technology and set the model for additional studies to come," said Francois Bethoux, M.D., Director of Rehabilitation Services at the Cleveland Clinic Mellen Center and the principal investigator of the INSTRIDE clinical trial. "We are very happy to have achieved this enrollment milestone and are thankful for the patients who kindly agreed to participate. Walking limitations have a profound impact on people's everyday lives. It is important for patients to have options for active devices that improve walking ability and potentially promote brain plasticity."

Granted 510(k) clearance by the U.S Food and Drug Administration (FDA) in 2005 and a CE Mark from the European Union in 2006, the WalkAide is an external stimulator that applies electrical pulses to restore proper foot flexion for patients who have suffered an upper motor neuron disruption from a stroke, incomplete spinal cord injury, traumatic brain injury, multiple sclerosis, or cerebral palsy. The device functions by using a microprocessor with a built-in tilt sensor that allows for precise timing of stimulus to create a normalized gait pattern. About the size of a deck of cards, the device fits on a small cuff worn around the calf; it has no external wires and can be worn with or without shoes. Developed and commercialized by Hanger's therapeutic solutions business unit Innovative Neurotronics, Inc., the WalkAide is currently being used by thousands of patients worldwide.

About Hanger – Hanger Orthopedic Group, Inc., headquartered in Austin, Texas, is the world's premier provider for services and products that enhance human physical capability. Hanger provides orthotic and prosthetic patient care services, distributes O&P devices and components and provides therapeutic solutions to the broader post-acute market. Hanger is the largest owner and operator of orthotic and prosthetic patient care centers with in excess of 700 O&P patient care centers located in 45 states and the District of Columbia. Hanger, through its subsidiary Southern Prosthetic Supply, Inc, is also the largest distributor of branded and private label O&P devices and components in the United States. Hanger provides therapeutic solutions through its subsidiaries Innovative Neurotronics and Accelerated Care Plus. Innovative Neurotronics introduces emerging neuromuscular technologies developed through independent research in a collaborative effort with industry suppliers worldwide. Accelerated Care Plus is a developer of specialized rehabilitation technologies and the nation's leading provider of evidence-based clinical programs for post-acute rehabilitation serving more than 4,000 long-term care facilities and other sub-acute rehabilitation providers throughout the U.S. For more information on Hanger, visit www.hanger.com and follow us at www.Facebook.com/HangerNews and www.Twitter.com/HangerNews.

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