

## **ONWARD Announces Topline Results from the LIFT Home Study Supporting Safety and Feasibility of ARC-EX Therapy to Treat People with Spinal Cord Injury at Home**

*LIFT Home study evaluated the safety and feasibility of ARC-EX Therapy in the home setting*

*100% of subjects completed the study with no reported serious adverse events*

*97% of therapy sessions were successfully completed supporting the feasibility of home use*

EINDHOVEN, the Netherlands, LAUSANNE, Switzerland, and BOSTON, MA USA—October 5, 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 reported topline results from the LIFT Home study, evaluating the safety and feasibility of ARC-EX Therapy when used at home. ARC-EX Therapy is a proprietary non-invasive spinal cord stimulation technology designed to restore movement and other functions in people with spinal cord injury (SCI) and other movement disabilities. The Company recently reported its Up-LIFT pivotal study evaluating ARC-EX Therapy in clinics achieved its primary endpoint, demonstrating statistically significant and clinically meaningful improvement in upper extremity strength and function.

“Today’s results from the LIFT Home study support the potential for ARC-EX Therapy to be used safely at home, which would enable people with spinal cord injury to live even more independently,” said Dave Marver, CEO of ONWARD. “We expect to launch first in clinics, but as the community gains more experience with ARC-EX Therapy, we envision many patients will also want to use this technology at home.”

“To maximize recovery after spinal cord injury, it’s critical that we develop treatments that can be safely and effectively delivered in the home environment,” said Principal Investigator, Candy Tefertiller, PT, DPT, Ph.D., NCS, Executive Director of Research and Evaluation at Denver’s Craig Hospital. “Integrating home-based therapy not only facilitates opportunities for ongoing recovery, but also allows therapy to focus on more relevant activities for that specific individual.”

The LIFT Home study is a single-arm observational study. The main objective of the study is to evaluate the safety and feasibility of ARC-EX Therapy when used at home. Seventeen people were enrolled at five leading spinal cord injury research centers in the United States: Craig Hospital in Denver, Colorado, Shepherd Center in Atlanta, Georgia, Spaulding Research Institute in Boston, Massachusetts, University of Minnesota, and the University of Washington. Participants performed training on activities of daily living three times per week over a one-month period. Approximately 97% of these sessions were completed without usability issues, supporting the feasibility of home-based treatment. The absence of any device-related adverse events confirmed the favorable safety results observed during the Up-LIFT Study when ARC-EX Therapy was used in clinics.

ONWARD plans to discuss the findings from the LIFT Home study with regulatory authorities to define the appropriate approval pathway for home use, with a goal to facilitate access to ARC-EX Therapy for as long as needed without the burden of continued visits to a clinic.

## **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. Positive top-line 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).

For Company Enquiries:

[info@onwd.com](mailto:info@onwd.com)

For Media Enquiries:

MC Services AG

US: Laurie Doyle, P: +1 339 832 0752

Europe: Dr. Johanna Kobler, Katja Arnold, Kaja Skorka P: +49 89 210 228 0

[media@onwd.com](mailto:media@onwd.com)

For Investor Enquiries:  
[investors@onwd.com](mailto:investors@onwd.com)

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