Phase 3 Study of LUM-201 in Children With Growth Hormone Deficiency

NCT06948214

Status	RECRUITING
Phase	Phase 3
Sponsor	Lumos Pharma
Enrollment	150 participants

Key Eligibility Criteria

Inclusion (10)

- Subjects must be naïve to treatment and prepubertal
- Subjects must have a maximal GH response of \< 10 ng/mL from 2 prior GH stimulation tests conducted within the preceding 12 months
- Impaired height defined as e 2.0 standard deviations (SDs) below the mean height for chronological age and sex
- Morning or random cortisol level of e 7.0 µg/dL
- e 3.0 years and age d 10.0 years for girls and d 11.0 years for boys

... and 5 more (see full listing online)

Exclusion (17)

- Any medical or genetic condition which, in the opinion of the Investigator or Medical Monitor (MM), can be an independent cause of short stature and/or limit the response to exogenous growth factor treatment.
- Arm span to height ratio \> 2 SDs below the mean for age and sex
- A medical or genetic condition that, in the opinion of the Investigator and/or MM, adds unwarranted risk to use of LUM-201
- Use of any medication that, in the opinion of the Investigator and/or MM, can independently cause short stature or limit the response to exogenous growth factors
- Current inflammatory diseases requiring systemic corticosteroid treatment for \> 2 consecutive weeks within the last 3 months prior to the Screening Visit

... and 12 more (see full listing online)

Locations (21 total)

Lumos Pharma Investigational Site, Birmingham, Alabama, United States
Lumos Pharma Investigational Site, Sacramento, California, United States
Lumos Pharma Investigational Site, Centennial, Colorado, United States
... and 18 more locations