

THIS PRESS RELEASE CONTAINS INSIDE INFORMATION WITHIN THE MEANING OF ARTICLE (7)(1) OF THE EUROPEAN MARKET ABUSE REGULATION (596/2014)

ONWARD® Medical Signs Agreement with CEA for Exclusive Rights to Clinatec's WIMAGINE® Brain-Computer Interface (BCI) Technology

Company secures exclusive rights to incorporate the WIMAGINE BCI into its ARC-BCI™ System

WIMAGINE BCI has 7-year human safety data

Deal provides opportunity for ONWARD to be first-to-market with a BCI-enabled system to restore thought-driven movement after paralysis

EINDHOVEN, the Netherlands — October 15, 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 signed an exclusive license with CEA to develop and commercialize the investigational WIMAGINE BCI designed by Clinatec as part of its investigational ARC-BCI System to restore thought-driven movement and function of the human body.

“Securing exclusive rights to the WIMAGINE BCI gives us an opportunity to be first to market with a BCI-enabled system to restore thought-driven movement after paralysis”, said ONWARD Medical CEO Dave Marver. “Clinatec is a world-renowned biomedical research institute and its BCI is ideal for our applications. We can now develop a truly integrated system that is well suited for the type of study required to gain regulatory approval and bring a BCI-enabled system to market,”

The ONWARD ARC-BCI System combines the WIMAGINE BCI from CEA with investigational ONWARD ARC-IM® Therapy (targeted implanted spinal cord stimulation) to form a DigitalBridge™ designed to enable thought-driven movement after paralysis. The WIMAGINE BCI has 7 years of human safety data and ONWARD ARC-IM Therapy has now been applied in more than 30 study participants.



THIS PRESS RELEASE CONTAINS INSIDE INFORMATION WITHIN THE MEANING OF ARTICLE (7)(1) OF THE EUROPEAN MARKET ABUSE REGULATION (596/2014)

In May 2023, researchers reported in [Nature](#) that when paired with ARC-IM Therapy, an implanted BCI allowed an individual to gain augmented control over when and how he moved his paralyzed legs. In September 2023, the Company announced a second individual was implanted with ARC-IM Therapy and a WIMAGINE BCI to restore upper limb function after paralysis. And in September 2024, a third individual was implanted with an ARC-BCI System to restore thought-driven movement of her legs after a spinal cord injury (SCI). Additional implants are planned in the coming months.

The Company has been working with CEA teams at Clinatec and .NeuroRestore to advance these studies, which are supported by grants from the Christopher & Dana Reeve Foundation and the European Innovation Council.

“The early clinical feasibility research demonstrates the remarkable potential of the ARC-BCI System to restore thought-driven movement and function after paralysis,” said Guillaume Charvet, head of the Neurotechnology Biomedical Research Unit at CEA. “We are pleased to partner with ONWARD Medical and look forward to seeing this technology further developed and made accessible for the benefit of those with spinal cord injury.”

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](https://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 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.

THIS PRESS RELEASE CONTAINS INSIDE INFORMATION WITHIN THE MEANING OF ARTICLE (7)(1) OF THE EUROPEAN MARKET ABUSE REGULATION (596/2014)

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 Paris, Brussels and Amsterdam (ticker: ONWD).

About Clinec

Clinec Edmond J. Safra biomedical research center combines technological innovation and medical research programs in the same place to provide new therapeutic solutions to patients. Clinec's activities are supported by a partnership between CEA, University Grenoble Alpes Hospital (CHUGA), University Grenoble Alpes (UGA) and Fonds Clinec. Clinec's mission is to design, develop and perform clinical validation of innovative medical devices based on medical needs and using cutting-edge technologies. These missions are fulfilled by a multidisciplinary team composed of mathematicians, physicists, electronic engineers, computer scientists, biologists, physicians and healthcare personnel.

CEA has developed the Clinec's WIMAGINE Brain-Computer Interface technology based on a brain recording implant and dedicated AI algorithms that record and decode patients' motor intentions, enabling them to regain mobility after paralysis.

The WIMAGINE implant is composed of 64 electrodes that can be placed epidurally, on the surface of the brain. The implant enables long-term multichannel recording with very stable signal quality lasting several years. Recorded brain data are transmitted wirelessly in real time to a computer to decode patients' movement intentions. The brain decoder uses adaptive AI based algorithms that can calibrate decoding models in real time in a few minutes. These algorithms are then able to decode patients' motor intentions in real time.

WIMAGINE has already contributed to two world firsts. In 2019, a tetraplegic patient was able to use his brain activity to control a four-limbed exoskeleton ([Benabid et al., Lancet Neurol., 2019](#)). In 2023, a paraplegic patient successfully regained natural control of his gait through the coupling of WIMAGINE technology with spinal cord stimulation technology ([Lorach et al., Nature, 2023](#)) currently being developed as ARC-IM® Therapy by ONWARD Medical. This work was supported by CEA (recurrent funding), Institut Carnot CEA-Leti, Fonds Clinec, Horizon Europe - European Innovation Council (EIC), French National Research Agency (ANR), Swiss National Science Foundation (SNF), French ministries in charge of research and health, and the Leenaards Foundation.

Clinec is located on the CEA site in Grenoble, France, a flagship facility for fundamental and applied research to imagine innovative solutions and transfer them to industry and society.

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

For ONWARD Medical Media Inquiries:

Aditi Roy, VP Communications

media@onwd.com

For ONWARD Medical Investor Inquiries:

Amori Fraser, Finance Director

investors@onwd.com

For CEA and Clinec Media Inquiries:

Vincent Coronini, Communications & Public Relations

presse@cea.fr

THIS PRESS RELEASE CONTAINS INSIDE INFORMATION WITHIN THE MEANING OF ARTICLE (7)(1) OF THE EUROPEAN MARKET ABUSE REGULATION (596/2014)

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, delays in regulatory approvals, 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.