



PRESS RELEASE

Concurrent Publications in *Nature* and *Nature Medicine* Highlight Advances in Blood Pressure Regulation after Spinal Cord Injury Using ONWARD ARC-IM Therapy

- *Detailed results from clinical feasibility studies show immediate improvement in blood pressure stability and durable reduction of hypotensive symptoms, resulting in improved quality of life*
- *Most people living with spinal cord injury experience blood pressure instability, which represents a key unmet need*
- *Today's concurrent publications provide clinical evidence for ARC-IM[®] Therapy ahead of the Company's planned initiation of the Empower BP global pivotal trial later this year*

Eindhoven, the Netherlands, September 18, 2025 — ONWARD Medical N.V. (Euronext: ONWD – US ADR: ONWRY), the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injuries (SCI) and other movement disabilities, today announces two simultaneous landmark publications in *Nature* and *Nature Medicine*, adding to the compelling body of scientific and clinical evidence supporting the Company's investigational ARC-IM System.

Published in *Nature Medicine*, results from multi-year clinical feasibility studies show that participants who received ARC-IM Therapy saw immediate and robust increases in blood pressure, as well as reduced frequency and severity of hypotensive symptoms. The enhanced hemodynamic stability resulted in improved quality of life and greater engagement in rehabilitation and daily life activities. The studies enrolled 14 participants at leading neurorehabilitation clinics in Switzerland, Canada, and the Netherlands.¹

Additional benefits included reduced fatigue, improved bowel management, and increased tolerance of upright postures. Participants reduced or discontinued traditional treatments for low blood pressure, including compression garments and medications. Benefits were observed throughout the studies for up to two years post-implant, and were consistent across study sites. No serious device-related adverse events were reported.

In another publication simultaneously published in *Nature*, authors were able to identify the neuronal architecture of the spinal cord that forms after SCI and leads to autonomic dysreflexia (AD), an uncontrolled, life-threatening elevation of blood pressure. Results showed that electrical stimulation targeting the specific region of the spinal cord responsible for blood pressure regulation, called the "Hemodynamic Hotspot", can activate a competing neuronal architecture to safely and precisely regulate blood pressure.²

A majority of people living with SCI experience blood pressure instability, characterized by chronic orthostatic hypotension (OH) and episodes of autonomic dysreflexia.³ Among individuals with tetraplegia, 78% are diagnosed with orthostatic OH, yet only 28% receive treatment – and of those, 91% continue to experience symptoms.⁴ Blood pressure instability and persistent low blood pressure can threaten



neurological recovery and negatively impact cardiovascular health and quality of life. The most frequent symptoms include dizziness, lightheadedness, blurred vision, and fatigue.⁵

"Today's landmark publications in *Nature* and *Nature Medicine* validate our commitment to introducing therapies that address critical autonomic functions impacted by spinal cord injury," said Dave Marver, Chief Executive Officer of ONWARD Medical. "These promising results bolster our mechanistic understanding and demonstrate that the investigational ARC-IM System has the potential to meaningfully improve quality of life and positively impact one's ability to participate in daily activities after SCI. These data also demonstrate the effectiveness of ARC-IM Therapy for managing blood pressure instability in advance of our planned initiation of the Empower BP global pivotal study later this year."

"These results are a significant breakthrough for managing blood pressure instability, one of the key recovery targets after spinal cord injury," said Dr. Aaron Phillips, neuroscientist and Director of the RESTORE Network at the University of Calgary. "We have demonstrated that ARC-IM Therapy can improve hemodynamic stability by delivering precise electrical stimulation to the specific region of the spinal cord responsible for blood pressure regulation, addressing both persistent low blood pressure and episodes of uncontrolled, life-threatening high blood pressure."

The ONWARD ARC-IM System is an implanted neuromodulation platform designed to deliver targeted and personalized spinal cord stimulation. It is the first neuroprosthetic system designed to manage blood pressure instability in people with SCI. It comprises the implanted ONWARD Neurostimulator (IPG) and the ARC-IM Thoracic Lead, optimized for surgical placement in the specific region of the thoracic spinal cord (T10-T12) containing a high density of neurons that regulate blood pressure. The Hemodynamic Hotspot is the optimal site for precise stimulation to address blood pressure instability after SCI.

ONWARD recently announced that the FDA has approved an investigational device exemption (IDE) for the ARC-IM System. This approval allows the initiation of Empower BP, a global pivotal study to assess the safety and efficacy of the implantable neurostimulation technology to address blood pressure instability after SCI. Empower BP is a randomized, double-blind, sham-controlled study expected to involve a minimum of 60 participants in 20 leading neurorehabilitation and neurosurgical research centers across the US, Canada, and Europe. First patient enrollment is anticipated before the end of the year. The study will target participants with injuries at spinal cord levels C2-T6 and injury severities of AIS A-D.

To stay informed about ONWARD's research studies, technologies, and the availability of therapies in your area, please complete [this webform](#).

About ONWARD Medical

ONWARD Medical is the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injuries and other movement disabilities. Building on decades of scientific discovery, preclinical research, and clinical studies conducted at leading hospitals, rehabilitation clinics, and neuroscience laboratories, the Company developed ARC Therapy. It has subsequently been awarded 10 Breakthrough Device designations from the FDA. The Company's ARC-EX[®] System is cleared for commercial sale in the US and Europe. The Company is also developing an investigational implantable system called ARC-IM[®], designed to address several unmet needs, including



blood pressure instability after spinal cord injury. It can also be paired with a brain-computer interface (BCI) and artificial intelligence (AI) to restore thought-driven movement.

Headquartered in the Netherlands, the Company has a Science and Engineering Center in Switzerland and a US office in Boston, Massachusetts. The Company is listed on Euronext Paris, Brussels, and Amsterdam (ticker: ONWD) and its US ADRs can be traded on OTCQX (ticker: ONWRY). For more information, please visit [ONWD.com](https://onwd.com).

To stay informed about ONWARD's research studies, technologies, and the availability of therapies in your area, please complete [this webform](#).

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