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NEUROPROSTHETICS

September 1, 2021

SensArs Neuroprosthetics Sàrl. announces that it has received **Breakthrough Device Designation** by the **US Food and Drug Administration** (FDA) for its **SENSY System**. This great achievement is a huge step towards SensArs' mission of bringing our therapy to millions suffering from chronic peripheral neuropathic pain and/or movement disabilities due to sensory loss.

SENSY is a system comprised of a novel implantable stimulator that enables access to fascicles inside the nerve thereby allowing highly selective stimulation. Along with a set of external sensors, the SENSY System is able to retrieve naturalistic sensations of the limb with pin-point selectivity, providing optimal coverage and mitigation of painful areas due to peripheral neuropathy and treatment of movement disabilities due to sensory loss.

The breakthrough designation is granted for *persons over 18, providing sensory feedback for those with limb loss to improve prosthesis function*. To gain Breakthrough Designation, the FDA believes that both of the following criteria have been met:

1. The device provides for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions
2. The device also meets **at least one** of the following:
    - Represents breakthrough technology
    - No approved or cleared alternatives exist
    - Offers significant advantages over existing approved or cleared alternatives
    - Device availability is in the best interest of patients

This breakthrough designation offers several **benefits to speed up market availability and patient access**, including:

- Interactive and timely communication with FDA
- Pre/postmarket balance of data collection
- Efficient and flexible clinical study design
- Review team support
- Senior management engagement
- Priority review

Francesco Petrini, PhD., Chief Executive Officer of SensArs, commented: "We are thrilled to have received the Breakthrough Designation, as it further confirms the novelty of our technology putting us at the forefront of peripheral neurostimulation. Our breakthrough approach for interfacing with the nerve will allow high selectivity enabling the patient to regain natural sensation of the limb like no other technology before. Furthermore, this designation is especially attractive due to the quicker path to Medicare reimbursement coverage we anticipate under the MCIT (Medicare Coverage of Innovative Technology), following FDA market authorization."

Guy Siman, Chief Operating Officer of SensArs, commented: "This is a true recognition of the innovation of our technology. The Breakthrough designation opens the door to the FDA for interactive and timely communication, especially beneficial in this crowded regulatory climate, eventually allowing a quicker introduction of the SENSY System to the market. We have a great opportunity to become the standard treatment for these patients helping them live a productive and fulfilling life"

Dan Merrill, PhD., Chief Science Officer of SensArs, commented: "Fewer than 400 devices have been granted FDA breakthrough status to date, with smaller numbers receiving the designation every year. An efficient and flexible clinical study design and a priority in review will allow us to provide long needed safe and effective treatment in a timely manner for millions of people around the world."

About SensArs Sarl.

Sensars is a med-tech company focused on **revolutionizing treatment of peripheral neuropathy,** affecting up to 7% of the world population. Peripheral neuropathy is a damage to a peripheral nerve that causes pain and sensory loss.

We have developed an implantable peripheral nerve stimulator that accesses **the nerve transversely,** enabling highly selective stimulation resulting in **pain relief** and **restoration of natural sensations** of touch and movement. The system includes external wearable sensors that facilitate the feedback to the implant through an exclusive set of algorithms thereby enabling an accurate set of stimulation parameters for sensory retrieval.

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The functionality and safety of this therapy has been shown using an early prototype in a feasibility trial with compelling results (published in acclaimed journals of medicine) demonstrating safety and efficacy of our approach.

The Company is now developing its next generation system for a wider set of indications intended to be evaluated in a larger pilot clinical trial.

For more information, please visit:

www.sensars.com

https://www.fda.gov/media/108135/download