# *Nature Medicine* Highlights Significant Improvement in Hand and Arm Function After Spinal Cord Injury with Use of ONWARD® ARC-EX® Therapy

*ARC Therapy™ shown to be safe and effective in global pivotal trial**

*90% of participants improved either strength or function of upper limbs**

*Improvement demonstrated in participants up to 34 years post-injury**

*87% of participants also reported improvement in overall quality of life**

EINDHOVEN, the Netherlands — May 20, 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 the publication of global Up-LIFT pivotal trial results in *Nature Medicine*. The study achieved all primary safety and effectiveness endpoints, and ARC-EX Therapy demonstrated significant improvements in upper limb strength, function, and sensation among people with chronic tetraplegia due to cervical SCI.

At the end of the trial, 72% of trial participants were considered responders to non-invasive ARC-EX Therapy* based on a conservative definition requiring responders to meet improvement criteria in both strength and functional domains vs. standard of care rehabilitation alone. Notably, the number of responders increased to 90% when the definition included participants with improvements in at least one strength or functional outcome*.

“Trial results far exceeded our hypothesis of a 50% response rate to ARC-EX Therapy, giving new hope to people with SCI and to rehabilitation providers,” said Chet Moritz, Ph.D., publication lead author, co-Principal Investigator, and Professor of Electrical & Computer Engineering and Rehabilitation Medicine at the University of Washington. “After only two months, more than half of Up-LIFT participants achieved average improvements in grasp force greater than that required to lift filled cups and in pinch force equivalent to that required to pick up an item with a fork or insert a key.[1,2] This indicates not only improved strength and function, but also the potential for greater independence with ARC-EX Therapy.”

---

* Moritz, Chet, et al. “Non-invasive spinal cord stimulation for arm and hand function in chronic tetraplegia: a safety and efficacy trial.” Nature Medicine. 2024.

[1] Feingold-Polak, Ronit, et al. “The effects of an object's height and weight on force calibration and kinematics when post-stroke and healthy individuals reach and grasp.” *Scientific Reports.* 2021.

[2] Smaby, Niels, et al. “Identification of key pinch forces required to complete functional tasks.” *Journal of Rehabilitation Research & Development*. 2004.


Study participants also reported reduced spasm frequency, improved sleep, and improved upper body sensation, including the sense of touch*. 87% of participants reported that ARC-EX Therapy delivered improvements in overall quality of life*. Self-care, a key component of independence after SCI, also improved significantly*.

“Improvement in arm and hand function is among the highest priorities for people with tetraplegia[3] who have endured far too long without effective therapies for functional recovery,” said Dave Marver, CEO, ONWARD Medical. “The findings published in *Nature Medicine* provide critical and compelling evidence that ARC-EX has the potential to restore independence in daily activities and improve quality of life. We are laser-focused on our commitment to bring this first-of-its-kind technology to the SCI Community as soon as possible.”

“We are proud that ONWARD has developed this first-ever therapy shown to improve strength and function after chronic incomplete tetraplegia,” said ONWARD Medical co-founders Grégoire Courtine, PhD, Professor of Neuroscience and Neurotechnology at the Swiss Federal Institute of Technology Lausanne (EPFL), and Jocelyne Bloch, MD, Head of Functional Neurosurgery at Lausanne University Hospital and Professor of Neurosurgery at EPFL. “We commend the outstanding researchers and study participants who contributed to this seminal trial.”

ARC-EX Therapy is external, programmed electrical stimulation that targets the spinal cord non-invasively and is designed to aid in functional recovery after SCI. The Up-LIFT study was a prospective, single-arm pivotal study designed to evaluate the safety and effectiveness of the ARC-EX System to treat upper extremity functional deficits in people with chronic tetraplegia. The global study was conducted with 65 participants at 14 leading SCI centers in the United States, Europe, and Canada.

[3] Anderson, KD. “Targeting recovery: priorities of the spinal cord-injured population.” *Journal of Neurotrauma*. 2004.

At the end of Q1, ONWARD Medical submitted a De Novo application to the US Food and Drug Administration for market clearance of the ARC-EX System. The Company plans to follow the US application with an application for market approval in Europe.

On Thursday, May 23rd at 2:30pm CET/8:30am ET following a brief Q1 Business Update, CEO Dave Marver will host a discussion of Up-LIFT pivotal trial results with a panel of principal investigators and study participants.

To join the webcast via Zoom, please register using this link.

Participants may also join by phone:

+32 2 290 9360 (Belgium)

+33 1 7037 2246 (France)

+49 69 3807 9884 (Germany)

+31 20 794 0854 (Netherlands)

+41 22 591 0156 (Switzerland)

+44 203 481 5240 (United Kingdom)

+1 346 248 7799 (US)

Additional telephone numbers available

Meeting ID: 879 5741 2479

A recording of the webcast will be available on the Company's website following the live event.

*Note: 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 scientific discovery, preclinical, and clinical research conducted at leading hospitals, rehabilitation clinics, and neuroscience laboratories, the Company has developed ARC Therapy™, which has been awarded ten Breakthrough Device Designations from the US Food and Drug Administration (FDA).

ONWARD ARC Therapy is targeted, programmed spinal cord stimulation designed to be delivered by the Company's external ARC-EX® or implantable ARC-IM® platforms. ARC Therapy can also be delivered by the Company's ARC-BCI™ platform, which pairs the ARC-IM System with brain-computer interface (BCI) technology to restore movement after SCI with thought-driven control.

Use of non-invasive ARC-EX Therapy significantly improved upper limb function after SCI in the global pivotal Up-LIFT trial, with results published by *Nature Medicine* in May 2024. The Company has submitted its regulatory application to the FDA for clearance of the ARC-EX System in the US and is preparing for regulatory submission in Europe. In parallel, the Company is conducting clinical studies with its ARC-IM Therapy, which demonstrated positive interim clinical outcomes for improved blood pressure regulation following SCI. Other ongoing clinical studies focus on using ARC-IM Therapy to address mobility after SCI

and gait challenges in Parkinson's disease as well as using the ARC-BCI platform to restore thought-driven movement of both upper and lower limbs after 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 is listed on Euronext Brussels and Amsterdam (ticker: ONWD).

For more information, visit ONWD.com, and connect with us on LinkedIn and YouTube.

For Media Inquiries:
Aditi Roy, VP Communications
media@onwd.com

For Investor Inquiries:
Amori Fraser, Finance Director
investors@onwd.com

**Disclaimer**

Certain statements, beliefs, and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company directors' current expectations and projections about future events. By their nature, forward-looking statements involve several risks, uncertainties, and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements. These risks, uncertainties, and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition, and technology, can cause actual events, performance, or results to differ significantly from any anticipated development. Forward-looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions, or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release. All ONWARD Medical devices and therapies referenced here, including but not limited to ARC-IM®, ARC-EX®, ARC-BCI™ and ARC Therapy™, are investigational and not available for commercial use.