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 CE Mark for ARC-EX, Enabling Commercial Launch of Breakthrough Spinal Cord Stimulation System in Europe

- *The CE Mark certification allows marketing for both clinic and home use*
- *First commercial sales of the ARC-EX® System in Europe are expected in Q4 2025*
- *The CE Mark enables commercialization in the European Union and facilitates a streamlined regulatory pathway in other countries, including in the UK and Switzerland*

Eindhoven, the Netherlands, September 8, 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 announced it has received CE Mark certification for its ARC-EX System under the European Union Medical Device Regulation (MDR), enabling commercialization in the European Union and certain other countries.

This certification enables the Company to promote the use of the ARC-EX System in conjunction with functional task practice to improve hand strength and sensation in adults with a chronic, non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive). The certification allows marketing for both clinic and home use. The ARC-EX System is non-invasive and delivers programmed, transcutaneous electrical spinal cord stimulation via electrodes placed on the back of the neck.

“Hand sensation and strength is a primary recovery target after spinal cord injury. The ARC-EX Therapy opens new doors for the SCI community in Europe, offering opportunities for recovery and care that were previously unavailable," said Dave Marver, Chief Executive Officer of ONWARD Medical. "The CE Mark certification for ARC-EX was awarded far earlier than expected and it gives us great satisfaction to bring this important new therapeutic option to the European spinal cord injury community. We will initiate a phased launch in Europe in the coming weeks, starting with Germany, and cascading to other countries as soon as possible thereafter."

The ARC-EX System is supported by a unique body of clinical evidence. Results of the Up-LIFT pivotal study published in *Nature Medicine* showed that 90% of study participants improved strength or function, 87% reported improvement in quality of life, and benefits were observed up to 34 years post-injury. The study also reported less spasm frequency, improved sleep quality, and improved upper body sensation and sense of touch. Additionally, results of the investigator-sponsored Pathfinder2 Study, published in *Neuromodulation: Technology at the Neural Interface*, showed that ARC-EX Therapy, combined with activity-based rehabilitation, delivered significant functional improvements and continued gains in upper body strength, trunk control, and balance after one year of treatment, with no plateau in therapeutic benefit[1].

As part of the CE Mark application process, ONWARD Medical achieved its first certification in accordance with the European Medical Device Regulation (MDR), meeting European standards and requirements relating to patient safety, clinical performance, risk management, and post-market surveillance.

Earlier this year, the Company initiated the phased launch of the ARC-EX System in US clinics following US Food and Drug Administration (FDA) clearance. The Company recently reported having met its commercial objective for the first half of 2025, with positive feedback and strong demand from its initial users. The ARC-EX System was selected as a *TIME Magazine Best Invention* in 2024 and it was also recognized as one of Fast Company's 2025 *World Changing Ideas* for its potential to transform lives.

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.

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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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.

[1]ARC-EX Indication for Use (EU): The ARC-EX System is intended to deliver programmed, transcutaneous electrical spinal cord stimulation in conjunction with functional task practice in the clinic and with take-home exercises in the home to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic (>1 year post-injury), non-progressive neurological deficit resulting from an incomplete spinal cord injury (C2-C8 inclusive).

Other Investigational Products: All other ONWARD Medical devices and therapies including ARC-IM and ARC-BCI are investigational and not available for commercial use.