



CorFlow Therapeutics Announces Successful Completion of Phase 1 and First Patients enrolled in Phase 2 of the MOCA II Pivotal Trial, Approval to Start the REVITALISE RCT in Europe, and Strengthening of Clinical Leadership

Milestones advance clinical progress and path to commercialization

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BAAR, Switzerland--(BUSINESS WIRE)-- [CorFlow Therapeutics AG \(CorFlow\)](#), a clinical-stage company focused on transforming the diagnosis and treatment for heart attack patients, today announced multiple milestones in advancing its clinical program and the strengthening of clinical leadership.

Phase 1 of the company's MOCA II FDA Pivotal Trial was successfully reached after safety and performance goals were met with STEMI heart attack patients who had the proprietary P_{CoFI} diagnostic measurement of microvascular obstruction (MVO) made during a stenting procedure, when compared to the reference standard diagnosis by cardiac MRI in the subsequent days. Phase 1 included 19 patients enrolled across 5 US and 3 European sites. MOCA II follows the FIH MOCA I study and primarily aims to validate the threshold value of the proprietary P_{CoFI} measurement for diagnosing MVO in the setting of primary angioplasty compared to cardiac MRI. This milestone achievement, which was confirmed by the study's independent DSMB (Data and Safety Monitoring Board) triggered the possibility for Phase 2 to begin in a larger wave of clinical trial sites in both the US and Europe.

The first patients in the MOCA II Phase II study were enrolled by Professor Marco Valgimigli at Cardiocentro Ticino Institute in Lugano, Switzerland. "I am excited to see the next generation of the CorFlow technology and advancement of the clinical program where the international pivotal study is now underway, for which the interventional cardiology community will eagerly await the results. Once the technology is readily available, it can help drive decision-making in the cath lab to improve our management of STEMI patients. Fast, accurate diagnosis of MVO is the key step we need to build from."

CorFlow also announced that its parallel flagship clinical trial is now approved and can start enrolling patients. The novel randomized REVITALISE trial is now set to begin enrolment across UK, with France, Netherlands, and Spain following in the coming weeks. REVITALISE is intended to prospectively test the effectiveness of the proprietary CorFlow Continuous Flow Infusion System (CoFI System) to deliver therapeutic agents in treating MVO in patients undergoing primary angioplasty for acute myocardial infarction with ST segment elevation MI (STEMI). The trial intends to enroll at least 250 patients with early results expected in 2027 and data read-outs expected through 2028. The adaptive platform approach was selected due to its ability to add subsequent arms to the trial, testing the effectiveness of additional drug candidates delivered through the CorFlow system. Additional countries and research centers are also under evaluation.

Paul Mead, CEO of CorFlow, commented "With the momentum for our expanded clinical program and high interest from KOLs, we are now fortunate to be partnering with many of the top research institutions and physicians in the US and Europe to help bring the technology forward. Between both studies, we will have close to 50 top-tier hospitals engaged, each with a team motivated to see these studies succeed. Interventional cardiology, specifically in the coronary space, is at an exciting time once again with growth drivers and new options for patients. Our technology and clinical studies aim to build on that with a major step forward towards truly complete revascularization, including superior diagnosis and treatment options."



Alongside the clinical program news, CorFlow has announced that Dr. Rick Kuntz has joined the CorFlow Board of Directors as an Observer and senior scientific advisor. Dr. Kuntz, a renowned interventional cardiologist, was a founder and Chief Scientific Officer of the Harvard Clinical Research Institute and later served at Medtronic as Chief Medical and Scientific Officer, where he oversaw medical affairs, health policy and reimbursement, clinical research activities, and corporate technology for the respected medical device leader. His experience includes guiding clinical programs for numerous technologies through market clearance and subsequent post market research for over 30 years.

CorFlow also announced the appointment of Dr. Pedro Eerdmans as Vice President Clinical. Pedro brings decades of experience from both industry, clinical research organizations, and notified bodies over his career, touching multiple medical fields. Notably, Dr. Eerdmans has helped scale medtech startups for clinical study execution, as well as spent time at larger medical companies such as Biosensors International where he served as VP Medical Affairs overseeing multiple coronary artery stent studies.

Chris O’Connell, the Chairman of the Board of CorFlow, commented, “We are thrilled with the clinical milestones that CorFlow continues to achieve, and equally excited by the added experience of our new team members. I personally had the chance to work with Dr. Kuntz at Medtronic for many years and cannot think of a better addition for CorFlow to help guide our strategic, scientific and regulatory path forward for this breakthrough technology. Our foundation will always be in medical science that puts the patient first, aiming for a new standard of care – which is possible thanks to this strengthened team and the path the company is now on with these landmark studies.”

About CorFlow Therapeutics: Founded and headquartered in Switzerland, with subsidiary operations in both Italy and the United States. The company is venture capital funded with an international VC firm syndicate, most recently with a Series B financing round announced first announced in September 2024. CorFlow aspires to be the leader in diagnostic and therapeutic solutions for restoring healthy microvascular blood flow, starting with cardiac applications for heart attack patients. Working in close partnership with scientists from the University of Bern, ETH Zurich and the University Hospital Zurich, in a collaboration funded by the Swiss Innovation Agency (Innosuisse), CorFlow continues to research applications for the unique patented technology with pharmaceutical options and new use cases.

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