**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 510(k) Clearance Expanding ARC-EX System Indication for Home Use

- *US FDA clearance now allows use of the ARC-EX® System both in clinics and homes*
- *ARC-EX is the first and only FDA-cleared technology demonstrated to improve hand strength and sensation in people with spinal cord injury*
- *Year to date, ARC-EX Systems have been purchased by more than 60 US clinics*

**Eindhoven, the Netherlands, November 17, 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 that it has received 510(k) clearance to expand the ARC-EX System indication for home use in the US.

The US Food and Drug Administration (FDA) has cleared the ARC-EX System for use in conjunction with functional task practice in the clinic and take-home exercises in the home to improve hand strength and sensation in adults with chronic, non-progressive neurological deficits resulting from an incomplete SCI (C2-C8 inclusive). The ARC-EX System is non-invasive and delivers programmed, transcutaneous electrical spinal cord stimulation. It is intended to be operated in medical centers by rehabilitation professionals and at home by patients and persons providing assistance to patients as needed.

“Today’s authorization expanding the ARC-EX System indication for home use greatly enlarges the US market opportunity and is a defining milestone for the spinal cord injury community,” said Dave Marver, CEO of ONWARD Medical. “People living with SCI will now be able to benefit from use of the ARC-EX System in the comfort and convenience of their own homes.”

“I’m excited to see this innovative SCI rehabilitation technology now available for home use,” said Dr. Candy Tefertiller, PT, DPT, PhD, NCS, Executive Director of Research and Evaluation at Craig Hospital in Denver, Colorado. “For people with limited mobility who navigate daily logistical challenges, having the option to use this therapy at home can make a meaningful difference. Integrating in-clinic and at-home therapy may help support and maintain improvements in hand strength and sensation, contributing positively to overall quality of life.”

“Today’s FDA clearance marks an important next step toward expanding multiple avenues of care — and ultimately cures — for people living with spinal cord injury and paralysis,” said Marco Baptista, Ph.D., Chief Scientific Officer of the Christopher & Dana Reeve Foundation. “By enabling therapy to be delivered at home, this milestone broadens access to technologies that may meaningfully improve health and quality of

life, including addressing the secondary complications of SCI. For more than 40 years, the Reeve Foundation and our community have invested boldly in high-risk, high-reward science, pairing funding and leadership with the lived experience of those living with SCI and those who care for them. Today's achievement demonstrates that we are now seeing breakthroughs once thought impossible."

ARC-EX Therapy is supported by a unique body of clinical evidence. Results of the Up-LIFT pivotal study, published in *Nature Medicine,* showed that 90% of participants improved strength or function, 87% reported improvement in quality of life, and benefits were observed up to 34 years post-injury. Study participants also reported less spasm frequency, improved sleep quality, and improved upper body sensation and sense of touch. The investigator-sponsored Pathfinder2 Study, published in *Neuromodulation: Technology at the Neural Interface,* demonstrated that ARC-EX Therapy, combined with activity-based rehabilitation, delivered significant functional improvements and continued gains over one year with no plateau in therapeutic benefit. Most recently, results of the LIFT Home Study, published in *Neurology: Clinical Practice,* showed that continued use of ARC-EX Therapy at home is effective in maintaining and extending gains achieved in the clinic.

Commercially available for less than one year, the ARC-EX System is now accessible in more than 60 clinics across the US. ARC-EX was named one of *TIME* magazine's Best Inventions and was recognized among *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.

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

**For Investor Inquiries:**
investors@onwd.com

**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.



*ARC-EX Indication for Use (US): 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, nonprogressive neurological deficits resulting from an incomplete spinal cord injury (C2-C8 inclusive). The ARC-EX System is intended to be operated in medical centers by rehabilitation professionals and at home by patients and persons providing assistance to patients, as needed.*

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