News release

Occlutech takes important step towards approval in China

Schaffhausen, Switzerland – June 1, 2021 – Occlutech AG ("Occlutech" or the "Company") today announces that the planned recruitment of 180 patients has been reached in the Company's trial in China for its ASD Occluder. The Occlutech ASD Occluder is used in the treatment of Atrial Septal Defects (ASD), which is a congenital heart condition. The completion of the patient recruitment represents a significant milestone in the process towards approval of Occlutech's ASD Occluder in China. The trial is conducted as a multicenter, randomized, prospective trial. It is commencing now and is supporting Occlutech's application for market approval of the ASD Occluder in China. Once the 12 months follow-up for all patients is completed the Company expects to file for regulatory approval by the Chinese National Medical Products Administration (NMPA).

An approval in China will be an important addition to Occlutech's global expansion. The ASD Occluder is today approved in more than 60 countries worldwide, among others Canada, Japan, South Korea and CE marked countries like Germany, France and Sweden. Furthermore, the ASD Occluder is in its final review with the FDA in the premarket approval (PMA) application in the United States.

Sabine Bois, CEO Occlutech Group, comments:

"To reach the intended recruitment goal despite the challenging impact of the Corona pandemic is an important milestone for Occlutech. The expansion towards China is a key part of our strategic ambition to drive sales growth over the coming years and the trial is another important step to bring us closer to file for market approval by the Chinese National Medical Products Administration (NMPA), once the 12 months follow up for all patients is completed."

About Atrial Septal Defect (ASD) Occluders

Atrial septal occluders are minimally invasive cardiac devices, addressing congenital heart defects. Atrial Septal Defect (ASD) is one of the most common types of congenital heart diseases and formed due to an unclosed connection between the upper chambers of the heart appearing during fetal development.

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

About Occlutech

Occlutech is a leading specialist in minimally invasive cardiac devices, addressing congenital heart defects, stroke prevention and heart failure. Since 2003, we have been developing, manufacturing, and commercializing structural heart and interatrial shunt products. We have a track record of over 15 years of gaining market share, developing and launching innovative products and building solid market positions. Occlutech has a broad and proven portfolio with 10 CE marked products covered by over 200 patents. We market and sell our products to hospitals and clinics in over 85 countries.

Occlutech maintains manufacturing and R&D facilities in Germany and Turkey, with a global supply, customer support hub located in Sweden.

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