

A clinical research study for people with indoor nasal allergies

PREPARED-2 Study



Study aim: To evaluate the efficacy and safety of lebrikizumab in participants with perennial allergic rhinitis, or indoor nasal allergies.

Study Design: A Phase 3, multinational, multicenter, randomized, double-blind, placebo-controlled, parallel group study.

Study population: Adults aged 18 years or older, and adolescents aged 12 years to less than 18 years with perennial allergic rhinitis, or indoor allergies.

Key benefits of taking part in the PREPARED-2:

- Study duration:
 - » Total duration for adults is about 8 and a half months
 - » There is a long-term extension period for adolescent participants, with a total study duration of about 1 year and 4 months
- This study will determine if the investigational medication is an effective treatment for perennial allergic rhinitis.
- Participants will have the option of injecting themselves at home. They also have the option to come to the study site to do this if they prefer.

Important requirements for participants of the study

- Participants will need to have a skin prick allergy test at the screening visit
- Participants will need to complete electronic clinical outcome assessments using an eDiary each day
- Participants will be required to take background therapy during the study. This will be provided by the study team.

Please see overleaf for key inclusion criteria.



Key inclusion criteria for participants:

1. Have physician-diagnosed PAR requiring treatment to control persistent symptoms on most days for more than 12 weeks per year for at least 2 consecutive years.
2. Have a history of inadequate response to standard-of-care intranasal corticosteroids with or without
 - oral antihistamine,
 - intranasal antihistamine, and/or
 - combination eye drops with antihistamine and/or mast cell stabilizing properties, despite its regular or consistent use.
3. Have moderate or severe nasal symptoms with a Total Nasal Symptom Score (TNSS) score ≥ 8 both at screening (Visit 1) and at baseline (Visit 3), averaged over 2 weeks prior to baseline (Visit 3), measured at least 4 days per week.
4. At screening (Visit 1), have a positive skin prick test (SPT) with indoor allergens (mean wheal diameter at least 5 mm greater than the negative control) and/or positive serum antigen-specific IgE for indoor allergens (for example, pet, mold, dust mites, cockroach, horse) ≥ 0.70 kU/L, utilizing a validated assay (central laboratory.)

Important: Please see the most recent version of the PREPARED-2 protocol for a full list of inclusion and exclusion criteria.

Note: This content is intended for investigators only. Do not share with participants.

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