

FDA ACCEPTS NEW DRUG APPLICATION FOR CELECOR'S INVESTIGATIONAL HEART-ATTACK DRUG

Agency assigns zalunfiban (Disaggpro™) a PDUFA target action date of June 18, 2027

DEL MAR, CALIF., USA (September 30, 2026) – The U.S. Food and Drug Administration has accepted CeleCor Therapeutics' New Drug Application (NDA) for zalunfiban (Disaggpro™) and assigned a target action date of June 18, 2027 under the Prescription Drug User Fee Act (PDUFA).

Zalunfiban is an investigational, subcutaneously injected inhibitor of the platelet GPIIb/IIIa receptor designed to treat patients with STEMI (ST-segment elevation) heart attacks, the most severe form of heart attack. The priority in treating STEMI heart attacks is to open the coronary artery as soon as possible to prevent death or irreversible heart damage.

"We look forward to working with the FDA as we seek approval for zalunfiban," said Rob Hillman, President and CEO of CeleCor.

CeleCor announced completion of its NDA filing on June 24, following presentation in November 2025 of positive Phase 3 results from its CeleBrate study at the American Heart Association Scientific Sessions and simultaneous publication of the results in *The New England Journal of Medicine Evidence*.

The multinational CeleBrate study found that rapid zalunfiban treatment for STEMI heart attacks at first point of medical contact reduced the risk of cardiovascular events over the 30 days following treatment.

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 for STEMI heart attacks.

CeleCor Therapeutics was founded to improve the treatment of heart attacks at the first point of medical contact. For more information, visit our website and follow us on LinkedIn.

CONTACT:

Michael Moye, Chief Commercial Officer
mmoye@celecor.com

