# Clinical Trials Data ALK - Document 18

# MK-8237 (SCH900237) Biomarker Study in Participants With Allergic Rhinitis or Rhinoconjunctivitis (MK-8237-009)

## Clinical Trial: https://clinicaltrials.gov/study/NCT01852825

"eligibilityCriteria": "Inclusion Criteria:\n\nPart 1:\n\n\* healthy participants\n\* has a Body Mass Index (BMI) =\\< 30 kg/m\\^2\n\* female of reproductive potential remains abstinent or uses two acceptable methods of birth control from 2 weeks before first allergen challenge to 2 weeks after last allergen challenge; alternatively hormonal contraception may be used.\n\nPart 2:\n\n\* has a Body Mass Index (BMI) =\\< 38 kg/m\\^2\n\* has a clinical history of allergic rhinitis/rhinoconjunctivitis to HDM for at least one year, and used medication to relieve symptoms within the last year\n\* does not have asthma, or has mild controlled asthma not requiring regular use over the 12 months prior to screening of any corticosteroids\n\* female of reproductive potential remains abstinent or use two acceptable methods of birth control from 2 weeks before first allergen challenge to at least 2 weeks after last allergen challenge or last dose of study drug, whichever is longer\n\* has not smoked or used tobacco for the prior 6 months, and agrees not to during study\n\nExclusion Criteria:\n\nParts 1 and 2:\n\n\* is experiencing at the first NAC visit, symptoms from an upper or lower respiratory tract infection (viral or bacterial)\n\* has participated within the prior 3 months in another investigational study (that included an investigational drug or agent)\n\* is directly associated with the administration of the study or is related to the investigational study staff\n\* is mentally or legally incapacitated, has significant emotional problems or has a history of clinically significant psychiatric disorder within the past 5 years\n\* has a history of clinically significant endocrine, gastrointestinal, cardiovascular, hematological, hepatic, immunological, renal, respiratory, genitourinary or major neurological (including stroke and chronic seizures) abnormalities or diseases\n\* has a history of cancer\n\* has a history of significant intolerability to drugs or food\n\* is positive for hepatitis B surface antigen, hepatitis C antibodies or HIV\n\* had major surgery or lost 1 unit (500 mL) of blood within the prior 4 weeks\n\* has a clinical history of chronic sinusitis during the prior 2 years\n\* has any nasal condition (e.g. nasal polyposis) that could confound efficacy or safety assessments\n\* is pregnant or expects to conceive during the study period\n\* is a nursing mother\n\* consumes more than 3 glasses of alcoholic beverages per day\n\* regularly uses any illicit drug, or has a history of drug or alcohol abuse within the prior 6 months\n\nPart 2 only:\n\n\* is experiencing allergic rhinoconjunctivitis exacerbation at Screening NAC\n\* consumes excessive daily amounts of caffeinated beverages\n\* has a known history of allergy, hypersensitivity or intolerance to investigational medicines\n\* is sensitized and regularly exposed to animal dander and molds in the home or workplace in a manner that might interfere with the study in the opinion of the investigator\n\* is sensitized and regularly exposed to seasonal allergens such as Birch or grass pollen (sensitized but out of season is acceptable however)\n\* has a history of chronic urticaria and/or angioedema within the prior 2 years\n\* has had previous immunotherapeutic treatment with any HDM allergen for more than 1 month during the prior 3 years\n\* is receiving any specific immunotherapy within prior 60 days\n\* has a history of anaphylaxis with cardiorespiratory symptoms with prior immunotherapy due to an unknown cause or an inhalant allergen",  
 "healthyVolunteers": true,  
 "sex": "ALL",  
 "minimumAge": "18 Years",  
"stdAges": [  
"ADULT"  
]

Question:  
Based on the following clinical trial information, would a patient with a ALK gene mutation be eligible for the clinical trial?

Answer:  
This trial has two parts. Part 1 is for healthy volunteers, while Part 2 is for people with house dust mite (HDM) allergies. Having an ALK gene mutation is not mentioned in the inclusion or exclusion criteria. Therefore, \*\*it's not possible to determine eligibility based solely on the ALK mutation.\*\*  
  
A patient with an ALK mutation \*could\* be eligible if they meet \*all\* other inclusion criteria and \*none\* of the exclusion criteria for either Part 1 (if healthy) or Part 2 (if they have HDM allergies). The ALK mutation itself doesn't automatically disqualify or qualify them.