

Phase 3, Open-label, Single-dose Study of CSL222 in Adolescent Male Subjects (≥ 12 to < 18 Years of Age) With Severe or Moderately Severe Hemophilia B

NCT07080905

Status	RECRUITING
Phase	Phase 3
Sponsor	CSL Behring
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (7)

- Assigned male sex at birth
- Aged ≥ 138 months (11 years and 6 months) to less than (<) 206 months (17 years and 2 months) at the time of informed consent / assent.
- Congenital hemophilia B with known severe or moderately severe FIX deficiency (less than or equal to \leq 2% of normal circulating FIX) for which the participant has been on continuous FIX prophylaxis.
- On stable continuous FIX prophylaxis for at least 2 months before Screening.
- Minimum of 75 previous exposure days of treatment with FIX protein before Screening.
- ... and 2 more (see full listing online)

Exclusion (21)

- History of FIX inhibitors or positive FIX inhibitor test at Screening (based on central laboratory results).
- Screening laboratory values (based on central laboratory results):
- Total bilirubin $> 2 \times$ the upper limit of normal (ULN).
- Alanine aminotransferase (ALT) $> 2 \times$ the ULN.
- Aspartate aminotransferase (AST) $> 2 \times$ the ULN.
- ... and 16 more (see full listing online)

Locations (9 total)

Center for Inherited Blood Disorders, Orange, California, United States
University of Florida, Gainesville, Florida, United States
Arthur M. Blank Hospital - Children's Healthcare of Atlanta, Atlanta, Georgia, United States
... and 6 more locations