SENSOME SIGNS EXCLUSIVE COMMERCIAL DISTRIBUTION AGREEMENT FOR CLOT-SENSING GUIDEWIRE IN JAPAN WITH COSMOTEC

First distribution agreement for Sensome's smart clot-sensing guidewire technology used in ischemic stroke treatment

Cosmotec to make upfront equity investment in Sensome

PARIS - JULY 10TH, 2024 – Sensome, the pioneer of microsensing technology for instant intra-operative tissue analysis, today announced an exclusive distribution agreement (the "Agreement") in Japan with Cosmotec, an M3 Group company, for its smart clot-sensing guidewire used in mechanical thrombectomy. Cosmotec made an upfront investment in Sensome upon finalizing the Agreement.

Under the terms of the Agreement, Cosmotec will assume responsibility for all activity associated with the Japanese regulatory approval process for the device used in ischemic stroke treatment and receive distribution rights in Japan upon regulatory approval from Japan's Pharmaceuticals and Medical Devices Agency (PMDA).

Sensome's 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. Japan's Ministry of Health, Labour and Welfare estimates there are approximately 15,000 thrombectomy cases performed each year in Japan, presenting a significant opportunity for Sensome's technology. The smart clot-sensing guidewire 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.

The Agreement follows presentation of positive first-in-human clinical data for the Sensome clot-sensing guidewire last month at the international LINNC Paris 2024 conference. The study demonstrated that the technology met all primary safety and performance endpoints of the trial.[1]

"The commitment by Cosmotec to lock in distribution rights for our smart clot-sensing guidewire in Japan clearly demonstrates their confidence in Sensome and enthusiasm for our proprietary tissue sensing technology that holds significant potential to improve the treatment of ischemic stroke," said Franz Bozsak, CEO and co-founder of Sensome. "We believe that Cosmotec is the right partner for us in Japan due to their deep understanding of the Japanese market and regulatory environment, extensive and long-standing relationships with physicians, and experience with smart medical technologies."

"We are successfully executing on our initial indication in ischemic stroke and pursuing distribution relationships in other regions, such as Europe, the U.S. and China. We look forward to bringing this same momentum to other indications we are currently pursuing, including lung cancer and peripheral vascular disease," concluded Bozsak.

"We are impressed with Sensome's unique clot-sensing guidewire and its potential to characterize clots in patients who are undergoing life-saving stroke treatment," said Suguru Ominato, CEO of Cosmotec. "Clot composition and length are not readily determined today, leading to a majority of thrombectomy cases requiring multiple passes, which adds risk, and the failure of up to 20% of cases to remove the entire clot. By being the exclusive distributor of this important technology in Japan, we expect to provide physicians with critical information that enables them to make the right treatment decisions that can help to improve patient outcomes after a stroke."

RM Global Partners LLC served as advisor to Sensome for this deal.

ABOUT THE SENSOME SMART CLOT-SENSING TECHNOLOGY

The company's unique technology is based on electrical impedance spectroscopy, which measures the 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 impedance-based tissue sensor. The current iteration of Sensome's clot-sensing guidewire is known as the "Clotild® Smart Guidewire System."

The Clotild Smart Guidewire System has been designated as a Breakthrough Device by the FDA. It 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. Sensome is partnered with leading guidewire manufacturer, Japan-based ASAHI INTECC, for the manufacturing of its smart clot-sensing guidewire.

ABOUT COSMOTEC

Cosmotec Co., Ltd., a wholly owned subsidiary of M3, has been developing its business by distributing medical devices in the fields of cardiovascular surgery, endovascular treatment, and emergency and plastic surgery, and has been introducing advanced devices from both Japan and overseas to the Japanese market since its establishment. Since becoming a subsidiary of M3 in 2017, Cosmotec has been actively pursuing marketing and sales through a combination of digital and in-person marketing by utilizing the digital marketing resources of the M3 Group, in addition to Cosmotec's sales resources covering the entire Japanese country.

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

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