

ONWARD[®] Medical Awarded 10th Breakthrough Device Designation for Brain-Computer Interface (BCI) from US FDA

Award gives priority US regulatory review to Company's ARC-BCI[™] System

EINDHOVEN, the Netherlands — February 29, 2024 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative spinal cord stimulation therapies to restore movement, function, and independence in people with spinal cord injury (SCI), today announces it has been awarded Breakthrough Device Designation (BDD) by the US Food and Drug Administration (FDA) for the ARC-BCI System, which uses brain-computer interface (BCI) technology in conjunction with its ARC-IM[®] Therapy to restore thought-driven lower limb mobility after spinal cord injury (SCI). This BDD is supported by clinical data from two feasibility studies.

This is the tenth FDA BDD awarded to ONWARD Medical. The designation is reserved for novel, cutting-edge therapies addressing an unmet need and provides many potential regulatory and reimbursement advantages. This latest award gives ONWARD Medical priority FDA review, the opportunity to interact with FDA experts throughout the pre-market regulatory review phase, and the potential to seek additional reimbursement for its ARC-BCI System.

“Brain-computer interface technology unlocks the transformative potential to enhance ARC-IM with thought-driven control of movement after paralysis,” said ONWARD Medical CEO Dave Marver. “We look forward to learning more about the potential for this combination of ARC Therapy[™] and a BCI to help people with spinal cord injury live more independently. We are also grateful to the FDA for recognizing our innovations and their potential to help people with profound unmet needs.”

An implanted BCI records brain activity, capturing signals that indicate a person's intention to move. The ARC-BCI System then uses artificial intelligence (AI) to decode those signals and translate them into specific instructions for the ARC-IM System, which converts the instructions into precise stimulation of the injured spinal cord. ARC-BCI creates a “digital bridge,” restoring communication between the brain and the body, enabling thought-driven movement after paralysis.

In 2021, a BCI was paired with ARC-IM Therapy for the first time in history to restore movement of the lower limbs, including walking, after SCI. In May 2023, *Nature* published the results of this groundbreaking feasibility study, highlighting the study participant's augmented control over his paralyzed legs with the addition of a BCI. ONWARD Medical was previously granted nine BDDs for multiple indications for its ARC Therapy platforms, including mobility and blood pressure regulation. The Company plans to launch its first product later this year.

All ONWARD Medical devices and therapies, including but not limited to ARC-IM[®], ARC-EX[®], and ARC Therapy[™], alone or in combination with a brain-computer interface (BCI), are investigational and not available for commercial use.

About ONWARD Medical

ONWARD® Medical is a medical technology company creating therapies to restore movement, function, and independence in people with spinal cord injury (SCI) and movement disabilities. Building on more than a decade of science and preclinical research conducted at leading neuroscience laboratories, the Company has received ten Breakthrough Device Designations from the US Food and Drug Administration for its ARC Therapy™ platform.

ONWARD® ARC Therapy, which can be delivered by external ARC-EX® or implantable ARC-IM® platforms, is designed to deliver targeted, programmed spinal cord stimulation. Positive results were presented in 2023 from the Company's pivotal study, called Up-LIFT, evaluating the ability for transcutaneous ARC Therapy to improve upper extremity strength and function. The Company is now preparing regulatory approval submissions for ARC-EX for the US and Europe. In parallel, the Company is conducting studies with its implantable ARC-IM platform, which demonstrated positive interim clinical outcomes for improved blood pressure regulation, a component of hemodynamic instability, following SCI. Other ongoing studies include combination use of ARC-IM with a brain-computer interface (BCI) to address multiple symptoms of SCI.

Headquartered in Eindhoven, the Netherlands, ONWARD Medical has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company also has an academic partnership with .NeuroRestore, a collaboration between the Swiss Federal Institute of Technology (EPFL), and Lausanne University Hospital (CHUV).

ONWARD Medical is listed on Euronext Brussels and Amsterdam (ticker: ONWD).

For more information, visit [ONWD.com](https://onwd.com) and connect with us on LinkedIn and YouTube.

For Media Enquiries:

Aditi Roy, VP Communications
media@onwd.com

For Investor Enquiries:

Khaled Bahi, Interim CFO
investors@onwd.com

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but not limited to ARC-IM[®], ARC-EX[®], and ARC Therapy[™], are investigational and not available for commercial use.