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ONWARD Reports Positive Topline Results from a Pivotal Study to Restore Arm and Hand Function in People with Spinal Cord Injury

Up-LIFT study achieves primary endpoint: Statistically significant and clinically meaningful improvement in upper extremity strength and functionⁱ

Improvement in arm and hand function is the highest priority among people with tetraplegiaⁱⁱ

Up-LIFT is the first large-scale clinical study of non-invasive spinal cord stimulation technology

ONWARD plans to submit for marketing approval in the U.S. and Europe with the goal to launch ARC-EX Therapy in the second half of 2023

EINDHOVEN, the Netherlands, LAUSANNE, Switzerland, and BOSTON, MA USA—September 13, 2022--ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injury (SCI), today announced that the Up-LIFT pivotal study evaluating ARC-EX Therapy achieved its primary effectiveness endpoint of improvement in upper extremity strength and function. ARC-EX Therapy is a proprietary non-invasive spinal cord stimulation technology designed to restore movement and other functions in people with movement disabilities.

“The Up-LIFT study results represent a turning point in the field of spinal cord injury and paralysis science,” said Marco Baptista, Ph.D., Chief Scientific Officer of the Christopher & Dana Reeve Foundation. Functional recovery once deemed impossible may now be in reach. The Reeve Foundation looks forward to this technology advancing and, we hope, becoming widely available to our community.”

“Our vision is to empower people with spinal cord injury to enjoy life in every way that matters to them. Today’s excellent results from the Up-LIFT study will help us transform that vision into reality”, said Dave Marver, ONWARD CEO. “Our team is working hard to prepare regulatory submissions and to get ready for launch in the U.S. and Europe. We are hopeful we can begin to positively impact the lives of people with spinal cord injury sometime during the second half of 2023.”

“Restoring hand and arm function after spinal cord injury is life-changing, freeing people with paralysis to feed and care for themselves and be more independent in everyday activities,” said Chet Moritz, Ph.D., study co-Principal Investigator (co-PI) and Professor of Electrical & Computer Engineering and Rehabilitation Medicine at the University of Washington.

“We are grateful to the many therapists, clinicians, and people with SCI who participated in this landmark study. There was very low attrition over thousands of clinic visits, a testament to the collective enthusiasm for this compelling therapy and for everyone’s determination to find new treatment options for people with SCI,” added Edelle Field-Fote, PT, Ph.D., FAPTA, FASIA, study

co-PI, Director of SCI Research at the Shepherd Center in Atlanta, GA, and Professor at Emory University School of Medicine in the Department of Rehabilitation Medicine.

The Up-LIFT study is a prospective, single-arm pivotal study designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation (ARC-EX Therapy) to treat upper extremity functional deficits in people with chronic tetraplegia (paralysis of all four limbs). The study enrolled 65 people at 14 leading SCI centers in the U.S., Europe, and Canada. Time since injury averaged 5.9 years (range 1 to 34 years) with an average subject age of 46.5 years. Detailed results will be made available after review by the FDA. The company plans to submit for regulatory approval in both the US and Europe within the next 6 months.

Participants completed an average of 50 training sessions over a period of about 4 months. A series of comprehensive assessments were performed at baseline and monthly thereafter to detect changes in sensory and motor function of upper extremities that directly translate into improved functional performance in activities of daily living. Rigorous measures such as CUE-T, GRASSP, ISNCSCIⁱⁱⁱ and pinch and grasp force were used to detect clinically meaningful changes resulting from the combination of ONWARD ARC-EX Therapy with a standard of care rehabilitation. An independent data safety monitoring board adjudicated the safe conduct of the study.

About Spinal Cord Injury

Spinal cord injury (SCI) represents a major unmet medical need for which there is no cure. Approximately 7 million people globally have a spinal cord injury, with over 650,000 in the U.S. and Europe alone. The quality of life of people with SCI can be poor, with paralysis and loss of sensation, issues with blood pressure control and trunk stability, increased potential for infection, incontinence, and loss of sexual function. Assistance is required for daily living activities. And SCI is costly, with the average lifetime cost for a paraplegic (paralysis of the legs) of \$2.5 million and \$5 million for a tetraplegic (paralysis of all four limbs). Treatments are urgently needed to restore movement and improve quality of life.

About ONWARD Medical

ONWARD is a medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injuries. ONWARD's work builds on more than a decade of basic science and preclinical research conducted at the world's leading neuroscience laboratories. ONWARD's ARC Therapy, which can be delivered by implantable (ARC-IM) or external (ARC-EX) systems, is designed to deliver targeted, programmed spinal-cord stimulation to restore movement and other functions in people with spinal cord injury, ultimately improving their quality of life.

ONWARD has received three Breakthrough Device Designations from the U.S. FDA encompassing both ARC-IM and ARC-EX. ARC-EX is an external, non-invasive platform consisting of a wearable stimulator and wireless programmer. Topline data were reported in September 2022 from the company's first pivotal study, called Up-LIFT, evaluating the ability of ARC-EX Therapy to improve upper extremity strength and function. The company is now preparing marketing approval submissions for the U.S. and Europe. ARC-IM consists of an implantable pulse generator and lead that is placed near the spinal cord. The company completed its first-in-human use of the ARC-IM neurostimulator in May 2022.

ONWARD is headquartered at the High Tech Campus in Eindhoven, the Netherlands. It maintains an office in Lausanne, Switzerland, and has a growing U.S. presence in Boston, Massachusetts, USA. For additional information about the company, please visit [ONWD.com](https://onwd.com). To access our 2022 Financial Calendar, please visit [IR.ONWD.com](https://ir.onwd.com).

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ⁱ Results pending review by FDA

ⁱⁱ Anderson KD. Targeting recovery: priorities of the spinal cord-injured population. *J Neurotrauma*. 2004 Oct;21(10):1371-83. doi: 10.1089/neu.2004.21.1371. PMID: 15672628.

ⁱⁱⁱ ISNCSCI = International Standards for Neurological Classification of Spinal Cord Injury
GRASSP = The Graded Redefined Assessment of Strength, Sensation, and Prehension
CUE-T = The Capabilities of the Upper Extremity Test