ONWARD Receives New FDA Breakthrough Device Designations for Bladder Control, Alleviation of Spasticity, and Blood Pressure Regulation after Spinal Cord Injury

The company has now been awarded a total of eight FDA Breakthrough Device Designations for its innovative SCI therapies

EINDHOVEN, the Netherlands, LAUSANNE, Switzerland, and BOSTON, MA USA—February 23, 2023 — ONWARD Medical N.V. (Euronext: ONWD), the medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injury (SCI), today announced it has been granted Breakthrough Device Designation status from the U.S. Food and Drug Administration (FDA) for the use of its ARC-EX platform for bladder control, alleviation of spasticity, and blood pressure regulation in people with SCI. ONWARD has now been awarded a total of eight Breakthrough Device Designations, highlighting the company's innovative approach to developing therapies for people with SCI.

ARC-EX is an external, non-invasive platform consisting of a stimulator and wireless programmer. Positive top-line data were reported in 2022 from the company's first pivotal study, called Up-LIFT, which evaluated the ability for ARC-EX Therapy to improve upper extremity strength and function. ONWARD is now preparing regulatory submissions for the U.S. and Europe, with the expectation that this therapy may be approved for commercialization in late 2023.

"Bladder control, spasticity, and blood pressure dysregulation are three of the many challenges people with spinal cord injury must manage in order to navigate their daily lives," said Dave Marver, Chief Executive Officer of ONWARD. "We are proud of our eight total Breakthrough Device Designations from the FDA, which validate the significant unmet needs of the SCI community and the pioneering nature of our work."

Breakthrough Device Designation is an FDA program designed to help patients and their physicians receive timely access to technologies that have the potential to provide more effective treatment or diagnosis for debilitating conditions of significant unmet need, such as spinal cord injury. As part of this designation, the FDA will provide ONWARD with priority review and the opportunity to interact with FDA experts throughout the premarket review phase as the technology moves toward eventual commercialization.

About Spinal Cord Injury

Spinal cord injury (SCI) represents a major unmet medical need for which there is no cure. Approximately 7 million people globally have a spinal cord injury, with over 650,000 in the U.S. and Europe alone. The quality of life of people with SCI can be poor, with paralysis and loss of sensation, issues with blood pressure control and trunk stability, increased potential for infection, incontinence, and loss of sexual function. Assistance is required for daily living activities. And SCI is costly, with the average lifetime cost for paraplegia (paralysis of the legs) of $2.5 million and $5 million for tetraplegia (paralysis of all four limbs). Treatments are urgently needed to restore movement and improve quality of life.

About ONWARD Medical

ONWARD is a medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injuries. ONWARD's work builds on more than a decade of basic science and preclinical research conducted at the world's leading neuroscience laboratories. ONWARD's ARC Therapy, which can be delivered by implantable (ARC-IM) or external (ARC-EX) systems, is designed to deliver targeted, programmed spinal cord stimulation to restore movement and other functions in people with spinal cord injury, ultimately improving their quality of life.

ONWARD has received eight Breakthrough Device Designations from the US FDA encompassing both ARC-IM and ARC-EX. ARC-EX is an external, non-invasive platform consisting of a stimulator and wireless programmer. Positive top-line data were reported in 2022 from the company's first pivotal study, called Up-LIFT, evaluating the ability of transcutaneous ARC Therapy to improve upper extremity strength and function. The company is now preparing marketing approval submissions for the US and Europe. ARC-IM consists of an implantable pulse generator and lead placed near the spinal cord. The company completed first-in-human use of the ARC-IM neurostimulator and reported positive interim clinical outcomes for ARC-IM Therapy for improved blood pressure regulation following SCI in 2022.

ONWARD is headquartered in Eindhoven, the Netherlands. It maintains a Science and Engineering Center in Lausanne, Switzerland and has a growing US presence in Boston, Massachusetts. The company has an academic partnership with .NeuroRestore, a collaboration between EPFL, the Swiss Federal Institute of Technology in Lausanne, and Lausanne University Hospital (CHUV). For additional information about the company, please visit ONWD.com. To access our 2023 Financial Calendar, please visit IR.ONWD.com.

For Company Enquiries:

info@onwd.com

For Media Enquiries:

MC Services AG
US: Laurie Doyle, P: +1 339 832 0752
Europe: Dr. Johanna Kobler, Katja Arnold, Kaja Skorka, P: +49 89 210 228 0
media@onwd.com

For Investor Enquiries:

investors@onwd.com

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