

A Phase 3 Study to Assess the Efficacy, Safety, and Tolerability of Itepekimab (Anti-IL-33 mAb) in Participants With Inadequately-controlled Chronic Rhinosinusitis With Nasal Polyps

NCT06834360

Status	RECRUITING
Phase	Phase 3
Sponsor	Sanofi
Enrollment	210 participants

Key Eligibility Criteria

Inclusion (12)

- Participants must be 18 years of age or older.
 - Participants with a history of chronic rhinosinusitis with nasal polyps (CRSwNP) for at least 1 year prior to screening
 - Participants must have at least one of the following features:
 - Prior sinonasal surgery for nasal polyps (NP).
 - Worsening symptoms of chronic rhinosinusitis (CRS) requiring treatment with systemic corticosteroid(s) (SCS) within the prior 1 year before screening (Visit 1).
- ... and 7 more (see full listing online)

Exclusion (14)

- Participants are excluded from the study if any of the following criteria apply:
 - Participants with a history of clinically significant renal, hepatic, metabolic, neurologic, hematologic, ophthalmologic, respiratory (excluding those with asthma and aspirin-exacerbated respiratory disease (AERD) which may be included in the study), gastrointestinal, cardiovascular, cerebrovascular, or other significant medical illness or disorder, which, in the judgment of the Investigator, could interfere with the study or require treatment that might interfere with the study.
 - Participants who are currently smoking tobacco and/or vaping, or participants in whom smoking/vaping cessation has occurred <6 months prior to Screening (Visit 1). Nicotine replacement therapy and/or noninhaled tobacco product use are not considered current smoking of tobacco.
 - Participants meet any contraindications for mometasone furoate nasal spray (MFNS) such as hypersensitivity to MFNS or any of its components; or participants with uncontrolled opportunistic infections.
 - Participants with a history of a severe systemic hypersensitivity reaction to a mAb.
- ... and 9 more (see full listing online)

Locations (108 total)

Excel ENT of Alabama- Site Number : 8400052, Birmingham, Alabama, United States
Velocity Clinical Research - San Diego- Site Number : 8400041, La Mesa, California, United States
Cedars-Sinai Medical Center- Site Number : 8400030, Los Angeles, California, United States
... and 105 more locations

<https://clinicaltrials.gov/study/NCT06834360>

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