FIRST-IN-HUMAN DATA FOR SENSOME CLOT-SENSING GUIDEWIRE USED IN ISCHEMIC STROKE TREATMENT DEMONSTRATE ABILITY TO AUTOMATE CLOT CHARACTERIZATION WITH NO SAFETY ISSUES

PARIS - JUNE 5TH, 2024 –Sensome, the pioneer of microsensing technology for instant intra-operative tissue analysis, today announced positive results from its first-in-human CLOT OUT clinical trial evaluating the safety and performance of its Clotild® Smart Guidewire System used during mechanical thrombectomy treating ischemic stroke. The results showed that the technology met all primary safety and performance endpoints of the trial.[1] There were no serious adverse events related to use of the Clotild device, and it successfully automated the identification of red blood cells (RBCs) and platelets in close alignment with human experts. The study was presented today at the renowned international LINNC Paris conference by Prof. Aymeric Rouchaud, principal investigator of the CLOT OUT study at CHU Limoges in France.

The Clotild clot-sensing guidewire integrates the world's smallest electrical impedance sensor with machine learning and is being developed to instantly identify clot composition and clot length in real-time in order to inform treatment approach during mechanical thrombectomy. It has the potential to be the first device to accurately identify clot length in fully occluded arteries in-situ, as well as the first to characterize clots that remain in the body after failed removal attempts.

In two previous peer-reviewed publications, the company's microsensor technology was shown to reliably predict the RBC composition of retrieved clot with good sensitivity and specificity consistent with histologic findings.[2,3] Data demonstrating the technology's ability to do the same with platelets is pending publication.[4]

The CLOT OUT study showed that, on a blinded validation dataset, the Clotild technology's predictive algorithms successfully identified RBCs and platelets, thereby demonstrating automated processing of thrombus signals acquired in-situ by the sensor during the thrombectomy procedure. The technology demonstrated sensitivity of 95% [95% CI, 86%-100%] and specificity of 93% [95% CI, 90%-96%] for RBCs, and sensitivity of 87% [95% CI, 76%-96%] and specificity of 94% [95% CI, 90%-96%] for platelets, when compared to analysis by a human expert.[1]

"Understanding the clot is critical to informing the approach we take to clot removal in life-saving stroke treatment, yet today's imaging provides incomplete information. This results in 60% of thrombectomy cases requiring two or more passes to remove clot - with each pass reducing patient outcomes – and 10-20% of cases being unsuccessful in removing clot altogether," said Prof. Rouchaud. "This first-in-human study showed that this smart guidewire safely navigated through the brain and successfully characterized common clot components without human analysis. This is an exciting development with the potential to give us a more complete picture of the clot that we are missing today in order to achieve better first pass success."

"In addition to the promise of improving our thrombectomy results, we appreciate that this technology integrated well with our current interventional workflow and didn't require a new technique," said Andrew Cheung, MD, co-coordinating investigator of the CLOT OUT trial at Liverpool Hospital in Australia. "The Clotild device is ingenious – by simply replacing our existing guidewire with a smart

wire, we may be able to gain better information that could help us significantly improve our patients' chances of a full recovery after stroke."

"Meeting all of the primary endpoints in our first-in-human study is an important milestone for our company and the first step in realizing the full potential of our novel microsensor technology across several indications," said Franz Bozsak, CEO and co-founder of Sensome. "In this first use in stroke treatment, we showed that our technology was able to automate clot component identification with the accuracy of human experts. We look forward to further clinical study of Clotild in larger numbers of patients that will grow its capabilities to ultimately provide recommendations for a personalized treatment approach for each clot and patient."

ABOUT THE CLOT OUT STUDY

CLOT OUT is a single-arm, prospective, multicenter, first-in-human trial in France and Australia encompassing 41 patients experiencing acute large-vessel ischemic stroke where the Clotild guidewire was used before any thrombectomy pass. The independent imaging core lab for the study was led by Prof. David Liebeskind, MD, at the University of California, Los Angeles (UCLA), while the histology core lab was at Mayo Clinic, Rochester, led by Kadirvel Ramanathan, Ph.D., The trial was overseen by an independent Data Safety Monitoring Board, chaired by Prof. Thomas Liebig at Ludwig-Maximilians-University Munich, that recommended the study proceed throughout its course. As a first-in-human study, the trial was intended to train the clot-sensing technology to further enhance Clotild's in-situ clot characterization performance.

ABOUT CLOTILD

The Clotild clot-sensing guidewire is based on electrical impedance spectroscopy, which measures the electrophysiologic characteristics of fluid or tissue in 360° surrounding the sensor, analyzed by Sensome's proprietary predictive algorithms. Impedance measurement of tissue is used today during such procedures as diagnosis of easily reached tumors and atrial fibrillation ablation, but it has never been used to examine thrombus due to the large size of existing technology. Sensome has miniaturized the technology down to fit on the distal part of a standard 0.014" guidewire, directly behind a soft, atraumatic tip, creating the world's smallest electrical impedance sensor. The Clotild Smart Guidewire System has been designated as a Breakthrough Device by the FDA.

The Clotild Smart Guidewire System is considered an investigational device and is not approved for commercial use in the U.S or any other jurisdiction.

ABOUT SENSOME

Sensome, a clinical-stage healthtech start-up, has developed a patented, breakthrough microsensor technology that combines the world's smallest impedance-based sensor with machine-learning algorithms to identify and characterize biological tissues in real-time. The technology is currently being studied in three different clinical indications: clot characterization (ischemic stroke), total occlusion characterization (peripheral vascular disease) and in-situ tool-in-lesion confirmation (lung cancer). Sensome intends to partner with leading medtech companies to design, manufacture and distribute smart medical devices integrating its proprietary microsensing technology. The company is partnered with leading guidewire manufacturer ASAHI INTECC for manufacturing of the Clotild Smart Guidewire System.

(1) The Clotild Smart Guidewire System Sensing Clot Features During Mechanical Thrombectomy - Results from the CLOT OUT Study. LINNC Paris 2024 Conference, Paris, France.

(2) Sahin C, Giraud A, Jabrah D, et al. Electrical impedance measurements can identify red blood cell-rich content in acute ischemic stroke clots ex-vivo associated with first pass successful recanalization. Res Pract Thromb Haemost. 2024;8:e102373. DOI:https://doi.org/10.1016/j.rpth.2024.102373.

(3) Darcourt J, Brinjikji W, François O, et al. Identifying ex vivo acute ischemic stroke thrombus composition using electrochemical impedance spectroscopy. Interventional Neuroradiology. 2023;0(0). doi:10.1177/15910199231175377.

(4) Data on file.

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