Maridebart Cafraglutide Versus Placebo in Adult Participants With Obstructive Sleep Apnea Not on Positive Airway Pressure (PAP) Therapy

NCT07226765

Status	RECRUITING
Phase	Phase 3
Sponsor	Amgen
Enrollment	250 participants

Key Eligibility Criteria

Inclusion (4)

- Participants must have an AHI of 15 or higher on polysomnography (PSG) at Day 1 before randomization.
- Body Mass Index (BMI) of 27 kg/m\^2 or more at the time of screening.
- History of at least one unsuccessful attempt at weight loss through diet and exercise.
- Participants must not have used PAP therapy for at least 4 weeks before screening, are unwilling/unable to use PAP, and do not plan to use PAP therapy during the study.

Exclusion (5)

- Individuals who have had any previous or planned upper airway surgery for sleep apnea or major ear, nose, or throat surgery.
- Those with significant craniofacial abnormalities that may affect breathing at screening.
- Participants diagnosed with Central Apnea with a percentage of central apneas/hypopneas of 50% or more, or those diagnosed with Cheyne Stokes Respiration.
- Active device treatment of OSA (eg, PAP, oral appliances), or other treatments, that in the opinion of the investigator, may interfere with study outcomes, unless willing to stop treatment at screening and throughout the study.
- Individuals with respiratory diseases like obesity hypoventilation syndrome or daytime hypercapnia, neuromuscular diseases or other conditions that could interfere with the trial results, according to the investigator's opinion.

Locations (28 total)

Peninsula Research Associates, Rolling Hills Estates, California, United States
Teradan Clinical Trials, Brandon, Florida, United States
Destiny Research Center, Palmetto Bay, Florida, United States
... and 25 more locations