CAMELLIA

NCT02019264

Principal Investigator: Dr. John Collins (S. Washington Office)

Condition: Cardiovascular Disease, High Cardiovascular Risk, Obesity, Overweight, Type 2 Diabetes

Drug: APD356-Lorcaserin hydrochloride or Placebo

Sponsor: Eisai Inc.

Official Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Effect of Long-term Treatment With BELVIQ (Lorcaserin HCl) on the Incidence of Major Adverse Cardiovascular Events and Conversion to Type 2 Diabetes Mellitus in Obese and Overweight Subjects With Cardiovascular Disease or Multiple Cardiovascular Risk Factors

Purpose: This is a multicenter, randomized, double-blind, placebo-controlled, parallel-group study in overweight and obese subjects with CV disease and/or multiple CV risk factors.

Inclusion Criteria

1. BMI greater than or equal to 27 kg/m^2
2. Subjects able and willing to comply with a reduced-calorie diet and an increased physical activity program
3. Age greater than or equal to 40 years with established CV disease as defined by one of the following:
    a. History of documented MI or ischemic stroke
    b. History of peripheral artery disease
    c. History of revascularization (coronary, carotid, or peripheral artery)
    d. Significant unrevascularized coronary arterial stenosis

    OR

    Age greater than or equal to 55 years for women or greater than or equal to 50 years for men who have T2DM without established CV disease plus at least one of the following CV risk factors:
    1. Hypertension, or currently receiving therapy for documented hypertension
    2. Dyslipidemia, or currently taking prescription lipid-lowering therapy for documented dyslipidemia
    3. Calculated creatinine clearance greater than or equal to 30 to less than or equal to 60 mL/min per the Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation
    4. High hsCRP
    5. Urinary albumin-to-creatinine ratio (ACR) greater than or equal to 30 ug/mg

    Subjects with T2DM may have a pre-existing or new diagnosis of T2DM. A new diagnosis of T2DM (ie, discovered at Screening) should be based on the 2013 American Diabetes Association (ADA) guidelines.

    All T2DM subjects must have an HbA[1c] less than 10% at Screening. If subjects are being treated, or upon diagnosis need to be treated with antidiabetic agents, the T2DM treatment regimen must be stable for at least 3 months prior to randomization.

Exclusion Criteria

1. Moderate or greater symptoms of congestive cardiac failure (New York Heart Association [NYHA] class III or IV)
2. Known left ventricular (LV) ejection fraction less than 20%
3. Moderate or greater symptoms of pulmonary hypertension (PH)
4. Known severe valvular disease Moderate renal impairment, severe renal impairment, or end stage renal disease (ESRD) (calculated creatinine clearance less than 30 mL/min per the CKD-EPI equation based on ideal body weight)
5. Severe hepatic impairment

Exclusion Criteria (continued)

6. Use of other products intended for weight loss including prescription drugs, over-the-counter (OTC) drugs, and herbal preparations
7. Use of more than one other serotonergic drug
8. Use of drugs known to increase the risk for cardiac valvulopathy prior to Screening including, but not limited to: cyproheptadine, amoxapine, TCAs, mirtazapine, pergolide, ergotamine, methysergide, cabergoline
9. History or evidence of clinically significant disease (e.g., malignancy, cardiac, respiratory, gastrointestinal, renal or psychiatric disease)
10. Use of lorcaserin HCl prior to Screening or hypersensitivity to lorcaserin HCl or any of the excipients
11. Planned bariatric surgery
12. Females must not be breastfeeding or pregnant

Source: https://clinicaltrials.gov/ct2/show/NCT02019264
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