FDA grants “Breakthrough Device Designation” to CorFlow Therapeutics to expedite clinical development and regulatory review of its *CoFI*™ (COF-fee) System

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BAAR, Switzerland--(BUSINESS WIRE)--CorFlow Therapeutics AG (www.corflow-therapeutics.ch) today announced that the FDA has designated the company’s ***CoFI* (CorFlow Controlled Flow Infusion) System** as a “Breakthrough Device” with a broad indication-for-use statement: "The CoFI™ System is indicated for diagnostic assessment of the coronary microcirculation immediately following PCI ("stenting"), *and* to be a platform for controlled infusion of therapeutic agents into the microcirculation with or without vessel occlusion."

This FDA designation is a process aimed at fast-forwarding clinical development and regulatory review of the CoFI™ System. Toward that end, CorFlow continues to enroll patients into the ongoing European “MOCA I” clinical trial of the CoFI™ System and will expedite US submissions for clinical trials as a result of the Breakthrough Designation. The MOCA I trial is a safety and feasibility trial in 40 acute heart attack patients.

"FDA’s Breakthrough Designation is a dramatic validation of the vision the CorFlow founders had when starting the company in June 2016: to develop a technology that not only fits into the standard workflow for acute heart attack patients but also provides a diagnostic tool as well as a therapeutic platform for the coronary microcirculation,” said **Jon Hoem**, CEO. “It also reflects the true spirit of the CorFlow team and how the team achieves demanding milestones that will bring the CorFlow technology to patients in dire need of improved coronary microcirculation."

Based on recent market research in the US and Europe, CorFlow estimates that more than 170,000 patients annually need new technologies to improve their coronary microcirculation after standard stent implantation. Although current stent technologies have proven to be crucial in saving patients from death and complications after a heart attack, these technologies do not address the unmet medical need for improved coronary *microcirculation*. Indeed, reduced coronary microcirculation has proven to be an independent marker for complications after a heart attack such as heart failure and death.

The objective of the FDA Breakthrough Designation Program is to provide patients and healthcare providers with timely access to innovative medical devices by speeding their development, assessment and review, while preserving the standards for medical device approvals. CMS has also instituted a new rule that will increase payments for medical devices designated by the FDA as breakthrough devices.

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