Efficacy of Tezepelumab in Peanut Oral Immunotherapy

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 12 years to 55 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

1. Participant and/or parent/legal guardian must be able to understand and provide informed consent (parental permission and informed assent of minor, if applicable).
2. Age 12 to 55 years inclusive with a personal history of an allergic reaction to peanut ingestion
3. A positive reaction at or below ingestion of 100 mg of peanut protein in a single dose (≤ 144 mg cumulative dose) during the Screening DBPCFC
4. A negative challenge to the placebo (oat) during the Screening DBPCFC
5. Sensitization to peanut as evidenced by either one of the following:
    1. positive sIgE to Ara h2 ≥ 0.35 kU/L by ImmunoCAPTM testing, or
    2. wheal ≥ 3 mm on skin prick test to peanut extract compared to a negative control
6. Female participants of childbearing potential must have a negative pregnancy test upon study entry
7. Female participants with reproductive potential must agree to use an FDA approved method of contraception for the duration of the study
8. Willing and able to comply with the study protocol requirements
9. Participants with other food allergies must agree to continue avoidance of these food items from their diet to avoid confounding the safety and efficacy data of the study

Exclusion Criteria:

1. Currently in build-up phase of aeroallergen immunotherapy
2. Current food allergen immunotherapy or use of any food allergen immunotherapy within the past 12 months
3. Pregnant, planning a pregnancy during the study, or breast-feeding
4. History of intolerance, hypersensitivity, or allergic reactions to tezepelumab, or the inactive ingredients (excipients) of tezepelumab, other IgG biologics, or rescue medications and their excipients
5. Allergy to oat (participant reported)
6. History of severe systemic allergic reaction to peanut with symptoms including the need for mechanical ventilation and/or severe hypotension requiring intensive care unit admission
7. Asthma requiring high dose inhaled corticosteroid therapy for control (2007 NHLBI Criteria Steps 5 or 6 in adults and adolescents)
8. History of a life-threatening asthma attack within 12 months prior to screening (e.g., requiring an ICU admission or intubation with mechanical ventilation), need for oral corticosteroids for asthma management within the last 6 months, or current Asthma Control Test score less than 19 at screening
9. History of ischemic cardiovascular disease or other cardiac disease, which, in the opinion of the site investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements, or that may impact the quality or interpretation of the data obtained from the study
10. History of eosinophilic gastrointestinal disease at screening
11. History of disease affecting the immune system such as autoimmune disease (e.g., systemic lupus erythematosus), immune complex disease (e.g., serum sickness), or immunodeficiency, which, in the opinion of the site investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements, or that may impact the quality or interpretation of the data obtained from the study
12. History of malignancy of any type, excluding basal cell and squamous cell cancers of the skin that only required surgical excision or in situ carcinoma of the cervix study provided that curative therapy was completed at least 12 months prior to screening
13. Current known helminth infection
14. Positive QuantiFERON - TB Gold test or TB Gold Plus, or T-SPOT® TB test unless the potential participant has been treated with appropriate chemoprophylaxis. In the case of an indeterminate or borderline Interferon Gamma Release Assay (IGRA), an IGRA may be repeated.
15. Any of the following:
    1. HIV
    2. Current or prior infection with hepatitis B virus (HBV)
    3. Current or prior infection with hepatitis C virus (HCV), except adequately treated HCV with sustained virologic response ≥ 12 weeks.
16. Active liver disease, defined as either:
    1. AST, ALT, and/or Alk phos >2x ULN, or
    2. other active liver disease which, in the opinion of the site investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements, or that may impact the quality or interpretation of the data obtained from the study
17. Any of the following:

1. Current use of beta-blockers, angiotensin-converting enzyme inhibitors, or angiotensin-receptor blockers
2. Received any investigational product within the past 4 months or 5 half-lives (whichever is longer) prior to screening
3. Received systemic corticosteroids within 14 days prior to screening
4. Receipt of immunoglobulin or other blood product within 30 days prior to screening
5. Receipt of live attenuated vaccine within 30 days prior to screening
6. Use of an immunosuppressant or immunomodulating drug within 30 days prior to screening
7. Use of biologics targeting the human immune system within the past 12 months prior to screening
8. Use of any herbal medications, which, in the opinion of the investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements, or that may impact the quality or interpretation of the data obtained from the study

18. Past or current medical problems or findings from physical examination or laboratory testing that are not listed above, which, in the opinion of the site investigator, may pose additional risks from participation in the study, may interfere with the participant's ability to comply with study requirements, or that may impact the quality or interpretation of the data obtained from the study

Conditions & Interventions

Interventions:
BIOLOGICAL: Tezepelumab, DRUG: Peanut Oral Immunotherapy (OIT), BIOLOGICAL: Placebo for Tezepelumab
Conditions:
Peanut Allergy
Keywords:
Tezepelumab, Peanut, Oral Immunotherapy

More Information

Description:
The proposed study is a proof-of-concept Phase 2, double-blind, randomized placebo-controlled clinical trial evaluating the safety and efficacy of tezepelumab and peanut Oral Immunotherapy (OIT) for the treatment of peanut allergy. Study participation is divided into 3 periods: (i) a monotherapy period comprised of injections of either Tezepelumab or placebo from week 0 to week 8, (ii) followed by a combination therapy period comprised of 56 weeks during which peanut OIT is built up and maintained, and (iii) a treatment withdrawal period comprised of 12 weeks. This study will enroll 62 peanut-allergic individuals from 12 to 55 years of age who experience dose-limiting symptoms to \<=100 mg of peanut protein in a single dose (\<= 144 mg cumulative dose) as assessed by DBPCFC. The primary objective is to determine whether 56 weeks of tezepelumab plus peanut OIT as compared to 56 weeks of placebo plus peanut OIT induces sustained unresponsiveness to peanut 12 weeks after stopping combination therapy.

Contact(s): Glenda Knox - glenda.knox@cchmc.org
Principal Investigator:
Principal Investigator ID:
Phase: PHASE2
IRB Number:
System ID: NCT07015996
