A Study to Assess the Efficacy, Safety, and Pharmacokinetics of Debio 4326 in Pediatric Participants With Central Precocious Puberty (LIBELULA™ Clinical Trial)

Status: RECRUITING

Eligibility Criteria

Age: 5 years to 8 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Diagnosis of central precocious puberty. 2. Onset of development of sex characteristics (i.e., breast development in girls or testicular enlargement in boys according to the Tanner method) before the age of 8 years in girls and 9 years in boys. 3. Initially, only participants aged (a) 5 to 8 years inclusive (i.e., \<9 years) are eligible. The Sponsor will determine based on the recommendation of the DMC following the interim analysis whether participants aged (b) 2 to 4 years inclusive (i.e., \<5 years) and/or (c) 9 to 10 years inclusive (i.e., \<11 years) may be recruited. 4. Participant to receive at least 1 year of gonadotropin-releasing hormone agonist (GnRHa) therapy from study treatment start. 5. (a) Pre-treated participants: Start of initial GnRHa therapy no later than 18 months after onset of the first signs of CPP. (b) Treatment-naive participants: Start of Debio 4326 treatment no later than 18 months after onset of the first signs of CPP. 6. (a) Pre-treated participants: Difference between bone age (Greulich and Pyle method) and chronological age of ≥1 year based on historical values at the initiation of the GnRHa therapy. (b) Treatment-naive participants: Difference between bone age (Greulich and Pyle method) and chronological age of ≥1 year. 7. (a) Pre-treated participants: Pubertal-type LH response (LH ≥6 IU/L) following a GnRH/GnRHa stimulation test, or random non-stimulated serum LH \>0.5 IU/L (if considered local standard of care), based on historical values prior to the initiation of GnRHa therapy. (b) Treatment-naive participants: Pubertal-type LH response (≥6 IU/L) 30 minutes following a GnRHa \[leuprolide acetate 20 micrograms per kilogram (µg/kg) subcutaneous injection (SC)\] stimulation test before treatment initiation. 8. (a) Pre-treated participants: Clinical evidence of puberty, defined as Tanner Staging ≥2 for breast development for girls and testicular volume ≥4 milliliter (mL) (cubic centimeter \[cc\]) for boys, prior to the initiation of GnRHa therapy. (b) Treatment-naive participants: Clinical evidence of puberty, defined as Tanner Staging ≥2 for breast development for girls and testicular volume ≥4 mL (cc) for boys.

Exclusion Criteria:

1. Gonadotropin-independent (peripheral) precocious puberty: gonadotropin-independent gonadal or adrenal sex steroid secretion. 2. (a) Pre-treated participants: Non-progressing, isolated premature thelarche prior to the initial GnRHa therapy. (b) Treatment-naive participants: Non-progressing, isolated premature thelarche. 3. Presence of an unstable intracranial tumor or an intracranial tumor potentially requiring neurosurgery or cerebral irradiation. Participants with hamartomas not requiring surgery are eligible. 4. Any other condition or chronic illness possibly interfering with growth (e.g., renal failure, diabetes, moderate to severe scoliosis, previously treated intracranial tumor). 5. Other than GnRHa therapy in pre-treated participants, any ongoing treatment with a potential effect on serum levels of gonadotropins or sex steroids, or possibly interfering with growth, opioids, central nervous system \[CNS\] stimulants). 6. Prior or current therapy with medroxyprogesterone acetate, growth hormone, or Insulin-like growth factor-1 (IGF-1). 7. Diagnosis of short stature, i.e., more than 2.25 standard deviations (SD) below the mean height-for-age. 8. Known history of seizures, epilepsy, and/or central nervous system disorders that may have been associated with seizures or convulsions. 9. Prior (within 2 months of study treatment start) or current use of medications that have been associated with seizures or convulsions. 10. Use of anticoagulants (heparin or coumarin derivatives). Note: Other inclusion/exclusion criteria mentioned in the protocol may apply.

Conditions & Interventions

Interventions:
DRUG: Debio 4326
Conditions:
Central Precocious Puberty

More Information

Contact(s): Debiopharm International S.A - clinicaltrials@debiopharm.com
Principal Investigator:
Phase: PHASE3
IRB
Number:
System ID: NCT06129539
