



PREDICT-LAA trial enrolls first patient

GENT, Belgium, January 17th 2020— <u>FEops</u>, a leader in personalized predictive planning for structural heart interventions, is proud to announce that today **the first patient** has been enrolled in the physician-initiated <u>PREDICT-LAA trial</u>. The trial is led by **Righshospitalet** (Copenhagen, Denmark) and aims to assess whether the use of **FEops HEARTguideTM** computer simulations based on cardiac CT-imaging can contribute to better preprocedural planning and improved procedural outcomes of percutaneous LAA closure procedures with the Abbott AmplatzerTM AmuletTM device. The trial is supported by both Abbott and FEops.

"Today we enrolled the first patient in PREDICT-LAA at our hospital. In a joined effort with 9 other sites, we will test the hypothesis that by using these new computer simulations, a **better preprocedural planning** of the intervention can be obtained. This is essential information, since today it is not always possible to determine the exact anticipated 'landing zone' or 'position' of the closure device and, hence, to select the appropriate device size." said **Dr Ole De Backer**, Principal Investigator of the PREDICT-LAA

PREDICT-LAA is a prospective, multicenter, randomized controlled trial. In total, 200 patients eligible for percutaneous LAA closure with an Amplatzer TM Amulet device (Abbott, USA) will be enrolled - 100 patients will be allocated to the computational simulation treatment arm and 100 patients to the standard treatment arm. Primary endpoints are closure of the LAA, and presence of device-related thrombus. Estimated enrollment completion date is March 2021.

"Our support together with Abbott in the PREDICT-LAA trial shows our strong commitment to **generate a robust body of clinical evidence** with FEops HEARTguide, contributing to better procedure planning and patient outcome." said **Christian Vincent**, Director Therapy Development at FEops.

FEops HEARTguideTM, currently available on the EU and Canadian market, is a one-in-its-kind cloud based procedure planning environment for structural heart interventions that provides **physicians** unique insights to **evaluate device sizing and positioning pre-operatively** using novel computational modeling and simulation technology. Such insights have the power to help improving clinical outcomes in real-world hospital settings. The current release includes workflows for transcatheter aortic valve implantation (**TAVI**) and left atrial appendage occlusion (**LAAo**) **procedures.**

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About FEops

Privately held FEops, headquartered in Gent, Belgium, is a leader in personalized predictive planning for structural heart interventions. In September 2017, FEops announced that it closed a 6 million euros financing, led by Valiance, and joined by existing investors Capricorn Venture Partners and PMV. In December 2019, FEops received a 3.2 million euros grant from the European Innovation Council (EIC) accelerator programme.

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