Phase 2b Study of RPT904 as Monotherapy in Participants With IgE-Mediated Food Allergy

Status: RECRUITING

Eligibility Criteria

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

- Participant and/or parent/legal guardian must be able to understand and provide informed consent and/or assent, as applicable.
- Male or female, 12 to less than 56 years of age at screening.
- Allergic to at least 1 of the following foods: peanut, milk, egg, cashew, or walnut, as confirmed by the following criteria:
- a. For participants aged 12 to <18 years:
- i. Allergic to peanut: participant must meet all criteria below:
- 1. Positive SPT (≥4 mm wheal greater than saline control) to peanut.
- 2. Positive peanut IgE (≥6 kUA/L) at screening or within 3 months of screening.
- 3. Positive blinded oral food challenge (OFC) to peanut during the screening DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤100 mg (ie, cumulative dose of ≤144 mg) of peanut protein.
- ii. Allergic to milk or egg: unable to tolerate both cooked and uncooked forms:
- 1. Positive SPT (≥4 mm wheal greater than saline control) to the specific food.
- 2. Positive food-specific IgE (≥6 kUA/L) at screening or within 3 months of screening.
- 3. Positive blinded OFC to the specific food during the screening DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤300 mg (ie, cumulative dose of ≤444 mg) of food protein.
- iii. Allergic to cashew: participant must meet all criteria below:
- 1. Positive SPT (≥4 mm wheal greater than saline control) to cashew. OR
- 2. Positive cashew IgE (≥6 kUA/L) at screening or within 3 months of screening. AND
- 3. Positive blinded OFC to cashew during the screening DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤100 mg (ie, cumulative dose of ≤144 mg) of cashew protein.
- iv. Allergic to walnut: participant must meet all criteria below:
- 1. Positive SPT (≥4 mm wheal greater than saline control) to walnut. OR
- 2. Positive walnut IgE (≥6 kUA/L) at screening or within 3 months of screening AND
- 3. Positive blinded OFC to walnut during the screening DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤300 mg (ie, cumulative dose of ≤444 mg) of walnut protein.
- b. For participants aged 18 to <56 years:
- i. Allergic to peanut or cashew: participant must meet all of the following criteria:
- 1. Positive SPT (≥3 mm wheal greater than saline control) to peanut or cashew.
- 2. Positive peanut or cashew IgE (≥0.35 kUA/L) at screening or within 3 months of screening.
- 3. Positive blinded OFC to peanut or cashew during the screening DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤100 mg (ie, cumulative dose of ≤144 mg) of peanut or cashew protein.
- ii. Allergic to milk or egg: participant must meet all of the following criteria:
- 1. Positive SPT (≥3 mm wheal greater than saline control) to the specific food.
- 2. Positive food-specific IgE (≥0.35 kUA/L) at screening or within 3 months of screening.
- 3. Positive blinded OFC to the specific food during the screening DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤300 mg (ie, cumulative dose of ≤444 mg) of food protein.
- iii. Allergic to walnut: participant must meet all of the following criteria:
- 1. Positive SPT (≥3 mm wheal greater than saline control) to walnut.
- 2. Positive walnut IgE (≥0.35 kUA/L) at screening or within 3 months of screening.
- 3. Positive blinded OFC to walnut during the screening DBPCFC, defined as experiencing dose-limiting symptoms at a single dose of ≤300 mg (ie cumulative dose of ≤444 mg) of walnut protein.
- With body weight (as measured at screening) and total serum IgE level (as measured within 3 months of screening) suitable for RPT904 dosing (per RPT904 dosing table).
- Female Participants:
- 1. Must not be pregnant or breastfeeding.
- 2. Women of non-childbearing potential (e.g., surgically sterile or postmenopausal) are eligible.
- 3. Women of childbearing potential must have a negative pregnancy test before starting study treatment, agree to use a protocol-defined method of contraception during the study and for at least 16 months after the last dose, and must not donate eggs or undergo egg retrieval during this period.
- Male Participants:
- 1. Must agree to either remain abstinent from heterosexual intercourse (if that is their usual lifestyle) or use protocol-defined contraception during the study and for 16 months after the last dose.
- 2. Must not donate semen or participate in sperm banking during this time, and if they have a female partner of childbearing potential, she should also use effective contraception.

Exclusion Criteria:

- Clinically significant lab abnormalities at screening.
- Sensitivity or suspected/known allergy to any component of the active or placebo OFC material (excluding the test allergens peanut, milk, egg, walnut, and cashew being tested), or drugs related to RPT904 (eg, monoclonal antibodies, polyclonal gamma globulin).
- Uncontrolled or severe asthma/wheezing at screening.
- Current use of oral, IM, or IV corticosteroids, tricyclic antidepressants, or β-blockers (oral or topical).
- Past or current immunotherapy to any study foods within 6 months of screening.
- Treatment with immunomodulatory therapy within 6 months of screening.
- Currently in the "build-up phase" of inhalant allergen immunotherapy (i.e., not yet on maintenance). Note: individuals on stable maintenance dosing may be eligible.
- Past or current medical problems (eg, severe latex allergy), chronic diseases (other than asthma/wheezing, atopic dermatitis, or rhinitis) requiring therapy (eg, heart disease, diabetes), abnormal physical findings or lab results not listed above that, in the Principal Investigator's opinion, may increase study related risks, hinder protocol compliance, or impact data quality or interpretation .

Conditions & Interventions

Interventions:
DRUG: RPT904, DRUG: RPT904, OTHER: Placebo, DRUG: RPT904, DRUG: RPT904, OTHER: Placebo
Conditions:
Ig-E Mediated Food Allergy
Keywords:
Ig-E Mediated food allergy, peanut allergy, milk allergy, egg allergy, cashew allergy, walnut allergy, RPT904, placebo, double-blind placebo-controlled food challenge (DBPCFC), ozureprubart, JYB1904

More Information

Description:
Phase 2b Study of RPT904 as Monotherapy in Participants With IgE-Mediated Food Allergy: This is a Phase 2b randomized, double-blind, placebo-controlled clinical trial evaluating RPT904, a next-generation anti-IgE monoclonal antibody, in people with food allergy. RPT904 is a long-acting antibody that may allow for dosing every 8 to 12 weeks. Approximately 100 participants between the ages of 12 and 55 with documented allergy to at least one of the following foods: peanut, milk, egg, cashew, or walnut will be enrolled. In Part 1 (24 weeks), participants will be randomly assigned to receive RPT904 every 8 or 12 weeks (plus a loading dose at Week 2), or placebo. In Part 2 (24 weeks), participants who received RPT904 will continue on their assigned dosing schedule, and those who previously received placebo will be re-randomized to receive RPT904 either every 8 or 12 weeks (plus a loading dose at Week 26). All participants will attend study visits approximately every 2-6 weeks throughout both Part 1 and Part 2 to maintain blinding, regardless of treatment group or dosing frequency. The study is being conducted at multiple sites. The primary goal is to assess whether RPT904 helps participants tolerate higher amounts of a food allergen without dose-limiting allergic symptoms during a food challenge. The study will also monitor the safety and side effects of RPT904 over time. Each participant is expected to be in the study for about 68 to 74 weeks, including screening, treatment, and follow-up.

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