A Research Study Looking Into How Ziltivekimab Works Compared to Placebo in Participants With Heart Failure and Inflammation

Status: RECRUITING

Eligibility Criteria

Age: 18 years and over

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Serum high-sensitivity C-reactive protein (hs-CRP) greater than or equal to 2 milligrams per liter (mg/L) at screening (visit 1) * Disease specific

•cardiovascular: * N-terminal-pro-brain natriuretic peptide (NT-proBNP) greater than or equal to 225 picograms per milliliter (pg/mL) (375 pg/mL for participants with atrial fibrillation/flutter) at screening * Diagnosis of heart failure (New York heart association (NYHA) Class II-III) * Left ventricular ejection fraction (LVEF) greater than 40 percent documented by echocardiography within 12 months prior to or at screening (visit 1). The LVEF must be documented in medical records and the most recent measurement must be used to determine eligibility with no interim event signalling potential deterioration in ejection fraction (example myocardial infarction (MI) or heart failure (HF) hospitalisation) * Structural heart disease and/or functional heart disease documented by echocardiography within 12 months prior to or at screening (visit 1) showing at least one of the following: 1. Left atrial (LA) volume index greater than 34 milliliter per square meter (mL/m\^2) 2. LA diameter greater than or equal to 3.8 centimeter (cm) 3. LA length greater than or equal to 5.0 cm 4. LA area greater than or equal to 20 square centimeter (cm\^2) 5. LA volume greater than or equal to 55 milliliter (mL) 6. Intraventricular septal thickness greater than or equal to 1.1 cm 7. Posterior wall thickness greater than or equal to 1.1 cm 8. LV mass index greater than or equal to 115 gram per square meter (g/m\^2) in men or greater than or equal to 95 g/m\^2 in women h) E/e' (mean septal and lateral) greater than or equal to 10 i) e' (mean septal and lateral) less than 9 centimeter per second (cm/s) * No heart failure hospitalisations or urgent heart failure visits between screening and randomisation * Able to perform the 6-minute walk test (6MWT) at screening with a minimum distance of 100 metres * Kansas City Cardiomyopathy Questionnaire (KCCQ) clinical summary score lesser than 80 at screening

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Exclusion Criteria:

* Medical conditions

•cardiovascular: * Myocardial infarction, stroke, unstable angina pectoris, transient ischaemic attack, or heart failure hospitalisation within 30 days prior to screening (visit 1) * Systolic blood pressure greater than or equal to 180 millimeters of mercury (mmHg) at screening (visit 1). If the systolic blood pressure is 160-179 mmHg, the patient should be receiving greater than or equal to 3 antihypertensive drugs * Heart rate above 110 or below 40 beats per minute as evaluated on the Electrocardiogram (ECG) performed at screening (visit 1) * Planned coronary, carotid or peripheral artery revascularisation known during the screening period (visit 1) * Planned cardiac device or atrial flutter/atrial fibrillation ablation procedure known during the screening period (visit 1) * Major cardiac surgical, non-cardiac surgical, or major endoscopic procedure (thoracoscopic or laparoscopic) within the past 60 days prior to randomisation (visit 2) or any major surgical procedure planned at the time of randomisation (visit 2) * Heart failure due to infiltrative cardiomyopathy (e.g., sarcoid, amyloid), arrhythmogenic right ventricular cardiomyopathy, Takutsubo cardiomyopathy, genetic hypertrophic cardiomyopathy or obstructive cardiomyopathy, active myocarditis, constrictive pericarditis, cardiac tamponade, uncorrected more than moderate primary valve disease * Primary pulmonary hypertension, chronic pulmonary embolism, severe pulmonary disease including chronic obstructive pulmonary disease (COPD) * Any other condition judged by the investigator that could account for heart failure symptoms and signs (e.g., anaemia, hypothyroidism) * Medical conditions

•infections/immunosuppression: * Clinical evidence of, or suspicion of, active infection at the discretion of the investigator

Conditions & Interventions

Interventions:
DRUG: Ziltivekimab, DRUG: Placebo
Conditions:
Heart Failure, Systemic Inflammation

More Information

Contact(s): Novo Nordisk - clinicaltrials@novonordisk.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06200207
