

Alladapt Commences Phase 1/2 Clinical Trial in Food Allergy

- Harmony Study began dosing patients who are allergic to one food or to multiple foods in a Phase 1/2 clinical trial –*
- ADP101 is an investigational oral immunotherapy product candidate representing the nine food groups responsible for the vast majority of significant food allergic reactions –*

MENLO PARK, Calif., April 22, 2021 – Alladapt Immunotherapeutics Inc., a private biopharmaceutical company focused on developing novel prescription therapeutics for food allergy, today announced that the first patients have been dosed in The Harmony Study, a first-in-human Phase 1/2 clinical trial to evaluate ADP101 for the treatment of food allergy.

“Alladapt’s lead program is based on more than a decade of research and clinical studies demonstrating that food allergic patients have the potential to achieve desensitization across all major allergenic food groups and that this can be accomplished whether patients are mono- or multi-food-allergic,” said Ashley Dombkowski, PhD, Alladapt’s Chief Executive Officer and co-founder. “The initiation of this clinical trial is a significant milestone underscoring our unwavering commitment to developing novel oral medicines capable of addressing food allergic disease triggered by an expansive set of antigens.”

Kari Nadeau, MD, PhD, scientific inventor of ADP101 and co-founder of Alladapt emphasized, “We need FDA-approved medicines that can address food allergy and help desensitize as many patients as possible. Food allergy is associated with a remarkably diverse set of foods, and patients are increasingly multi-allergic. For these reasons, I am excited that ADP101, a standardized, multi-allergen, oral immunotherapeutic agent, is now being evaluated in patients through the FDA-regulated clinical trials process.”

The Harmony Study is a Phase 1/2, randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of ADP101 for oral immunotherapy (OIT) in children and adults diagnosed with allergy to either one food or to multiple foods from a set of the most commonly allergenic foods. The Harmony Study plans to enroll patients across 20 sites in the United States.

“With the initiation of the ADP101 clinical program, we are honored to collaborate with leading allergy clinics and food allergy patients across the United States,” said Dana McClintock, MD, Chief Medical Officer at Alladapt. “The rigorous design of our Phase 1/2 Harmony Study was informed by the growing body of clinical data from oral immunotherapy studies around the world. Our study has been further supported by bioinformatics analyses, including insights from large epidemiology data sets along with *in silico* evaluation of allergenic protein structures.”

“Food allergy is a serious, unpredictable, widespread disease that not only causes severe reactions but also places disabling and chronic limitations on the lives of patients and their families,” said Daniel H. Petroni, MD, PhD, Executive Director of the Seattle Allergy & Asthma Research Institute and Director of the Northwest Food Allergy Treatment & Research Center. “As one of the first clinical sites enrolling patients in the Harmony Study, we are delighted to participate in a study designed to assess the efficacy

and safety of an intervention with the potential to broadly treat the most common causes of food allergy.”

About ADP101 and Oral Immunotherapy

ADP101 is a proprietary, standardized, oral immunotherapy drug candidate that is being studied for the treatment of food allergy to one or more foods. ADP101 is formulated to consistently deliver a well-characterized investigational drug product sourced from the most commonly allergenic food groups and designed to be administered as part of a clinically monitored dosing protocol. The goal of oral immunotherapy is to induce a state of clinically meaningful desensitization to food proteins, defined as the absence of moderate or severe allergic reaction following the ingestion of small but potentially dangerous amounts of food.

About Food Allergy

Food allergy is a serious disease posing significant challenges for affected patients and families ranging from social isolation and anxiety to potentially life-threatening consequences from inadvertent exposure. Food allergy affects 32 million people in the United States alone and it is estimated that 240 million to 550 million are affected by food allergy worldwide.^{1, 2, 3} There are 9 food groups responsible for 90 percent of food allergic reactions.⁴ Of the food allergy-related emergency department visits in the U.S. in a single year, 15 times as many were reported in patients with at least one non-peanut allergy versus those who report food allergy to peanut alone.^{1, 2, 5} Furthermore, of patients with food allergy, 30-60 percent are multi-allergic, which can increase the relative risk of reactions from accidental exposures by several fold.^{1, 2, 6} There are no FDA-approved therapies for the vast majority of patients.

About Alladapt Immunotherapeutics

Alladapt Immunotherapeutics is a private, clinical-stage biopharmaceutical company developing prescription therapeutics targeting food allergy. Alladapt was co-founded in 2018 by allergist and protein biochemist Kari Nadeau, MD, PhD and biotechnology entrepreneur, Ashley Dombkowski, PhD. Academic clinical research conducted by Dr. Nadeau has demonstrated that a food allergic immune system in an individual person can be receptive to remodeling by gradually increasing exposure under tightly controlled clinical supervision to the proteins that activate the inappropriate cascade of reactions. This work, combined with research illuminating disease mechanisms, pathways, and protein structures, led the founders to envision biopharmaceutical interventions capable of addressing food allergy provoked by a wide-ranging set of antigens. Gurnet Point Capital, a private investment firm focused on the healthcare and life sciences sectors, is Alladapt’s primary investor.

For more information, please visit the Company's website at www.alladapt.com.

References

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