

CeleCor submits FDA application for investigational heart attack drug

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The NDA submission follows positive Phase III data for zalunfiban, a first-point-of-care antiplatelet therapy for STEMI heart attacks.



CeleCor Therapeutics has completed submission of its New Drug Application to the U.S. FDA for zalunfiban, its investigational heart attack drug.

The filing follows positive Phase III results from the CeleBrate study, which were presented at the American Heart Association Scientific Sessions and published in The New England Journal of Medicine Evidence. Zalunfiban has FDA Fast Track status and was granted Rolling Review in January, allowing the company to submit sections of the application as they became available.

This is relevant because ST-segment elevation myocardial infarction, or STEMI, is the most severe form of heart attack. Clinical outcomes depend heavily on how quickly the blocked coronary artery is reopened and how effectively early thrombotic complications are controlled.

Zalunfiban is a novel small-molecule inhibitor of the platelet GPIIb/IIIa receptor. It is specifically designed for subcutaneous injection at the first point of medical contact, before patients reach a catheterisation laboratory.

The development addresses a practical gap in STEMI care. Current hospital-based intervention remains essential, but the earliest phase of treatment often occurs in ambulances, emergency departments or community settings where speed is critical. A treatment that can be administered earlier could help reduce the risk of more severe heart damage before definitive revascularisation.

The multinational CeleBrate study found that rapid zalunfiban treatment at first medical contact lowered the risk of more severe heart damage in combination with other serious heart-attack complications. This supports the company's strategy of targeting the earliest stage of STEMI care rather than waiting until patients reach specialised facilities.

The company has also appointed Michael Moye as Chief Commercial Officer to lead commercial strategy and operations for zalunfiban. This is commercially relevant because the therapy's adoption will depend not only on approval, but also on emergency care protocols, hospital networks, ambulance services and clinician confidence in early administration.

Zalunfiban remains investigational and has not been approved for any use. Its safety and efficacy have not yet been established by regulators.