PRESS RELEASE
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Occlutech progress in US – first patient has been enrolled in important US FDA study

Occlutech Holding AG ("Occlutech"), one of the world's leading providers of minimally invasive structural heart disease implants, continues its progress in the US market. The company announce today the first patient to be enrolled in the OCCLUFLEX study. The OCCLUFLEX study aims to investigate the safety and efficacy of Occlutech's PFO Occluder compared with the standard of care PFO Occluders approved by the Food and Drug Administration (FDA) in patients who have suffered a cryptogenic stroke.

In 2021, FDA granted Occlutech IDE approval for a prospective, randomized, multi-center, controlled, clinical study. The study allows Occlutech to collect safety and effectiveness data to support a Premarket Approval (PMA) application to the FDA upon completion. The OCCLUFLEX study aims to enroll 450 patients in the US, Canada, and Europe.

An important step in the OCCLUFLEX study was achieved, when the first patient at the Ottawa Heart Research Institute in Ottawa, Canada was enrolled by study investigators, Dr. Benjamin Hibbert, Dr. Marino Labinaz, and Dr. Dylan Blacquiere.

"Our team is pleased to be part of Occlutech's US Study and contributing data to support FDA approval for patients who suffer from a cryptogenic stroke in the presence of a PFO," says Dr. Hibbert, Interventional Cardiologist, University of Ottawa Heart Institute (UOHI).

"It's a great achievement as we continue on our path to execute our US growth strategy. Accounting for
around 30 percent of the global Structural Heart Defect occluder market, and characterized by an attractive pricing and reimbursement system, the US is a key market for Occlutech," says Sabine Bois, CEO of Occlutech.

For more information about the OCCLUFLEX clinical study, please visit https://clinicaltrials.gov.

About PFO
PFO is a common structural heart defect in which the foramen ovale does not close completely after birth, resulting in a flap-like opening between the left and right atria of the heart. PFOs exist in around 25 percent
of the general population.

Blood clots that commonly develop outside the heart may pass directly through the PFO from the right atrium into the left atrium without passing through the lungs, where they are normally filtered out of the blood. Such clots may cause occlusion of a small blood vessel and, if located in the brain, can cause a stroke.

Occlutech's Flex II PFO Occluder, which has regulatory approval in over 60 markets globally, enables physicians to close the PFO through a minimally invasive procedure

For additional information about the company's products, the Occlutech PFO Occluder, or to inquire about participation in the company's patient registries, please go to Occlutech's website at www.occlutech.com or send an email to info@occlutech.com.

For more information, please contact:

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About Occlutech

Occlutech is a leading specialist provider of minimally invasive structural heart implants, with a mission to improve the quality of life for people with heart conditions. The vision is to become a leading global specialist in cardiac implants, addressing congenital heart defects, stroke prevention and heart failure. Since 2003, the company has developed, manufactured, and commercialized occluders and interatrial shunt products. Occlutech has a broad and proven portfolio, based on proprietary technology, and over 200 patents with more than 146,000 products sold. The company markets and sells its products in around 85 countries. The company has around 290 employees and is a public limited liability company registered in Switzerland. For more information: www.occlutech.com.

Image Attachments

Sabine Bois CEO
PFO Figulla Flex II High Resolution

Attachments

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