

ONWARD® Announces Start of HemON NL Clinical Study

HemON NL is evaluating the use of ARC-IM® Therapy to address hemodynamic instability after spinal cord injury

EINDHOVEN, the Netherlands — January 18, 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 start of the HemON NL clinical feasibility study at Sint Maartenskliniek in Nijmegen, the Netherlands.

In late 2023, a study participant was implanted with an investigational ARC-IM Neurostimulator and Lead to assess the safety and effectiveness of ARC-IM Therapy to address hemodynamic instability after SCI. The surgery was performed by neurosurgeon Erkan Kurt, MD at Radboud University Medical Center, which has a neurosurgery department affiliated with Sint Maartenskliniek.

Building on the Swiss HemON clinical feasibility study, HemON NL prepares the Company for expected initiation of a global pivotal trial, called Empower BP, which is designed to provide the evidence necessary to submit a pre-market approval (PMA) to the US Food and Drug Administration (FDA) and other global regulatory authorities. In December 2022, the Company announced positive interim clinical results from its early feasibility studies showing improved regulation of blood pressure, thereby improving hemodynamic stability, after SCI.

The Company plans to enroll participants in both HemON and HemON NL as it finalizes the design of the Empower BP pivotal study.

“Sint Maartenskliniek has long been an outstanding research partner, and we are delighted to work with them on this new and exciting study to evaluate the use of ARC-IM Therapy to stabilize disruptive and potentially life-threatening fluctuations in blood pressure after SCI,” said Dave Marver, CEO of ONWARD. “This is an important but underappreciated recovery target after SCI. We hope this research and the expected upcoming pivotal study will shine a light on the importance of hemodynamic stability in this population.”



Dr. Erkan Kurt, MD implants his first ARC-IM Neurostimulator

The Principal Investigator of the HemON NL study is Dr. Ilse van Nes, a leading rehabilitation physician in the spinal cord injury department of Sint Maartenskliniek.

“The procedure went smoothly and the participant is responding well,” said Dr. van Nes. We are excited to monitor this and additional patients’ ongoing response to this groundbreaking therapy, which is designed to deliver programmed electrical stimulation to the area of the spine responsible for regulating blood pressure after SCI.”

ONWARD has received nine FDA Breakthrough Device Designations for its ARC-IM System, one of them for hemodynamic instability after SCI, inclusive of blood pressure regulation.

**All ONWARD devices and therapies, including but not limited to ARC-IM, ARC-EX, and ARC Therapy, alone or in combination with a BCI, are investigational and not available for commercial use.*

About ONWARD Medical

ONWARD 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 nine 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 is now preparing regulatory approval submissions for ARC-EX for the US and 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 has a Science and Engineering Center in Lausanne, Switzerland and a US office in Boston, Massachusetts. The Company also has an academic partnership with .NeuroRestore, a collaboration between the Swiss Federal Institute of Technology (EPFL), and Lausanne University Hospital (CHUV).

For more information, visit [ONWD.com](https://onwd.com), and connect with us on [LinkedIn](#) and [YouTube](#).

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