A Research Study to Look at How Ziltivekimab Works Compared to Placebo in People 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 equal to 2 milligrams per liter (mg/L) at screening (visit 1) Disease specific

•cardiovascular * At least one of the following: 1. N-terminal-pro-brain natriuretic peptide (NT-proBNP) greater than equal to 300 picograms per milliliter (pg/mL) at screening (Visit 1) for patients without ongoing atrial fibrillation/flutter. If ongoing atrial fibrillation/flutter at screening (visit 1), NTproBNP must be greater than equal to 600 pg/mL. Note that the screening electrocardiogram (ECG) must be obtained the same day as sampling for NT-proBNP. 2. Hospitalisation or urgent/unplanned visit with a primary diagnosis of decompensated heart failure which required intravenous loop diuretic treatment, within the last 9 months prior to screening (visit 1) in combination with NT-proBNP greater than equal to 200 pg/mL at screening (Visit 1) for patients without ongoing atrial fibrillation/flutter. If ongoing atrial fibrillation/flutter at screening (visit 1), NT-proBNP must be greater than equal to 600 pg/mL. * Diagnosis of heart failure (New York Heart Association \[classification\] \[NYHA\] Class II-IV). * Left ventricular ejection fraction (LVEF) greater than 40 percentage (%) 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 (e.g., 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: * Left atrial (LA) volume index greater than 34 milliliter per meter square (mL/m\^2). * LA diameter greater than equal to 3.8 centimeter (cm). * LA length greater than equal to 5.0 cm. * LA area greater than equal to 20 cm square. * LA volume greater than equal to 55 milliters (mL). * Intraventricular septal thickness greater than equal to 1.1 cm. * Posterior wall thickness greater than equal to 1.1 cm. * Left ventricular (LV) mass index greater than equal to 115 grams per meter square (g⁄m\^2) in men or greater than equal to 95 g⁄m\^2 in women. * E/e' (mean septal and lateral) greater than equal to 10. * e' (mean septal and lateral) less than 9 centimeter per second (cm/s). * No heart failure hospitalisations or urgent heart failure visits between screening (visit 1) and randomisation (visit 2).

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 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 equal to 3 antihypertensive drugs. (Note: Potential participants may be retested for this criterion within the visit window and without rescreening, at the discretion of the investigator). * Heart rate above 110 or below 40 beats per minute as evaluated on the electrocardiogram (ECG) performed at screening (visit 1) (Note: Potential participants may be retested for this criterion within the visit window and without rescreening, at the discretion of the investigator). * Planned coronary, carotid or peripheral artery revascularisation known during the screening period (visit 1). (Note: Planned coronary angiogram is not exclusionary). * 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 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

More Information

Contact(s): Novo Nordisk - clinicaltrials@novonordisk.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT05636176
