SENSOME ANNOUNCES DATA FROM TWO NEW STUDIES SHOWING CLOT-SENSING GUIDEWIRE SUCCESSFULLY IDENTIFIES FRESH CLOT TO SUPPORT DECISION-MAKING IN PERIPHERAL ARTERY DISEASE TREATMENT

Data showcased in two late-breaking clinical trial presentations at Paris Vascular Insights Course

PARIS - DECEMBER 13TH, 2024 – Sensome, the pioneer of microsensing technology for instant intra-operative tissue analysis, today announced positive results from two studies of its Clotild® Smart Guidewire System demonstrating its ability to successfully identify "fresh" clot – thrombus rich in red blood cells (RBCs) – in peripheral artery disease (PAD) and differentiate it from other tissue encountered during PAD procedures. Results from the SEPARATE and E-SEPARATE studies were presented today in a late-breaking trial session at the Paris Vascular Insights Course.

The Clotild clot-sensing guidewire integrates the world's smallest electrical impedance sensor with machine learning. For PAD, the clot-sensing technology is being developed to instantly identify "fresh" clot and differentiate it from organized clot – thrombus poor in RBCs – as well as plaque, calcium and other tissue in real-time in order to inform individualized PAD treatment. The technology can be integrated into devices commonly used during PAD procedures, such as guidewires and catheters, and has the potential to enable the first device capable of objectively identifying "fresh" clot during a procedure without changing current workflow.

PAD affects 113 million people worldwide.[1] Yet, in current clinical practice, there is no simple method for physicians to easily determine what type of clot or tissue they are encountering when treating PAD. Reliably recognizing tissue type is an important factor in choosing the best treatment for any given patient – which varies from open surgery to endovascular procedures – and in achieving positive long-term patient outcomes. Today, identifying "fresh" clot with a high degree of certainty requires significant experience and expertise.

The prospective, single-arm SEPARATE study encompassed 17 patients treated by acknowledged PAD expert Koen Deloose, MD, Head of the Department of Vascular Surgery at AZ Sint Blasius Hospital, Belgium, where the Sensome clot-sensing technology was used in these patients to evaluate its ability to identify "fresh" clot. The study showed in a post procedure analysis that there was a high level of agreement between the technology's identification of "fresh" clot, the expert's assessment of "fresh" clot and the treatment decisions appropriate for "fresh" clot.

"Differentiating among tissues in an obstructed vessel in order to achieve successful peripheral revascularization is often limited by indistinct angiographic imaging, inaccurate patient medical history and a lack of tactile guidewire feedback. The SEPARATE study shows us that Sensome's clot-sensing technology could become a novel, real-time modality to reliably identify 'fresh' clot at an expert level in interventional procedures, with the potential to improve vessel preparation and treatment decision-making for physicians of all experience levels treating PAD," said Dr. Deloose.

A second study of the Sensome technology – E-SEPARATE – was conducted with 15 PAD patients (scheduled for amputation or bypass) at Groupe Hospitalier Paris Saint-Joseph in France and had two interesting findings. The study showed the technology's ability to differentiate "fresh" clot from other tissue collected from these PAD patients and examined ex-vivo. It also demonstrated an excellent correlation between the technology's ability to determine the RBC content of clots collected from PAD patients with sub-acute and chronic lesions, and a histological analysis of the same clot by an outside core lab.

"The E-SEPARATE study findings clearly demonstrate that symptom onset is an unreliable way to judge clot composition prior to treating a patient with PAD. The clots retrieved from both chronic and sub-acute lesions contained both RBC-rich 'fresh' clot and organized RBC-poor clots. In light of this, it's important for us to know the clot type to decide how to treat these patients...do we aspirate, dissolve the clot, or use another method? The Sensome technology has the potential to provide us with important information we are missing today to more effectively guide treatment and achieve better patient outcomes," said Professor Yann Gouëffic, Professor of Vascular Surgery at Groupe Hospitalier Paris Saint-Joseph, France.

In two previous peer-reviewed publications, the company's microsensor technology was shown to reliably predict the composition of red blood cells (RBC) in retrieved clot with good sensitivity and specificity consistent with histologic findings.[2,3]

"The ability of our technology to accurately identify 'fresh' clot is an exciting achievement in the evolution of PAD treatment that we expect will improve operator success and patient experience," said Sensome CEO Franz Bozsak. "We have now seen positive outcomes from our initial clinical work in PAD and ischemic stroke and anticipate similarly positive findings from our current study in lung cancer. We are enthusiastic about the potential of our real-time, intra-operative tissue analysis technology to enhance the efficacy of a variety of minimally invasive procedures that are currently limited by existing imaging modalities."

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 models. 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) Kim, Min Seo et al. Global burden of peripheral artery disease and its risk factors, 1990–2019: a systematic analysis for the Global Burden of Disease Study 2019. Lancet Glob. Health. 2023;11(10): e1553–e1565.

(2) 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.

(3) 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.

###

MEDIA CONTACT:

Michelle McAdam, Chronic Communications, Inc.

michelle@chronic-comm.com

+1 310-902-1274

INVESTOR RELATIONS CONTACT:

Chuck Padala

chuck@lifesciadvisors.com

+1 646-627-8390