

ONWARD[®] Medical Accepted to New US FDA TAP Program for Development of its ARC-BCI[™] System

The Company is one of the first brain-computer interface entrants accepted into this program, intended to optimize the commercialization pathway for breakthrough medical technology

EINDHOVEN, the Netherlands — March 11, 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 that it has been accepted into the US FDA's new Total Product Lifecycle Advisory Program (TAP) for its brain-computer interface (BCI) technology.

This acceptance follows ONWARD Medical's announcement last week that its investigational ARC-BCI System was awarded FDA Breakthrough Device Designation (BDD), a requirement for TAP consideration. ONWARD Medical is only the second BCI company to be accepted into the program.

TAP provides ONWARD Medical with early and frequent strategic engagement from the FDA, patients, providers, and payers to facilitate more rapid development and widespread patient access to safe, effective, high-quality medical devices of public health importance. As part of TAP, the Company benefits from more timely premarket interactions, earlier identification and mitigation of device development risk, and a more efficient premarket review process.

"We are honored to be one of the first BCI companies included in this important program, which allows for the fastest FDA review times of new medical technology," said ONWARD Medical CEO Dave Marver. "TAP enables us to reduce the time and cost to deliver the benefits of ARC-BCI to people living with paralysis."

The ONWARD ARC-BCI System pairs BCI technology with ARC-IM[®] Therapy to restore mobility after spinal cord injury (SCI). To date, two clinical feasibility studies support the potential of ARC-BCI, including one in 2021 and one in 2023 that restored lower and upper limb movement after SCI respectively. These were the first studies in history in which a human regained thought-driven movement of their limbs after paralysis.

**All ONWARD Medical devices and therapies, including but not limited to ARC-IM[®], ARC-EX[®], ARC-BCI[™], 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[®] systems, 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).

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