PRESS RELEASE

THIS PRESS RELEASE CONTAINS INSIDE INFORMATION WITHIN THE MEANING OF ARTICLE 7(1) OF THE EUROPEAN MARKET ABUSE REGULATION (596/2014)

ONWARD Medical Receives FDA IDE Approval to Initiate the Empower BP Pivotal Study with the ARC-IM System

- *The investigational device exemption (IDE) allows initiation of a global pivotal study designed to assess the safety and efficacy of the ARC^{IM} System®, an implantable neurostimulation technology developed to address blood pressure instability after spinal cord injury (SCI).*

- *Managing blood pressure instability is a major unmet need after SCI, with a significant impact on cardiovascular health and quality of life.*

- *Approximately 20 leading neurorehabilitation and neurosurgical research centers across the US, Canada and Europe are expected to participate.*

Eindhoven, the Netherlands, August 18, 2025 — ONWARD Medical N.V. (Euronext: ONWD and US ADR: ONWRY), the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injury and other movement disabilities, today announces that the US Food and Drug Administration (FDA) has approved an investigational device exemption for the ARC-IM System. With this approval, the Company can initiate the Empower BP pivotal study to assess the safety and efficacy of its implantable spinal stimulation system to address blood pressure instability after SCI.

Empower BP is the Company's second global pivotal study, and the first to evaluate the implantable ARC-IM System. The randomized, double-blinded, sham-controlled study is expected to involve approximately 20 leading neurorehabilitation and neurosurgical research centers across the US, Canada and Europe, with first patient enrollment anticipated before the end of the year. The study will target participants with injuries at spinal cord levels C2-T6, injury severities of AIS A-D, and blood pressure instability characterized by chronic orthostatic hypotension (OH) and episodes of autonomic dysreflexia (AD).

“This is an important milestone for ONWARD and the SCI community,” said Dave Marver, CEO of ONWARD. “Our ARC-IM System is designed to address several unmet needs, including blood pressure instability which is a major recovery target after spinal cord injury. With this IDE approval, we continue to advance our innovation pipeline and inspire realistic hope in restoring autonomic functions and independence after SCI and other movement disabilities.”

Over 50% of people with SCI experience blood pressure instability, affecting nearly 350,000 people in the US and Europe.[1] 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.[2]

“Blood pressure instability, especially chronic low blood pressure, is one of the most hidden and unrecognized functional complications of spinal cord injury,” explains Dr. James Guest, neurosurgeon and Professor of Neurological Surgery at the University of Miami. “It leaves people feeling unwell and can significantly impact their overall quality of life. Blood pressure instability also increases the risk of cardiovascular disease, making addressing this unmet need critical for improving the long-term outcomes of SCI.”

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. The ARC-IM Thoracic Lead is optimized for surgical placement in a specific region of the thoracic spinal cord, called the “*Hemodynamic Hotspot*”. The location was first discovered by the Company’s research partners at the Swiss Federal Institute of Technology Lausanne (EPFL), Centre Hospitalier Universitaire Vaudois (CHUV), and the University of Calgary in a study published in *Nature* in January 2021.[3]

In December 2022, the Company announced positive top-line interim clinical results from its feasibility studies showing improved blood pressure regulation and improved hemodynamic stability after SCI. In addition to immediate and sustained improved blood pressure levels, participants taking anti-hypotension drugs prior to the study significantly reduced or discontinued their medication. Participants also reported improved general well-being and a reduction in orthostatic hypotension, including reduced dizziness and increased energy. Detailed interim results from these studies are expected to be published later this year.

Managing blood pressure instability is among the major unmet needs for which the FDA has awarded the Company one of its 10 Breakthrough Device Designations. This award is reserved for novel, cutting-edge therapies addressing unmet needs and provides potential regulatory and reimbursement benefits.

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 over a decade 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. The Company is also developing an investigational implantable system called ARC-IM, which can be paired with a brain-computer interface (BCI) 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.

For Media Inquiries:
Sébastien Cros, VP Communications
media@onwd.com

For Investor Inquiries:
investors@onwd.com

Notes and 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. 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)

3. Squair, J.W. et al. Neuroprosthetic baroreflex controls haemodynamics after spinal cord injury. Nature 590, 308–314 (2021)

Forward-Looking Statements

Certain statements, beliefs, and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' current expectations and projections about future events. By their nature, forward-looking statements involve several risks, uncertainties, and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, delays in regulatory approvals, changes in demand, competition, and technology, can cause actual events, performance, or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions, or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.