A Platform Trial for Pediatric Participants With Obesity or Overweight (LY900040)

Status: RECRUITING

Eligibility Criteria

Age: 6 years to 17 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* Have a history of at least 1 unsuccessful effort to lose sufficient body weight after participation in a structured lifestyle modification program (diet and exercise counseling for at least 3 months) prior to screening. * Obesity as defined by BMI equal to or above the 95th percentile for age and sex (on age- and gender-specific growth chart \[CDC-NCHS, 2022\]); OR * Applies to participant age between 12 and \<18 years old. Overweight as defined by BMI equal to or above the 85th percentile but less than the 95th percentile for age and sex, on age- and sex-specific growth chart (CDC-NCHS, 2022), and at least 1 weight-related comorbidity, * hypertension * type 2 diabetes (T2D) * prediabetes * dyslipidemia * obstructive sleep apnea * metabolic dysfunction-associated steatohepatitis (MASH) or metabolic dysfunction-associated steatotic liver disease (MASLD)

Exclusion Criteria:

* Have undergone or plan to undergo weight reduction procedure during the study, such as, but not limited to: * gastric bypass * sleeve gastrectomy * restrictive bariatric surgery, such as Lap-Band® gastric banding, or * any other procedure intended to result in weight reduction. * Have a diagnosis that is a secondary cause of obesity or have a history of abrupt onset of obesity suggesting a secondary cause, such as hypothalamic, monogenetic, syndromic, or endocrine causes. * Have a self-reported, or by parent or legal guardian where applicable, decrease in body weight greater than 5 kg (11 lbs) within 90 days before screening irrespective of medical records * Have type 1 diabetes or history of ketoacidosis, or hyperosmolar state. * Have HbA1c \>9.0% (75 mmol/mol) as measured by central laboratory at screening. * Have a family or personal history of medullary thyroid carcinoma or Multiple Endocrine Neoplasia Syndrome Type 2.

Conditions & Interventions

Interventions:
DRUG: Orforglipron, DRUG: Placebo
Conditions:
Obesity, Overweight

More Information

Contact(s): Trial questions or participation questions: 1-877-CTLILLY (1-877-285-4559) or - LillyTrials@Lilly.com
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