Docket #: S14-444

Special Oral Formula for Decreasing Food Allergy Risk

Stanford researchers have developed an oral formula and method to reduce the risk of developing food allergies. This patented formula can reduce the risk of food allergy in different age groups when given as part of a normal daily diet. The formula combines different proteins/allergens, including at least two of the following high allergen food groups: cashew, walnut, wheat, shrimp, fish, cow's milk, almond, peanut, eggs, and hazelnut, almond, and flour/powders. Clinical trial results indicate that this proprietary oral formulation exhibits synergistic effects in reducing food allergy risk. The biotic, vitamin, and mixed allergen component approach is particularly attractive as the industry moves toward more holistic approaches to allergy prevention rather than single-allergen treatments.

Stage of Development
Studies showed continual feeding of this complex food allergens mixture at a very young age can prophylactically protect from developing an allergenic immune profile to a wide variety of allergens. Phase 1/2 trial demonstrated formulation safety and increased reactive threshold in DBPCFC in pediatric participants with single or multiple food allergies across multiple endpoints.

Applications

- Oral formula to **reduce risk of immune-mediated inflammatory diseases** (e.g. food allergies)

Advantages

- **Easy to administer** for all age groups from infancy to adulthood

- **Flexible schedule** - can be given daily or on any schedule appropriate for subject
- **Novel oral formula** that addresses broad risk of food allergies
- **Preventative**
- **Available over the counter**
- **Large, growing market** (1 in 12 children have food allergies, US allergy-free food market > $10B, 10% CAGR)

Publications

- Kim, E. H., Carr, W. W., Assa'ad, A. H., Gogate, S. U., Petroni, D. H., Casale, T. B., ... & McClintock, D. **(2025)**. ADP101 multi-food oral immunotherapy for food-allergic patients: Harmony phase 1/2 randomized clinical trial. *Journal of Allergy and Clinical Immunology: Global*, 4(1), 100382.
- Petroni, D., Archer, A., Wang, M. L., Tuomi, L., Bradley, S., Piscia-Nichols, C., ... & McClintock, D. **(2024)**. Treatment of single and multiple food allergies with ADP101: results of the Harmony Phase 1/2 Trial. *Journal of Allergy and Clinical Immunology*, 153(2), AB240.

Patents

- Published Application: 20160243217
- Published Application: WO2016134291
- Published Application: 20170112919
- Published Application: 20170056494
- Published Application: 20170112920
- Published Application: 20170112921
- Published Application: 20190060444
- Published Application: 20190060445
- Published Application: 20190381168
- Published Application: 20200306368
- Published Application: 20200171145
- Published Application: 20210236627
- Published Application: 20220133882
- Published Application: 20220241404
- Published Application: 20230218749

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