

SENSOME ANNOUNCES INITIATION OF CLINICAL TRIAL ASSESSING ITS TISSUE MICROSENSOR TECHNOLOGY IN PERIPHERAL ARTERY DISEASE

MILLIONS OF PATIENTS WORLDWIDE COULD BENEFIT FROM BETTER LONG-TERM OUTCOMES BY THE COMPANY'S EXPANSION INTO PERIPHERAL ARTERY DISEASE

PARIS, FRANCE - FEBRUARY 12TH, 2024 – Sensome, the company pioneering the connected medical device revolution with the world's smallest biological tissue sensor, announced today enrollment of the first patients into a feasibility clinical study using the Clotild[®] Smart Guidewire in peripheral artery disease (PAD). Clotild[®] was designated a breakthrough medical device for use in brain arteries by the FDA in 2021.

The clinical trial, named SEPARATE, is designed to assess the Clotild[®] sensor's capability to detect various characteristics of blood vessel blockages in PAD patients. The first 5 patients have been enrolled at AZ Sint-Blasius Hospital in Dendermonde, Belgium. Preliminary results are anticipated in mid-2024.

PAD is a manifestation of systemic atherosclerotic disease estimated to affect over 200 million patients worldwide. This represents a significant health burden globally, particularly related to the development of blood vessel blockages which are challenging to treat. A key focus of the SEPARATE clinical trial is to evaluate the Clotild[®] sensor's capacity in differentiating between soft and friable "fresh" clots and organized "old" clots. This critical information empowers physicians to select the most suitable endovascular therapeutic approach, thereby mitigating complications, avoiding embolization, and enhancing long-term treatment outcomes.

"Understanding the makeup of a total occlusion in peripheral artery disease is essential to choose an adequate treatment approach to ensure lower complication rates and more durable long-term outcomes in this complex group of vascular patients," said Dr. Koen Deloose, Head of Vascular Surgery at AZ Sint-Blasius Hospital, and principal investigator of the SEPARATE clinical trial. "Sensome's tissue microsensor technology could become a novel tool to characterize the total occlusion in an objective and simple-to-use way that integrates perfectly with our current existing workflow."

Franz Bozsak, CEO and co-founder of Sensome, expressed enthusiasm about extending the company's reach beyond ischemic stroke treatment: "After successfully applying our technology to the treatment of ischemic stroke patients, we are excited about the opportunity to build on this work to potentially help millions of patients around the world whose lives have been impacted by PAD".

ABOUT SENSOME

Sensome, a clinical stage Healthtech start-up, developed a breakthrough sensor technology that turns invasive medical devices into connected healthcare devices. This patented technology combines the world's smallest impedance-based microsensors with machine-learning algorithms to characterize biological tissues in real-time. The flagship product of Sensome, the Clotild[®] Smart Guidewire System, is a connected neurovascular guidewire designed to provide blood clot characterization during the endovascular management of acute ischemic stroke. Clotild[®] is currently being evaluated in a clinical trial. Sensome's tissue sensing technology also holds significant potential for integration into minimally invasive medical devices used in other areas of treatment such as peripheral vascular disease and oncology.

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