



PRESS RELEASE

ONWARD Medical Files 510(k) with US FDA for ARC-EX System Home Use and Submits CE Mark Application

- FDA 510(k) application submitted to allow marketing of the ARC-EX® System for home use in the United States
- CE Mark application filed with notified body to enable commercialization of the ARC-EX System in the European Union and other countries

Eindhoven, the Netherlands, July 1, 2025 — ONWARD Medical N.V. (Euronext: ONWD and US OTCQX: ONWRY), the leading neurotechnology company pioneering therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and other movement disabilities, today announced the submission of two major regulatory applications for its ARC-EX System. The Company has submitted a 510(k) application to the US Food and Drug Administration (FDA) seeking clearance to expand its indication for home use. In parallel, ONWARD has filed an application with the notified body for CE Mark certification in accordance with the European Union Medical Device Regulation (MDR) to enable commercialization of the ARC-EX System in the EU. Completed in June, these submissions represent significant milestones as the Company advances its mission to bring breakthrough therapies to people with SCI around the world.

The ARC-EX System is the first and only FDA-cleared technology indicated to improve hand sensation and strength after SCI. Following the successful initial phase of its US launch to clinics, ONWARD is pursuing FDA clearance to expand marketing of the ARC-EX System for use at home. Strong early demand and positive feedback from users suggest the Company is on track to meet its 2025 expectations. Clearance for home use would significantly broaden access to this innovative technology.

Simultaneously, ONWARD is preparing for the commercialization of the ARC-EX System through its CE Mark submission. Once approved, the ARC-EX System would be available in the European Union and other countries recognizing CE Marking.

“These two submissions are further evidence of our ability to execute against our innovation roadmap,” said Dave Marver, Chief Executive Officer of ONWARD Medical. “Gaining regulatory authorization for ARC-EX in Europe and broadening the ARC-EX label in the US will greatly expand the market while offering improved and more convenient access for those with SCI.”

Earlier this year, ONWARD also announced the publication of positive results from the investigator-sponsored Pathfinder2 Study in *Neuromodulation: Technology at the Neural Interface*. This peer-reviewed paper further expands the body of clinical evidence supporting the ARC-EX System. The one-year trial



demonstrated that ARC-EX Therapy combined with activity-based rehabilitation delivered significant functional improvements when administered to people with SCI in community-based rehabilitation centers. Participants experienced continued gains in upper body strength, trunk control, and balance after one year of treatment, with no plateau in therapeutic benefit¹.

About ONWARD Medical

ONWARD Medical is the leading neurotechnology company pioneering therapies to restore movement, function and independence in people with spinal cord injury and other movement disabilities. Building on more than a decade of scientific discovery, preclinical research, and clinical studies conducted at leading hospitals, rehabilitation clinics, and neuroscience laboratories, the Company has developed ARC Therapy, which has been awarded ten Breakthrough Device Designations from the US FDA. The Company's ARC-EX System is cleared for commercial sale in the US. In addition, the Company is developing an investigational implantable system called ARC-IM with and without an implanted brain-computer interface (BCI).

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, visit [ONWD.com](https://onwd.com) and connect with us on [LinkedIn](#).

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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¹ARC-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 to improve hand sensation and strength in individuals between 18 and 75 years old that present with a chronic, 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.