Rapid zalunfiban treatment at 1st point of medical contact lowered risk of more severe heart damage in combination with other serious heart-attack complications

CeleBrate results presented today at AHA Annual Scientific Sessions

DEL MAR, CALIF., USA (Nov. 10, 2025) – Rapid treatment with CeleCor Therapeutics' investigational heart-attack drug, zalunfiban, resulted in higher levels of blood flow to the heart and an approximately 21% reduction in a patient's risk of experiencing a larger MI or one complicated by death, stroke, reinfarction, stent thrombosis or heart failure, new Phase 3 data show.

The results of the pivotal CeleBrate study, which met both its primary efficacy and safety endpoints, were presented today during a late-breaking session at the American Heart Association's Annual Scientific Sessions in New Orleans. They were published simultaneously in *The New England Journal of Medicine Evidence*.

CeleBrate involved patients who suffered STEMI (ST-segment elevation) heart attacks – the most severe form of heart attack, in which blood flow to a portion of the heart is almost always cut off by a blood clot. The priority in treating STEMI heart attacks is opening the coronary artery as soon as possible to prevent death or irreversible heart damage.

In the study, zalunfiban was administered at the first point of medical contact – such as in the home, ambulance, or at a hospital emergency department. The study showed that rapid pre hospital treatment with zalunfiban improved and preserved blood flow to the heart until patients could be treated in the cardiac catheterization laboratory.

"The CeleBrate data show that we have the potential to transform how we treat STEMI heart attacks," said CeleBrate principal investigator Professor Arnoud WJ van 't Hof, M.D., Ph.D., head of interventional cardiology at Maastricht University Medical Center and Zuyderland Medical Center in the Netherlands.

Importantly, zalunfiban treatment did not significantly increase major bleeding, meeting the study's primary safety endpoint. Minor or moderate bleeding was more common in zalunfiban treated patients, but was not related to long-term outcome and was not associated with mortality in this study.

The need for rapid heart-attack treatment is especially urgent for patients in rural areas or others who don't live near hospitals with percutaneous coronary intervention (PCI) centers. These patients often experience major treatment delays before they reach the PCI center. In fact, 83% of U.S. STEMI patients who are transferred to a PCI center from another hospital or medical facility don't get there in time to meet guidelines set by the American Heart Association for effective treatment. This time delay results in a three- to fourfold higher death rate.

Nearly all treated patients in the CeleBrate study did meet the AHA time-to-treatment guidelines, and were given standard-of-care treatment based on best practices in each country.

About 750,000 people in the U.S. each year suffer STEMI heart attacks.[1] The extent of irreversible heart-muscle damage increases with every minute a coronary artery blood vessel remains closed. This damage can later result in heart failure, one of the most common causes of hospitalization and death. By limiting the amount of irreparable damage to the heart, zalunfiban may reduce the risk of developing heart failure immediately and in the long term.

"If zalunfiban is approved by the FDA, we'll be able to provide rapid, effective treatment for STEMI heart attacks at the first point of medical contact," said C. Michael Gibson, M.D., professor of medicine at Harvard Medical School. "These data show that we can make heart attack care more effective by opening arteries and significantly reducing the risk of severe, irreversible heart damage for those who experience these dangerous events."

Zalunfiban is a next-generation investigational GPIIb/IIIa inhibitor, the most powerful category of antiplatelet therapies. It was specifically designed for medical first responders and emergency department staff to administer by subcutaneous injection. It reaches maximal effect within 15 minutes, and its effects wear off after about 2 hours.

About the CeleBrate study

CeleBrate was a pivotal Phase 3 prospective, blinded, randomized, placebo-controlled, international multicenter study designed to assess the efficacy and safety of a single subcutaneous injection of zalunfiban in STEMI patients in the pre-hospital setting. It enrolled 2,467 patients at 45 sites in the United States, Canada, Mexico and Europe. More information about the study can be found here.

[1] Reddy A, Ganti L, Banerjee A, Banerjee P. Continuous quality improvement for prehospital STEMI improved triage rates and achievement of gold standard < 90-min EMS-to-balloon time. *Int J Emerg Med.* 2025 Mar 12;18(1):53. doi: 10.1186/s12245-025- 00863-x. PMID: 40075278; PMCID: PMC11905686.

CeleCor plans to file a New Drug Application for zalunfiban with the U.S. Food and Drug Administration in early 2026.

About zalunfiban (Disaggpro™)

Zalunfiban is an investigational agent; it has not been approved for any use and its safety and efficacy have not been established. Zalunfiban is a novel small-molecule inhibitor of the platelet GPIIb/IIIa receptor and was specifically designed for subcutaneous injection at the first point of medical contact for STEMI heart attacks.

GPIIb/IIIa inhibitors are the most potent antiplatelet drugs because they can block platelet aggregation induced by all platelet activators, including thrombin, thromboxane A2 and ADP. Other GPIIb/IIIa inhibitors are not optimal for pre-hospital administration, as they must be given by an intravenous (IV) injection followed by continuous IV delivery using an infusion pump.

“Zalunfiban was designed to be easily administered by a healthcare professional and to act within minutes to block the receptor platelets use to clump together. As a result, the platelets are severely limited in their ability to start the clotting process,” said zalunfiban lead inventor Barry S. Coller, M.D., David Rockefeller Professor, head of the Allen and Frances Adler Laboratory of Blood and Vascular Biology, vice president for medical affairs and physician-in chief at The Rockefeller University.

“Its effects wear off after about two hours – when it is no longer needed, because by that time the cardiologists in the hospital have opened the artery and inserted a stent to keep the artery open,” Dr. Coller said.

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