NEWS RELEASE

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

Schaffhausen, Switzerland - Dec. 18th, 2020 – Occlutech, a privately-held company, announced today that the US Food and Drug Administration (FDA) has granted the company a Breakthrough Device designation for its first-in-class, implantable Atrial Flow Regulator (AFR) for Pulmonary Arterial Hypertension (PAH).

PAH affects hundreds of thousands in the U.S. and globally and is resulting from changes in cells that causes damages of the lung arteries. Consequentially, the heart is forced to work harder to supply enough oxygen. The patient experiences symptoms such as shortness of breath, dizziness and fatigue. The severity of these symptoms usually correlates with progression of the disease and significantly reduced quality of life. Over time, the right ventricle enlarges to hold more blood and the additional strain gradually causes the heart to fail. By placing the Occlutech AFR device into the septum and creating a restrictive atrial septal opening by maintaining the correct sizing of a created shunt, the intra cardiac pressure is substantially reduced, thereby improving the heart's function.

Breakthrough Device Designations are aimed 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 breakthrough designation." says Sabine Bois, Co-CEO Occlutech Group. "We are very proud and excited to work closely with the FDA in this opportunity to develop an important new therapy that positively impacts the lives' of critically ill patients."

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.

Contact:

Sabine Bois
Co-CEO Occlutech Group
Mobile: +49 160 90792130
Email: sabine.bois@occlutech.com