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ONWARD Medical Receives FDA De Novo Classification and US Market Authorization for World's First Non-Invasive Spinal Cord Stimulation System for People with Chronic Spinal Cord Injury

ARC-EX System is the first and only FDA approved technology shown to improve hand strength and sensation after chronic spinal cord injury

ARC-EX System is an FDA Breakthrough Device and 2024 TIME Magazine Best Invention

EINDHOVEN, the Netherlands — 5:45pm December 19, 2024 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative therapies to restore movement, function, and independence in people with spinal cord injury (SCI), today announced that it has received de novo classification and authorization to market its ARC-EX System from the US Food and Drug Administration (FDA).

"With today's FDA de novo classification and authorization to market the ARC-EX System in the US, a new era begins for people with chronic spinal cord injury. For the first time, there is an approved therapy shown to improve hand strength and sensation after chronic SCI," said Dave Marver, CEO of ONWARD Medical. "No longer will people be sent home and told nothing can be done to help them regain these abilities after their injury. We hope this is the first of many therapies we will introduce to help people regain independence from paralysis and other movement disabilities."

The ARC-EX System delivers programmed electrical stimulation through the skin to the spinal cord via electrodes placed on the back of the neck. The device is non-invasive and does not require surgery like other spinal cord stimulation devices.

"Regaining hand ability is the highest treatment priority for people with paralysis, five-fold higher than regaining all other abilities lost to injury," said Chet Moritz, PhD, Professor of Rehabilitation Medicine at the University of Washington. "I believe the ARC-EX System will have a tremendous impact on the quality of life of people living with SCI. My clinical and research colleagues in the US are eager and excited to have access to this important breakthrough technology."

Results of the Up-LIFT clinical 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.[1]

"This approval represents a watershed moment for the SCI Community. For those living with SCI and paralysis, the wait for even a single therapy to enhance their health and quality of life has been long and arduous. Now, we believe this milestone signals the opening of the floodgates for future advancements," says Maggie Goldberg, President & CEO of the Christopher & Dana Reeve Foundation. "The Reeve Foundation, along with our donors and supporters, has been steadfast in our commitment to this cause. Nearly 20 years ago, we recognized epidural stimulation as one of the most promising avenues in SCI research. Today, this historic approval affirms our belief that it is the beginning of more to come."

Today's FDA market authorization is for use of the ARC-EX System in clinics; home use authorization is anticipated in mid-2025. The Company plans to seek CE Mark certification to commercialize the ARC-EX System in Europe in early 2025, with authorization expected 2H 2025. The Company is developing a pipeline of technologies, including its investigational implantable ARC-IM System and its investigational ARC-BCI System, an implanted platform that uses a brain-computer interface (BCI) powered by artificial intelligence (AI).

For questions about the ARC-EX System and its availability in the US, visit survey.onwd.com/support.

About Spinal Cord Injury (SCI)

Spinal cord injury affects approximately seven million people worldwide, including more than 300,000 in the United States. Half of injuries result in tetraplegia, affecting function of all four limbs, and making everyday tasks like eating, grooming, or using a phone extraordinarily challenging. Beyond the immediate loss of motor and sensory function, individuals with SCI face numerous secondary complications such as incontinence, poor blood pressure regulation, and loss of sexual function. The economic impact is equally significant, with lifetime treatment costs for tetraplegia exceeding $5 million.[2] Historically, these injuries have been considered permanent with limited options for functional recovery, particularly for those more than one-year post-injury.

About ARC-EX System

The ARC-EX System is a non-invasive neuromodulation technology consisting of an external stimulator and wireless programmer which stimulate the spinal cord via electrical pulses from electrodes placed on the back of the neck. The system parameters can be optimized for each patient's unique needs. The ARC-EX System is the first and only approved technology indicated

[1] *Moritz, Chet, et al. "Non-invasive spinal cord stimulation for arm and hand function in chronic tetraplegia: a safety and efficacy trial." Nature Medicine. 2024.
[2] NSCISC Traumatic Spinal Cord Injury Facts and Figures at a Glance (2023 SCI Data Sheet) and Company analysis.

to improve hand sensation and strength after chronic spinal cord injury. It was selected as a TIME Magazine Best Invention in 2024.

About ONWARD Medical

ONWARD Medical is a medical technology company creating therapies to restore movement, function, and independence in people with SCI 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 Food and Drug Administration (FDA). In addition to the ARC-EX System, which is now cleared for commercial sale in the US, the Company is developing an 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).

For more information, visit ONWD.com and connect with us on LinkedIn and YouTube. If you are a clinician or person with a spinal cord injury, visit survey.onwd.com/support.

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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 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.