



PRESS RELEASE

ONWARD Medical Announces First Participant Enrolled in Global Pivotal Study Evaluating ARC-IM System to Address Blood Pressure Instability After Spinal Cord Injury

- *Empower BP is a landmark global pivotal study evaluating the safety and effectiveness of the implantable ARC-IM® System to address blood pressure instability after spinal cord injury (SCI)*
- *Blood pressure instability is a key unmet need after SCI, with a significant impact on cardiovascular health and quality of life*
- *The first participant was enrolled at Craig Hospital in Denver, Colorado, USA*

Eindhoven, the Netherlands — February 4, 2026 — ONWARD Medical N.V. (Euronext: ONWD and US OTCQX: ONWRY), the neurotechnology company pioneering spinal cord stimulation therapies to restore movement, function, and independence, today announces the enrollment of the first participant in Empower BP, a global pivotal study assessing the safety and effectiveness of the investigational ARC-IM® System in managing symptomatic blood pressure instability in people with chronic spinal cord injury (SCI).

Empower BP is the first global pivotal study to evaluate the Company's implantable spinal cord stimulation system. The randomized, double-blinded, sham-controlled study is expected to involve participants across approximately 20 leading neurorehabilitation and neurosurgical research centers in the US, Canada, France, Germany, Spain, and the UK. The study targets individuals with injuries at spinal cord levels C2-T6 and injury severities of AIS A-D. The first participant was enrolled at Craig Hospital in Denver, Colorado.

"The initiation of Empower BP marks another significant milestone in our journey to restore critical autonomic functions impacted by spinal cord injury," said Dave Marver, CEO of ONWARD Medical. "The ARC-IM System is designed to address several unmet needs after SCI, including symptomatic blood pressure instability. The clinical feasibility results published last year in *Nature Medicine* were outstanding, and we are hopeful Empower BP will provide the data needed to bring this important therapy to hospitals and clinics worldwide."

Blood pressure instability is a key unmet need after SCI, characterized by chronic orthostatic hypotension and episodes of autonomic dysreflexia¹. Among individuals with tetraplegia, 78% are diagnosed with orthostatic hypotension, yet only 28% receive treatment – and of those, 91% continue to experience symptoms including dizziness, lightheadedness, blurred vision, and fatigue. Over time, persistent low blood pressure can threaten neurological recovery and negatively impact cardiovascular health.^{2,3}

"Blood pressure instability is a silent yet debilitating complication of spinal cord injury, with serious consequences for cardiovascular health and quality of life," said Dr. Candy Tefertiller, Executive Director of Research and Evaluation at Craig Hospital and Empower BP Principal Investigator. "We are eager to



evaluate the potential of ARC-IM Therapy to improve hemodynamic stability through precise stimulation of the spinal cord region responsible for blood pressure regulation.”

The Company’s ARC-IM System comprises the implanted ONWARD Neurostimulator and the ARC-IM Thoracic Lead, optimized for surgical placement in the specific region of the thoracic spinal cord containing a high density of neurons that regulate blood pressure. Published in [Nature Medicine](#) in September 2025, detailed 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. 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 for the duration of the studies, which lasted up to two years following implant.⁴

To learn more about the Empower BP study and view a list of active centers in your area, please visit the following [webpage](#).

About ONWARD Medical

ONWARD Medical is the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injuries (SCI) 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 its proprietary 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).

To learn more about ONWARD Medical’s commitment to partnering with the spinal cord injury community to develop innovative solutions for restoring movement, function, and independence after spinal cord injury, please visit [ONWD.com](https://onwd.com).

To be kept informed about the Company’s technologies, research studies, and the availability of therapies in your area, please [complete this webform](#).

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References

1. Katzelnick CG et al. Blood Pressure Instability in Persons With SCI: Evidence From a 30-Day Home Monitoring Observation. *Am J Hypertens*. 2019 Sep 24;32(10):938-944
2. Noreau, L. et al. Development and assessment of a community follow-up questionnaire for the Rick Hansen spinal cord injury registry. *Archives of Physical Medicine and Rehabilitation* 94, 1753–1765. ISSN: 0003-9993
3. Carlozzi, N. E. et al. Impact of blood pressure dysregulation on health-related quality of life in persons with spinal cord injury: development of a conceptual model. *Arch. Phys. Med. Rehabil.* 94, 1721–1730 (2013)
4. Phillips, A.A., Gandhi, A.P., Hankov, N. et al. An implantable system to restore hemodynamic stability after spinal cord injury. *Nat Med* 31, 2946–2957 (2025). <https://doi.org/10.1038/s41591-025-03614-w>

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