

A Study to Investigate Mibavademab in Adult Women With Functional Hypothalamic Amenorrhea

NCT07235917

Status	RECRUITING
Phase	Phase 2
Sponsor	Regeneron Pharmaceuticals
Enrollment	34 participants

Key Eligibility Criteria

Inclusion (3)

- Diagnosis of FHA after exclusion of anatomic or organic causes of amenorrhea
- Has had no menstrual bleeding episode within 3 months (or longer) prior to day 1, as described in the protocol
- Has a Body Mass Index (BMI) ≥ 18.5 and $< 25 \text{ kg/m}^2$ at screening, or BMI ≥ 25 to $< 30 \text{ kg/m}^2$ at screening AND percentage of body fat $< 20\%$ from rigorous exercise as determined by the investigator through Standard of Care (SoC) methods (eg, skinfold thickness, DXA, bioimpedance) within 6 months of screening, as described in the protocol

Exclusion (6)

- Has presence of primary amenorrhea (failure to reach menarche, first menstrual cycle)
 - Has blood estradiol $\geq 50 \text{ pg/mL}$ or blood progesterone $\geq 1 \text{ ng/mL}$ at screening
 - Has uterine (eg, absence of uterus, prior endometrial ablation, endometriosis, outflow tract disorders) or ovarian (eg, absence of an ovary, presence of polycystic ovaries) conditions that impact assessment of menses or of the HPO axis
 - Has conditions other than FHA that may cause amenorrhea or menstrual cycle disturbances (eg, polycystic ovarian syndrome, hyperprolactinemia, primary ovarian insufficiency, untreated primary hypothyroidism, primary hyperthyroidism)
 - Polycystic ovarian morphology with an ovarian volume $> 10 \text{ cc}$ on TransVaginal UltraSound (TVUS) [or TransAbdominal Pelvic Ultrasound (TAPU) if applicable] at baseline
- ... and 1 more (see full listing online)

Locations (5 total)

Arensia Exploratory Medicine Clinic, Phoenix, Arizona, United States
Focus Clinical Research, West Hills, California, United States
OBGYN Associates of Erie, Erie, Pennsylvania, United States
... and 2 more locations