

# Efficacy and Safety of CSL222 (Etranacogene Dezaparvovec) Gene Therapy in Adults With Hemophilia B With Pretreatment Adeno-associated Virus Serotype 5 (AAV5) Neutralizing Antibodies (Nabs)

NCT06003387

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Status	RECRUITING
Phase	Phase 3
Sponsor	CSL Behring
Enrollment	35 participants

## Key Eligibility Criteria

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### Inclusion (9)

- Considered legally an adult, as defined by country regulations.
  - Has 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 is on continuous routine FIX prophylaxis.
  - Has 2 consecutive detectable AAV5 NAb titer results between Screening and Visit L-Final using a validated AAV5 NAb assay (based on central laboratory results).
  - Has greater than ( $>$ ) 150 previous exposure days to FIX replacement therapy.
  - Has been on stable FIX prophylaxis for at least 2 months before Screening.
- ... and 4 more (see full listing online)

### Exclusion (15)

- History of FIX inhibitors or positive FIX inhibitor test at Prescreening, Screening or Visit L-Final (based on central laboratory results).
  - Screening or Visit L-Final laboratory values (based on central laboratory results) of total bilirubin  $>$  2  $\times$  the upper limit of normal (ULN) (except if caused by Gilbert's syndrome).
  - Screening or Visit L-Final laboratory values (based on central laboratory results) of any of the following laboratory abnormalities:
    - a) ALT  $>$  2  $\times$  the ULN
    - b) AST  $>$  2  $\times$  the ULN
- ... and 10 more (see full listing online)

## Locations (26 total)

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University of California, San Diego (UCSD), San Diego, California, United States  
University of Michigan, Ann Arbor, Michigan, United States  
Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia  
... and 23 more locations

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<https://clinicaltrials.gov/study/NCT06003387>

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