NEWS RELEASE

Occlutech's Atrial Flow Regulator (AFR) Receives U.S. FDA Breakthrough Device Designation for Heart Failure (HF)

Schaffhausen, Switzerland - Jan 16th, 2021 – Occlutech, a privately-held company, announced today that the U.S Food and Drug Administration (FDA) has granted the Company a Breakthrough Device designation for its first-in-class, implantable Atrial Flow Regulator (AFR) for heart failure (HF) patients with preserved (HFpEF) or reduced (HFrEF) ejection fraction.

Heart failure (HF) is a serious condition characterized by the heart's inability to pump an adequate blood supply to the body. Worldwide, HF affects over 30 million people, and the lifetime risk of HF increases with age, with over 50% of hospitalizations of persons aged 65 or older attributable to HF. Heart Failure Symptoms include fatigue, palpitations, and exertional dyspnea. HF may result from disorders of the pericardium, myocardium, endocardium, heart valves, great vessels, or specific metabolic abnormalities. These disorders affect the heart's structure or function, which results in reduced cardiac output and/or elevated intracardiac pressures at rest or during exercise. When HF is left untreated, symptoms gradually worsen, resulting in increased morbidity, clinically driven hospitalizations, and higher mortality.

The AFR is for use in patients with Heart Failure with Preserved Ejection Fraction (HFpEF) or Reduced Ejection Fraction (HFrEF) and who, despite optimal medical therapy, experience worsening symptoms. The AFR maintains an interatrial shunt with a predetermined diameter allowing for controlled blood flow from the left to the right atrium enabling the left atrium to decompress and lower left atrial pressure. Reduced left atrial pressure has been shown to reduce heart failure symptoms and improve exercise tolerance.

Breakthrough Device Designations aim to accelerate the development, assessment, and approval of new treatments in severe diseases, including a prioritized review all the way through market approval.

"It is an important milestone for us to have received this second breakthrough designation for our AFR device." says Sabine Bois, CEO Occlutech Group. "After receiving the first Breakthrough Device designation for pulmonary arterial hypertension (PAH) in December 2020, the heart failure (HF) indication addresses a substantial market with rapid growth and only limited options for the treatment for critically ill patients. We are looking forward to developing an important new therapy and working closely with the FDA on both indications.

Occlutech is one of the leading companies in its field, with several major products including state-of-the-art PFO occluders, ASD occluders among others. Occlutech has sales of congenital and structural heart products in over 80 countries and maintains manufacturing and R&D facilities in Jena, Germany and Istanbul, Turkey. Occlutech has developed many novel products and technologies to improve treatment of patients in these and related areas.

For additional information about the Company's products, the Occlutech AFR, or to inquire about participation in our patient registries, please visit Occlutech´ s website at www.occlutech.com, or contact us directly at AFR@occlutech.com.

The AFR is not approved in the United States. Product availability is subject to local regulatory clearance. The AFR is under clinical investigation for use in patients with pulmonary arterial hypertension and use in these patients is limited by applicable national laws.

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