PRESS RELEASE
13 March 2023 08:00:00 CET

Occlutech announces first patient enrollment in important US pivotal study for the Atrial Flow Regulator (FROST-HF)

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. Today, the company has announced that the first patient has been enrolled in the FROST-HF study. The FROST-HF study is a global study investigating Occlutech's Atrial Flow Regulator ("AFR") in the treatment of patients with heart failure with either preserved ejection fraction ("HFpEF") or reduced ejection fraction ("HFrEF").

The study is a randomized, double-blinded, multi-center, sham[1]-controlled investigation that allows Occlutech to collect data on safety and effectiveness of the AFR device in patients[2]. The data will support a marketing application to the US Food & Drug Administration ("FDA") for commercial use in the US. The FROST-HF Investigational Device Exemption study is planned to randomize 588 patients, plus an additional roll-in cohort of 110 patients, in the US, Canada, and Europe.

The first patient is now enrolled in this important study examining new treatment options for people with heart failure via the Occlutech AFR device. Dr. Miquel Alvarez Villela along with Dr. Craig Basman at Northwell Health Lenox Hill Hospital are the first physicians to enroll in this innovative trial, leading the way for over 70 centers in the US and 70 centers in Europe; an important milestone for the study and for Occlutech.

"Inter-atrial shunt devices represent an important promise for heart failure patients who remain symptomatic despite medications. At Lenox Hill Hospital we are proud to be participating in this clinical trial, offering our patients cutting-edge technology for the potential treatment of this serious condition. We look forward to continuing our collaboration for the advancement of the field" says Dr. Miquel Alvarez, Principal Investigator at Lenox Hill Hospital.

At least 12 million people suffer from heart failure in the EU and the US3. Occlutech's Atrial Flow Regulator therapy aims at improving lives of several hundred thousand patients yearly suffering from this disabling condition. The AFR has potential to save lives and improve quality of life for a growing number of patients, for which there are very limited treatment options. The market potential in the EU and the US is steadily growing and estimated to be worth several billion euros4.

"The FROST-HF trial will contribute significantly to our knowledge regarding the safety and effectiveness of inter-atrial shunting in patients with heart failure, with both preserved and reduced left ventricular ejection fraction. In addition, testing two different sizes of inter-atrial shunts in this study will provide unique insights, and potentially signal how different magnitudes of inter-atrial shunting may contribute to the clinical benefit", says Prof. Dr. Gregg W. Stone, FROST-HF executive committee co-chair and professor at Icahn School of Medicine at Mount Sinai Heart Health System, New York.

“In this regard, The FROST-HF trial is the most comprehensive trial comparing inter-atrial shunting to the latest guideline directed therapies across the broad heart failure phenotype with potential to impact on advancing existing standard of care”, adds Prof. Dr. Stefan Anker, FROST-HF executive committee co-chair and professor at the German Heart Center of Charité University Medicine Berlin.

“Kicking off the FROST-HF study is an important milestone for Occlutech. It takes us one step closer to becoming the global leader in the interventional heart failure market at the same time as we are focusing our development efforts on the large US market. The potential US market size for shunt devices designed for treatment of heart failure is significant, and with a continued focus on the US, we deem it as a future key market for our portfolio of market leading devices,” says Sabine Bois, CEO of Occlutech.

Additional information about FROST-HF can be found on https://clinicaltrials.gov/ct2/show/NCT05136820.

About heart failure
Heart failure occurs when the heart is not pumping efficiently enough to keep a person healthy. Most commonly, patients with heart failure will experience shortness of breath, congestion, swollen limbs, among other symptoms.

Left-sided heart failure is divided into heart failure with reduced ejection fraction (HFrEF or systolic heart failure) and heart failure with preserved ejection fraction (HFpEF or diastolic heart failure). Both are caused by changes in the walls of the heart’s chambers (ventricles) causing them to become either weak or stiff. The result is that the heart becomes less efficient at pumping blood.

No matter how forceful the heart pumps, it can never pump all the blood out of a ventricle. The term “ejection fraction” (EF) refers to the percentage of blood that is pumped out of a filled ventricle with each heartbeat.

About Atrial Flow Regulator (AFR)
The Atrial Flow Regulator (AFR) is a small device that can be used to keep a shunt between the two upper chambers of the heart open and control its size. The device has two disks with a central opening (fenestration or shunt) so that blood can flow through the AFR, from the left to the right side of the heart. The device is made from metal wires (nitinol) that are braided and molded into the final shape of the AFR. Nitinol has been used safely for decades to make medical devices that have been implanted in hundreds of thousands of patients. The AFR is implanted using established and safe minimally invasive (transcatheter) techniques performed by specialized doctors (interventional cardiologist).

Several clinical studies have shown that the AFR and other interatrial shunting devices developed in recent years can be safely implanted and improve symptoms in HFpEF and HFrEF patients.

[1] Sham procedure is a procedure that omits the step thought to be therapeutically necessary. In device clinical trials sham procedures serve an analogous purpose to placebo drugs, neutralizing biases in the assessment of outcomes.
[2] In early 2021, the Occlutech Atrial Flow Regulator (AFR) received a US Food and Drug

Administration (FDA) breakthrough device designation assigned to devices that potentially provide more effective treatment to patients.
3 Roland Berger Market Study.
4 Roland Berger Market Study.

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 announces first patient enrollment in important US pivotal study for the Atrial Flow Regulator (FROST-HF)