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ONWARD® Medical Submits De Novo Application to FDA for its ARC-EX® System

FDA clearance would allow the Company to market its breakthrough therapy to improve or restore hand and arm function after spinal cord injury in the US

EINDHOVEN, the Netherlands — April 2, 2024 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative spinal cord stimulation therapies to improve or restore movement, function, and independence in people with spinal cord injury (SCI), today announces it has submitted its De Novo application to the US Food and Drug Administration (FDA) to allow marketing of its breakthrough ARC-EX System to restore function of the upper extremities after SCI.

The submission marks an historic milestone for the Company in its mission to restore mobility and function for people with SCI. Once cleared by the FDA, ARC-EX will be the first-ever spinal cord stimulation therapy to restore hand and arm function after SCI and the first commercial product for ONWARD Medical. ONWARD prioritized upper limb function as its first indication for the ARC-EX System given feedback from the SCI Community of the importance of arm, hand, and finger function in empowering independence after SCI.

“We are delighted to be one step closer to bringing our breakthrough ARC-EX System to people living with SCI after submitting this De Novo application for regulatory clearance in the United States,” said ONWARD Medical CEO Dave Marver. “This therapy has the potential to transform the lives of people living with paralysis, while also positively impacting their loved ones.”

The De Novo application follows the Company’s global pivotal study - called Up-LIFT - the first large-scale pivotal study of transcutaneous spinal cord stimulation. The study investigated the safety and effectiveness of ARC-EX Therapy in improving upper limb strength and function in 65 study participants with chronic tetraplegia at 14 leading SCI neurorehabilitation centers in the United States, Canada, the United Kingdom, and the Netherlands. The study met all primary

safety and effectiveness endpoints and demonstrated that 72% of participants responded to ARC-EX Therapy[1], showing improvement both in strength and function.

“The SCI Community is eager to have access to this innovative technology,” said Candy Tefertiller, PT, DPT, PhD, NCS, Executive Director of Research and Evaluation, Craig Hospital in Lakewood, Colorado. “Even a small difference in hand and arm function can have a profound impact on independence and quality of life. The results of the Up-LIFT trial that led to this submission represent a significant advancement in the use of neuromodulation for individuals with spinal cord injury.”

The ONWARD ARC-EX System delivers ARC-EX Therapy™ - targeted, programmed electrical stimulation – transcutaneously to the spinal cord to increase strength, movement, and function of the upper limbs after SCI. The ARC-EX System was previously awarded FDA Breakthrough Device Designation (BDD) for upper limb function, which provided prioritized FDA review, the opportunity to interact with FDA experts, and the potential for additional reimbursement.

Nearly 200,000 people in the US and Europe have incomplete impaired upper extremity function after spinal cord injury.[2,3] The Company is preparing for regulatory submission in Europe next.

To learn more about ONWARD Medical’s commitment to partnering with the SCI Community to develop innovative solutions for restoring movement, function, and independence after spinal cord injury, please visit ONWD.com.

**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 has submitted its De Novo regulatory clearance submission for ARC-EX for the US and is preparing for regulatory submission in 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

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[1]Responder was defined as a participant who met or exceeded the minimally important difference criteria for at least one outcome of the strength domain and at least one outcome of the functional performance domain.
[2]NSCISC Annual Report, US and Europe only, World Health Organization Fact Sheet, November 2013, estimate 40-80 cases per million
[3] Kumar et al. 2018, Traumatic Spinal Injury: Global Epidemiology and Worldwide Volume

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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