

EXAMINE

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Sponsor:

Takeda Global Research & Development Ctr, Inc.

Study Purpose:

Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study Comparing **SYR-322** Alone and Combination **SYR-322** With Pioglitazone Versus Placebo on Postprandial Lipids in Subjects With Type 2 Diabetes

Objective:

To compare the efficacy of **SYR-322** taken by itself and with pioglitazone on lipid measures in type 2 diabetes subjects after eating.

Inclusion Criteria

- Diagnosis of type 2 diabetes
- Females of childbearing potential who are sexually active must agree to use adequate contraception, and can neither be pregnant nor lactating from Screening throughout the duration of the study.
- Either failed treatment with diet and exercise for 3 months prior to Screening or has been receiving a stable dose of metformin, sulfonylurea, nateglinide, or repaglinide for more than 3 months prior to Screening.
- Inadequate glycemic control as defined by glycosylated hemoglobin concentration between 6.5 and 9.0%, inclusive.
- Fasting plasma glucose less than 13.3 mmol per L.
- Fasting serum triglyceride level of 1.7 to 5.0 mmol per L, inclusive.
- Has not been receiving any lipid-lowering therapy within 3 months prior to Screening or on a stable statin and/or ezetimibe therapy (same drug and dose) for at least 3 months.
- Body mass index greater than 23 kg/m² and less than 45 kg/m².
- If has regular use of other, non-excluded medications, must be on a stable dose for at least 4 weeks prior to Screening. Use of as needed

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prescription medications and over-the-counter medications is allowed at the discretion of the investigator.

- Is to be Apolipoprotein E 3/3 or Apolipoprotein E 3/4 phenotype positive prior to baseline.

Exclusion Criteria

- History of type 1 diabetes.
- History of drug abuse (defined as illicit drug use) or a history of alcohol abuse (defined as regular or daily consumption of more than 4 alcoholic drinks per day) within the past 2 years.
- Diastolic blood pressure greater than 100 mm Hg or a systolic blood pressure of greater than 160 mm Hg.
- History of cancer, other than basal cell carcinoma, that has not been in remission for at least 5 years prior to the first dose of study medication.
- Hemoglobin less than 120 g per L for males and less than 100 g per L for females.
- Alanine transaminase level greater than 2.5 times the upper limit of normal, active liver disease, or jaundice.
- Serum creatinine level greater than 133 μmol per L.
- Fasting total cholesterol greater than 6.5 mmol per L.
- New York Heart Association heart failure of any Class (I-IV) regardless of therapy.
- History of coronary angioplasty, coronary stent placement, coronary bypass surgery, or myocardial infarction within 6 months prior to Screening.
- History of acute metabolic diabetic complications.
- History of any hemoglobinopathy that may affect determination of glycosylated hemoglobin.
- History of infection with human immunodeficiency virus.
- History of diabetic gastro paresis.
- History of gastric bypass surgery.
- Excluded Medications:
 - Treatment with any antidiabetic agent other than metformin, sulfonylurea, nateglinide, or repaglinide is not allowed within 3 months prior to Screening through the completion of the end-of-treatment/early termination procedures.
 - Treatment with a statin and/or ezetimibe therapy will be allowed during the course of the study provided the subject has been on a stable dose for at least three months and remains on a stable dose and the therapy is not changed during the study.

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- Treatment with any weight loss drugs, any investigational antidiabetic, lipid-lowering agents (other than statins and/or ezetimibe), or oral or systemically injected glucocorticoids is not allowed for 3 months prior to randomization through the completion of the end-of-treatment/early termination procedures.
- Subjects must not take any medications, even over-the-counter medications, without first consulting with the investigator.

Status:

Active enrollment

If you have any questions, please feel free to contact the coordinators, and they will be happy to answer any questions you have regarding this study.