

ONWARD Announces First-in-Human Use of ARC-IM™ Lead to Restore Movement and Function after Spinal Cord Injury

New lead is purpose-designed to optimize the delivery of ONWARD ARC Therapy™

EINDHOVEN, the Netherlands — May 15, 2023 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative therapies to restore movement, function, and independence in people with spinal cord injury (SCI), today announced the successful first-in-human use of its investigational ARC-IM Lead.

The ARC-IM Lead delivers targeted electrical pulses to the spinal cord and is a key component of the ONWARD ARC-IM system, an innovative platform engineered to deliver ARC Therapy to address multiple indications. The ARC-IM Lead is designed to be used with the ARC-IM neurostimulator (IPG) and is purpose-built for placement along the spinal cord to stimulate the dorsal roots, with specific parameters designed for each anatomical location. ONWARD is developing a portfolio of ARC-IM Leads in a range of sizes, shapes, and electrode arrays for the many indications the Company is developing or exploring, such as improved blood pressure management, mobility, upper extremity function, and bladder control.

The ARC-IM Lead was implanted today by Jocelyne Bloch, MD, neurosurgeon at Centre Hospitalier Universitaire Vaudois (CHUV) in Lausanne, Switzerland, to benefit a patient with poor blood pressure regulation following SCI.

“The shape and electrode placement of the ARC-IM Lead are unique, providing characteristics I have long wanted for my patients with spinal cord injury, while exhibiting the same feel as the leads I have implanted for many years,” said Dr. Bloch.

During today’s surgery, the ARC-IM Lead was placed in the “Hemodynamic Hotspot” along the thoracic spinal cord, an area in which targeted electrical stimulation may restore better blood pressure regulation after an SCI. This specific location and accompanying mechanism of action were first discovered by the Company’s research partners at the Swiss Federal Institute of Technology Lausanne (EPFL) and University of Calgary and published in [Nature](#) in January 2021.

In December 2022, ONWARD announced positive interim results from the first ten people treated with targeted ARC-IM Therapy to improve blood pressure regulation following SCI. All participants reported improved quality of life. ONWARD received an FDA Breakthrough Device Designation in 2021 for this indication.

“The purpose-designed ARC-IM Lead will unlock our ability to optimally deliver ARC Therapy to address many of the challenges faced by people with spinal cord injury,” said Dave Marver, CEO of ONWARD. “We look forward to using the lead to pursue restoration of mobility and other indications in the future.”

All ONWARD devices and therapies referenced here, including but not limited to ARC-IM, ARC-EX, and ARC Therapy, are investigational and not available for commercial use.

About ONWARD® Medical

ONWARD is a medical technology company creating innovative therapies to restore movement, function, and independence in people with spinal cord injuries. The Company's work builds on more than a decade of basic science and preclinical research conducted at the world's leading neuroscience laboratories. ONWARD 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 eight Breakthrough Device Designations from the US FDA. ARC-EX is an external, non-invasive platform consisting of a stimulator and wireless programmer. Positive top-line data were reported in 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 US and Europe. ARC-IM consists of an implantable pulse generator and lead placed near the spinal cord. The Company completed the first-in-human use of the ARC-IM neurostimulator and reported positive interim clinical outcomes for ARC-IM Therapy for improved blood pressure regulation following SCI in 2022.

ONWARD is headquartered in Eindhoven, the Netherlands. It maintains a Science and Engineering Center in Lausanne, Switzerland, and has a growing US presence in Boston, Massachusetts. The Company has an academic partnership with .NeuroRestore, a collaboration between EPFL, the Swiss Federal Institute of Technology in Lausanne, and Lausanne University Hospital (CHUV). For additional information about the Company, please visit [ONWD.com](https://onwd.com). To access our 2023 Financial Calendar, please visit [IR.ONWD.com](https://ir.onwd.com).

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