PRESS RELEASE
31 January 2023 08:00:00 CET

Occlutech continues its progress in US FDA study OCCLUFLEX – enrolls first patient in Europe

Occlutech Holding AG ("Occlutech"), one of the world's leading providers of minimally invasive structural heart disease devices, continues its progress in the US market. The first patient has now been enrolled in the global US study OCCLUFLEX in Europe.

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.

In Q2 2022, Occlutech enrolled its first patients in the US and in Canada, and now the first patient has been enrolled in Europe in the OCCLUFLEX study. The enrollment took place in Asklepios Klinik Altona in Hamburg, Germany, by study investigators Dr. med Felix Meincke and Dr. med. Peter Michels.

"We are pleased to be part of Occlutech's US Study and contribute with data to support FDA approval for the PFO Occluder to help patients who suffer from a cryptogenic stroke," says Dr. Meincke, Principal Investigator, Asklepios Klinik Altona.

"I am happy that we are continuing to move forward with our US studies which is in line with our growth strategy. The US is a future key market for Occlutech, and it stands for a large part of the global Structural Heart Defect occluder market," 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.

Sabine Bois
CEO
Email: sabine.bois@occlutech.com

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 155,000 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.

Attachments

Occlutech continues its progress in US FDA study OCCLUFLEX – enrolls first patient in Europe