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ONWARD Announces Completion of Enrollment in the Up-LIFT Pivotal Trial of ARC Therapy for Spinal Cord Injury

Enrollment was completed in less than 12 months despite COVID-related challenges, demonstrating strong interest in the therapy

EINDHOVEN, the Netherlands & LAUSANNE, Switzerland—December 16, 2021--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, today announces it has completed enrollment in the Up-LIFT study, a pivotal trial to evaluate the safety and effectiveness of ARC Therapy to restore hand and arm function in people with spinal cord injury (SCI). Up-LIFT is the first large-scale pivotal trial of non-invasive spinal cord stimulation technology.

ONWARD has now reached the study's enrollment ceiling of 65 subjects, enrolled at 14 leading SCI research sites throughout the United States, Canada, the United Kingdom, and the Netherlands. The Up-LIFT Study is a prospective, single-arm study designed to evaluate the safety and effectiveness of non-invasive electrical spinal cord stimulation (ARC Therapy) to treat upper extremity functional deficits in people with chronic tetraplegia.

"The study reached its enrollment objective in under 12 months despite lock-downs, travel restrictions, and other COVID-related challenges," said Dave Marver, Chief Executive Officer of ONWARD. "This milestone underscores the SCI community's enthusiasm for this promising therapy. We will now work with determination to prepare submissions to regulatory authorities in the US and Europe so we can bring this important therapy to market for the benefit of people with SCI and their loved ones."

"For individuals with impaired arm and hand function due to spinal cord injury, improved hand function directly translates into meaningful gains in terms of quality of life - being able to eat, dress or perform other daily life activities," said Edelle Field-Fote, PT, PhD, FAPTA, FASIA, co-PI of the Up-LIFT trial and Director of Spinal Cord Injury Research at Shepherd Center and Professor of Rehabilitation Medicine at Emory University School of Medicine. "It was very rewarding to take part in this important trial and collaborate with many of the most highly respected SCI rehabilitation centers across the globe."

"The end of enrollment for this trial marks a significant milestone in bringing non-invasive stimulation for restoring hand and arm function to people living with spinal cord injury" said Chet Moritz, PhD, co-PI of the Up-LIFT trial and Associate Professor in the Departments of Electrical & Computer Engineering and Rehabilitation Medicine at the University of Washington in Seattle. "We are hopeful this study can lead to the broad availability of this important therapy."

The company expects to initially commercialize ARC Therapy in the US, Germany, France, UK, Switzerland, and the Netherlands. To learn more about ONWARD's ARC Therapy and the company's vision to restore movement, independence and health in people with spinal cord injury, please visit ONWD.com.

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About ONWARD

ONWARD is a medical technology company creating innovative therapies to restore movement, independence, and health in people with spinal cord injury. 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 stimulation of the spinal cord to restore movement and other functions in people with spinal cord injury, ultimately improving their quality of life. ONWARD has received three Breakthrough Device Designations from the FDA encompassing both ARC^{IM} and ARC^{EX}. The company's first FDA pivotal trial, called Up-LIFT, commenced in January 2021 and has now completed enrollment with 65 subjects worldwide.

ONWARD is headquartered at the High Tech Campus in Eindhoven, the Netherlands. It maintains an office at the EPFL Innovation Park in Lausanne, Switzerland and has a growing U.S. presence in Boston, Massachusetts, USA. For additional information about the company, please visit ONWD.com.

About Dr. Edelle Field-Fote

Dr. Edelle Field-Fote has a 20+ years of SCI research, building on her clinical background as a physical therapist and Ph.D. training in an animal model of SCI. Her contributions to SCI literature include the largest study to date of locomotor training for persons with chronic, motor-incomplete SCI, as well as the first-ever study of a rehabilitation intervention to promote neuroplasticity for improved hand function in persons with tetraplegia. Dr. Field-Fote's research has been funded by the National Institutes of Health (NIH) since 1997, and also by the National Institute on Independent Living, Disability and Rehabilitation Research (NILDRR) and the Department of Defense (DoD). Dr. Field-Fote is the editor/author of the textbook Spinal Cord Injury Rehabilitation (FA Davis Publishers).

About Dr. Chet Moritz

Dr. Chet Moritz is Associate Professor in the departments of Electrical & Computer Engineering, Rehabilitation Medicine, and Physiology & Biophysics at University of Washington, Seatlle. He was named an Allen Distinguished Investigator and appointed to the Christopher & Dana Reeve International Consortium on Spinal Cord Repair. Chet serves as the Co-Director for the Center for Neurotechnology, an NSF Engineering Research Center (ERC). Chet directs the Restorative Technologies Laboratory (RTL) which focuses on developing technologies to treat paralysis due to spinal cord injury. Current research in the lab includes a multi-site clinical trial of spinal stimulation to restore hand function for people with spinal cord injury, stimulation to improve walking for children with cerebral palsy, and optogenetic stimulation to guide neuroplasticity and recovery in the injured spinal cord of animals.

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