PRESS RELEASE
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Occlutech continues positive progress in the U.S. – granted conditional FDA approval for Heart Failure study for AFR device

Occlutech Holding AG ("Occlutech"), a leading provider of minimally invasive structural heart disease devices, continues its positive progress towards on the U.S. market. Today the company announces that an important milestone has been achieved with the Food and Drug Administration ("FDA") granting a conditional approval of Occlutech's Investigational Device Exemption ("IDE") application to conduct a pivotal human clinical study concerning Occlutech's Atrial Flow Regulator ("AFR") for Heart Failure.

Occlutech has a strong market position today and sells its products in over 85 countries. The company has a clear focus on growth, both in existing markets and further global expansion. Capturing the significant U.S. market, as well as launching the AFR product[1] globally, are two important growth opportunities for Occlutech.

The granted conditional FDA approval of the company's IDE application to conduct a pivotal human clinical study regarding the AFR device for Heart Failure is an important milestone in the company's growth strategy. The study is designed to show safety and efficacy in a randomized controlled trial ("RCT").

"The developing market for interatrial shunt devices, such as Occlutech's Atrial Flow Regulator for Heart Failure, has an estimated market potential of about €3.9 bn in 2021 in EU5[2] and the U.S.[3]. The conditional approval is an important milestone for the company towards an FDA market approval for Occlutech's Atrial Flow Regulator in the U.S." says Sabine Bois, CEO of Occlutech.

Patient enrollment is expected to commence during the first half of 2022. The study's primary endpoints will be evaluated at the 12-month patient follow-up. Occlutech plans to complete the enrollment of patients in 2025 while finalizing the premarket approval and anticipate receiving an FDA market approval for the U.S. in 2026.

Earlier this year Occlutech achieved another important milestone when the FDA also conditionally granted Occlutech an IDE for a study, which aims to compare outcomes of Patent Foramen Ovale (PFO) closure by Occlutech's Flex II PFO Occluder to the standard of care in patients with cryptogenic stroke.

For additional information about Occlutech's products, 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.

[1] Occlutech Atrial Flow Regulator is an interatrial shunt device for transcatheter delivery. More information about the AFR product can be found on www.occlutech.com.
[2] EU5 Countries include France, Germany, Italy, Spain and the United Kingdom.
[3] The estimate is based on a market study commissioned by Occlutech by the consulting firm Roland Berger.

Contacts

Claudia Scalia
Marketing Communications Manager
claudia.scalia@occlutech.com
Phone: +46 735 199782

Contacts

Stefan Kleidon
Vice President Sales & Marketing
stefan.kleidon@occlutech.com
Phone: +49 176 31514136

Image Attachments

Occlutech AFR
CEO Sabine Bois

Attachments

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