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## **ONWARD Reports Interim Clinical Outcomes for Implantable ARC Therapy Demonstrating Potential to Improve Blood Pressure Regulation after Spinal Cord Injury**

*Low blood pressure is a major issue for people with spinal cord injury that impacts  
cardiovascular health and quality of life*

*ARC Therapy resulted in immediate improvement in blood pressure regulation in  
all study participants*

EINDHOVEN, the Netherlands, LAUSANNE, Switzerland, and BOSTON, MA USA—December 8, 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 interim clinical outcomes from the first ten<sup>1</sup> people treated to regulate blood pressure with implantable ARC Therapy, ONWARD's targeted spinal cord stimulation technique. ARC Therapy immediately improved blood pressure levels for all participants; this benefit has been sustained for the duration of the current follow-up period. Participants have also reported improved quality of life, increased energy and vitality, and reduced dizziness.

Aaron Phillips, PhD, Associate Professor, Physiology and Pharmacology, Biomedical Engineering, Cardiac Sciences, Clinical Neurosciences, Cumming School of Medicine, University of Calgary, and the Principal Investigator of the HEMO study, said: "Low blood pressure has long been a hidden complication of spinal cord injury that often goes unrecognized and leaves people feeling unwell. It also potentially predisposes them to cardiovascular disease. The results reported today with ARC Therapy are compelling and may open a new avenue to help people with spinal cord injury truly feel better, while also addressing heart health."

The interim outcomes reported today are from ten people with spinal cord injury who were treated at clinical centers in Canada and Switzerland. In addition to a sustained increase in blood pressure levels, participants who were taking an anti-hypotension drug prior to entering the study were able to significantly reduce or discontinue their medication. Participants also reported improved general well-being: Participants reported a reduction in orthostatic hypotension, including reduced dizziness and improved energy, and those prone to fainting or light-headedness prior to implant indicated that such incidents declined dramatically following treatment with ARC Therapy. Participants continue to be followed, in one case for as long as three years, and the therapy remains beneficial in all cases.

Dave Marver, CEO of ONWARD, said: "We are excited by these highly promising outcomes, which reinforce our plan to further develop and bring ARC-IM to the market for this important indication. Today, there are limited and ineffective options for treating people with low blood pressure after spinal cord injury, and our therapy has the potential to address an issue that significantly impacts their quality of life."

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<sup>1</sup> A total of 10 people have received ARC Therapy across three studies: [STIMO-HEMO](#), [HEMO](#), and [HemON](#), as well as a clinical proof-of-concept, [published in Nature in January 2021](#)

Over 40% of people with spinal cord injury, or approximately 262,000 people in the U.S. and Europe<sup>2</sup>, are estimated to experience hypotension, or low blood pressure. Hypotension may limit active participation in physical rehabilitation programs and facilitate the deterioration effects of immobilization and development of undesirable secondary medical complications.

Based on the promising interim outcomes from these feasibility studies, ONWARD is preparing to initiate further clinical trials to include U.S. participants in 2023.

## 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 paraplegia (paralysis of the legs) of \$2.5 million and \$5 million for tetraplegia (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 five 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 transcutaneous ARC 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 in Eindhoven, the Netherlands. It maintains a Science and Engineering Center in Lausanne, Switzerland, and has a growing U.S. presence in Boston, Massachusetts. The company has an academic partnership with .NeuroRestore, a collaboration between the Swiss Federal Institute of Technology (EPFL) and Lausanne University Hospital (CHUV). For additional information about the company, please visit [ONWD.com](https://onward.com).

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<sup>2</sup> 2020 NSCISC Annual Statistical Report Complete Public Version; company data

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