Colorado Prevention Center Clinical Research, Hospital Israelita Albert Einstein And Uppsala Clinical Research Launch A New Study Using A Pragmatic Approach To Push The Boundaries of Innovative and Efficient Study Design

Study to evaluate the impact of rapid and intensive cholesterol lowering in patients hospitalized with acute myocardial infarction.

Aurora, CO, 1 April 2022 - CPC Clinical Research, an academic research organization affiliated with the University of Colorado Anschutz Medical Campus, today announced the launch of EVOLVE-MI: EVOLocumab Very Early After Myocardial Infarction (NCT05284747), a pragmatic clinical trial evaluating Repatha® (evolocumab) in patients hospitalized with acute myocardial infarction (MI). Pragmatic trials evaluate a treatment's effectiveness in real-life routine practice conditions. The Amgen-sponsored Phase 4 trial represents a new approach to collecting data in cardiovascular disease and is being conducted in partnership with Uppsala Clinical Research in Uppsala, Sweden and Hospital Israelita Albert Einstein in Sao Paulo, Brazil. Enrollment is anticipated to start in the second quarter of 2022.

EVOLVE-MI is designed to evaluate the impact of rapid and intensive cholesterol lowering in patients who receive evolocumab within 10 days of a non-ST-elevation myocardial infarction (NSTEMI) or ST-elevation myocardial infarction (STEMI).

"This trial will use an innovative approach to test the impact of rapid and intensive cholesterol lowering at a time when patients are particularly vulnerable to recurrent heart attack," said Dr. Mikhail Kosiborod, cardiologist and Vice President of Research at Saint Luke's Health System in Kansas City, Missouri, and co-Chair of the trial's Executive Committee. "EVOLVE-

MI builds upon the FOURIER trial which studied patients with cardiovascular disease, but who had no heart attack or stroke within the preceding four weeks."

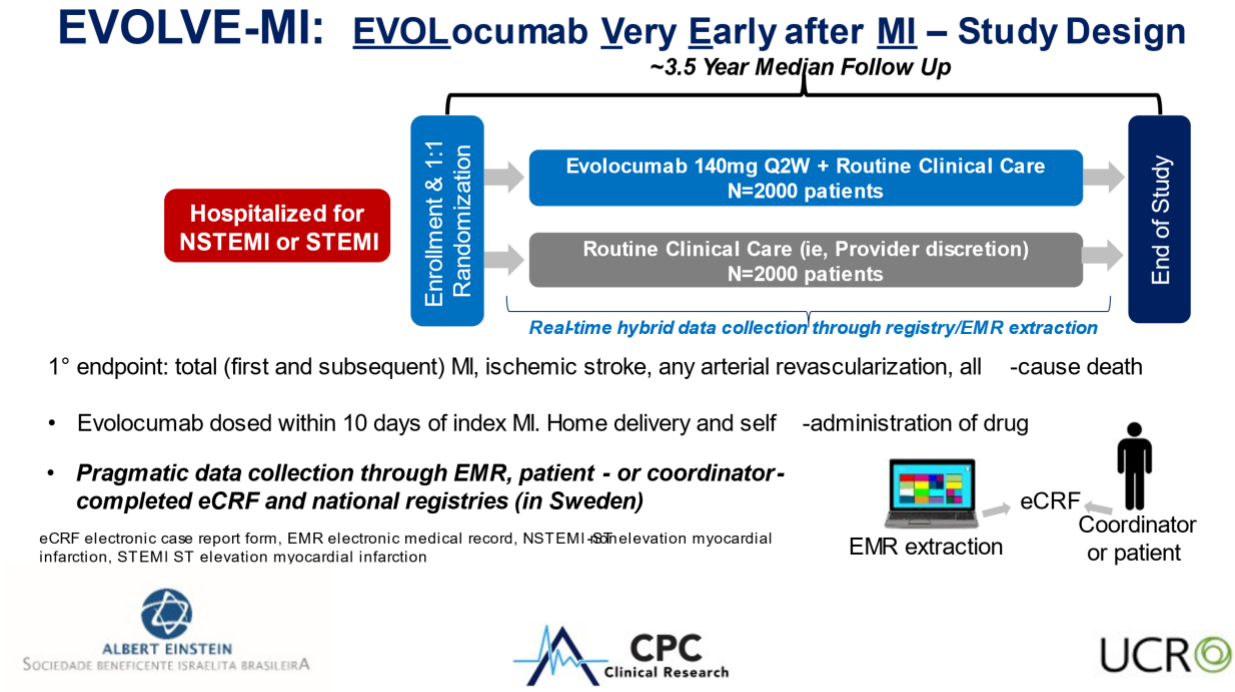
In FOURIER, evolocumab reduced the composite endpoint of heart attack, stroke or cardiovascular death by 20% ($p<0.001$) compared to placebo, in a median study duration of 2.2 years.[1] In contrast to FOURIER, EVOLVE-MI will enroll a more acute population, will include longer follow up and will employ streamlined methodology to optimize recruitment and data collection.

"We're excited that the EVOLVE-MI design includes a number of novel pragmatic features that will assure this is an innovative clinical trial," said Dr. Christopher Cannon, cardiologist at Brigham and Women's Hospital, Professor of Medicine, Harvard Medical School, and Executive Committee co-Chair.

"This trial is a truly collaborative initiative to push the boundaries of innovative and efficient study design while protecting trial quality and integrity to ensure both informative findings for this study hypothesis as well as providing a blueprint for future studies," said Dr. Marc Bonaca, Professor of Medicine at University of Colorado School of Medicine and Executive Director of CPC. Dr. Otavio Berwanger, Director of the Academic Research Organization (ARO) at Hospital Israelita Albert Einstein, reinforces the importance of the international collaboration. "Conducting a fully collaborative study carried out in countries with different realities can positively contribute to generate reliable evidence that can inform clinical practice."

[1] Sabatine MS et al. Evolocumab and Clinical Outcomes in Patients with Cardiovascular Disease. N Engl J Med 2017; 376:1713-1722

"The EVOLVE MI trial is taking the pragmatic approach a step further than most pharmacological trials," says Dr. Jonas Oldgren, Professor of Cardiology and executive director of Uppsala Clinical Research Center in Sweden. "Our country has a strong track record of conducting pragmatic trials linked to the clinical registries and as a Swedish ARO we believe that we can contribute to make the trial very closely integrated with clinical routine to facilitate enrollment with very limited burden on sites, investigators and patients."



To view slide decks & resources for the EVOLVE-MI trial, visit https://cpcclinicalresearch.org/news-and-presentations/

About CPC

CPC Clinical Research, an academic research organization and affiliate of the University of Colorado Anschutz Medical Campus, is a mission-driven non-profit organization that exists to improve health through innovative science and community engagement. For over 30 years, CPC has been a leader in research and implementation, experienced in clinical trial design, oversight,

and management, including registration trials (Phase I-IV), real-world data, and pragmatic trials. Our proximity to and affiliation with the University of Colorado School of Medicine enables experienced faculty in a diverse group of specialties to spend time at the university and CPC. Our faculty members are on the cutting edge of scientific, clinical, and regulatory developments. Members of CPC's leadership team have chaired and/or served on FDA advisory committees, including the Cardiovascular and Renal, Endocrine and Metabolism, and Reproductive Health committees. Through our Community Health Programs, we develop innovative and evidence-based health promotion programs, interactive health technology, and community partnerships to help win the fight against cardiovascular disease in Colorado. As a result of these efforts, CPC Community Health has provided health education and/or coaching to over 82,000 individuals and made significant improvements in the lives of those at risk for cardiovascular disease.

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