A Phase 2 Study of Vosoritide in Children With Idiopathic Short Stature

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 3 years to 11 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Key Inclusion Criteria:

1. Height assessment corresponding to a height Z-score of ≤ -2.25 SDs in reference to the general population of the same age and sex, as calculated using the Centers for Disease Control and Prevention (CDC) growth charts
2. If participant is ≥ 5 years at Screening,must be Tanner Stage I to be eligible for enrollment and randomization3. Historic stimulation test result with serum or plasma GH level greater than 10 µg/L or serum IGF-1 in the normal range for age (≥ -1.00 SDs and ≤+2.00 SDs).

Key Exclusions:

1. Known chromosomal imbalance or genetic variant causing short stature syndrome, including but not limited to Laron syndrome, Prader-Willi syndrome, Russell-Silver Syndrome, Turner syndrome, disproportionate skeletal dysplasias, abnormal SHOX gene analysis, or Rasopathy (including Noonan syndrome), ACAN deficiency.
2. Previous treatment with a growth promoting agent

Conditions & Interventions

Interventions:
DRUG: Vosoritide Injection, DRUG: Human Growth Hormone, DRUG: Placebo
Conditions:
Idiopathic Short Stature

More Information

Description:
The purpose of this study is to evaluate i) the effect of multiple doses of vosoritide and ii) the effect of the therapeutic dose of vosoritide compared to human growth hormone (hGH)(hGH; only in the United States), in children with idiopathic short stature (ISS).

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