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## INITIAL STUDY RESULTS PUBLISHED IN AMERCIAN HEART ASSOCIATION'S STROKE JOURNAL REVEAL THAT THE BIONESS L300 PRODUCES SIGNIFICANT WALKING IMPROVEMENTS AND IS PREFERRED BY STROKE SURVIVORS WITH FOOT DROP

**VALENCIA, CALIF. – Date** – Bioness, Inc. today announced that 30-week results from the company's study of the Bioness L300® Foot Drop System in persons with stroke have been published in the premier journal of the American Heart Association; *Stroke*. The results demonstrate that persons with drop foot following stroke had significant performance improvements using the Bioness L300 matching that of the standard of care, the ankle foot orthosis (AFO). Subjects who used the Bioness L300 specifically reported significantly greater satisfaction and willingness to continue use of the L300 after 30 weeks.

"For individuals who have experienced a stroke and suffer from physical deficits like foot drop, after a certain point the course of rehabilitation tends to be focused on helping them live with their limitations rather than gain functional improvement," said Dr. Patricia Kluding, Associate Professor in the Department of Physical Therapy & Rehabilitation Science at the University of Kansas, and lead investigator on the study. "This initial data shows that there is some hope – even years after a stroke – that with the right therapy and device support, patients can potentially make significant gains with walking, opening the door to independence."

The study, titled Foot Drop Stimulation Versus Ankle Orthosis After Stroke (30 week results from the FASTEST trial), involved 197 patients at 11 U.S. centers. Subjects were on average 4.5 years post-stroke and were randomized to receive 30 weeks of foot drop stimulation via the Bioness L300 or AFO. Both groups received dose-matched physical therapy in the first 6 weeks of the trial. Performance was assessed by testing subject's walking speed, distance walked, and balance through accepted standardized outcome measures. In addition, estimates for total steps taken per day, quality of life, and user satisfaction was also collected. Subjects were followed for a total of 42 weeks and the initial 30-week results were published in *Stroke*.

Participants in the L300 Group experienced an immediate increase of walking speed of 19.0 percent and continued to improve to a 33.3 percent improvement at 30 weeks. Additionally, nearly 90 percent of participants in the L300 Group were enthusiastic about continuing use of the device and rated it more useful than other walking aids, compared to only 45 percent and 56 percent, respectively, in the AFO Group.

"Rehabilitation physicians and therapists are all well aware of the challenges that their patients face with the physical limitations after stroke. Addressing these challenges with interventions and devices that provide immediate and long-term benefit while facilitating recovery, motivation, and compliance is desirable to providers and people with stroke alike," said Keith McBride, Vice President of Global Marketing for Bioness. "The 30-week data from the FASTEST study indicates that not only can patients experience lasting benefits with the L300 even years after stroke, but that the Bioness technology can encourage and motivate patients."

"With compliance being such a critical component of any therapy and rehabilitation program, we are encouraged by these initial 30-week results, and look forward to sharing the full 42 week results of the FASTEST study once available, added McBride. "Our ultimate goal is to expand accessibility to solutions like the L300, for providers and their patients."

## **About the L300 Foot Drop System**

The award winning L300 from Bioness, Inc. provides functional electrical stimulation to the muscles of the lower leg to help lift the foot up through wireless synchronization while walking. The L300 has been cleared by the FDA to improve gait in individuals with neurological impairments such as stroke, multiple sclerosis and spinal cord injury. The L300 is used as a primary medical device to address drop foot for individuals in the community and is also used for gait rehabilitation in inpatient or outpatient rehabilitation settings to potentially realize a variety of clinical benefits including improved mobility, maintaining or increasing range of motion, reeducating muscles, the prevention or slowing of muscle loss and increased local blood flow.

## **About Bioness Inc.**

Bioness is the leading provider of innovative technologies to help people regain mobility and independence and improve quality of life. Neurological solutions for people suffering from hand and lower extremity paralysis include the L300® Foot Drop System, L300® Plus System, and the H200® Wireless Hand Rehabilitation System which utilize functional electrical stimulation (FES) to promote motor recovery and function for individuals affected by central nervous system disorders including stroke, multiple sclerosis, spinal cord injury, traumatic brain injury and cerebral palsy. Patients may also benefit from the Vector Gait and Safety System<sup>TM</sup>, providing over-ground gait rehabilitation through dynamic body weight support. Bioness also distributes the Dynavision D2 which is a rehabilitative technology designed to help patients achieve new levels of physical independence and productivity. Individual results vary. Consult with a qualified physician to find out if these products are right for you. Additional information about Bioness can be found at www.bioness.com.

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