Alladapt Immunotherapeutics Presents Phase 1/2 Harmony Data Demonstrating Therapeutic Potential and Safety of ADP101 for the Treatment of Food Allergy at 2023 ACAAI Annual Meeting

– Results aligned with patient needs and clinical practice priorities –

– Alladapt preparing for ADP101 Phase 3 study in 2024 –

MENLO PARK, Calif., November 9, 2023 -- Alladapt Immunotherapeutics, Inc., a private, clinical-stage biopharmaceutical company developing prescription therapeutics to address IgE-mediated food allergy, today announced that data from the Phase 1/2 Harmony study will be presented at the 2023 Annual Scientific Meeting of the American College of Asthma, Allergy and Immunology (ACAAI) taking place Nov. 9-13. The data demonstrate that ADP101, an investigational multi-allergen oral immunotherapy (OIT), generated dose-dependent, clinically meaningful responses, and a favorable safety and tolerability profile in pediatric patients allergic to one or more of the food sources in the product. This is the first time these data have been presented in the United States.

Ashley Dombkowski, Ph.D., Chief Executive Officer and Co-Founder of Alladapt, said, "We are excited to present the encouraging Phase 1/2 safety and efficacy data from our Harmony study at ACAAI. The Harmony data underscore the value of our multi-allergen approach and the potential for ADP101 to address a profound unmet need for patients and their families. Further, these data align with several insights from our extensive market research: We know that a significant majority of patients seeking food allergy care are multi-allergic and are seeking broad therapeutic solutions. Healthcare professionals are motivated to provide these patients with substantial levels of desensitization across the most common causes of food allergy to maximize protection against accidental exposures. They understand the importance of reliability and consistency of allergenic materials used in a therapeutic setting, and they prioritize fostering a positive patient experience during both in-office and at-home components of a treatment. We are incorporating these data and insights into an enhanced Phase 3 program and look forward to advancing ADP101 further towards a future BLA and potential FDA approval."

Alladapt's ADP101 is the first standardized, pharmaceutical-grade, multi-allergen OIT, designed to simultaneously treat allergy to one or more of the world's most significant food allergens – namely almond, cashew, chicken's egg, codfish, cow's milk, hazelnut, peanut, pecan, pistachio, salmon, sesame, shrimp, soy, walnut and wheat.

Warner Carr, M.D., Allergist at Allergy & Asthma Associates of Southern California, a primary investigator in the Harmony study, and the presenting author of these data at ACAAI, added, "The Harmony data is notable for several reasons. First, the diversity of disease presentation was remarkable, with 31 unique food allergen combinations confirmed among the 61 pediatric patients in the study.

Next, the safety and tolerability data were strong as evidenced by a study discontinuation rate due to adverse events of just 5% – a rate that was indistinguishable from the rate seen in placebo patients and well below rates commonly reported in the literature for other OIT protocols. Finally, the efficacy analysis was promising; after less than a year on therapy, 56% of multi-allergic patients were simultaneous responders across two or more food allergies compared to none on placebo. Based on these results, ADP101 has the potential to transform the value proposition of oral immunotherapy for the treatment of food allergy and expand the patient population that could be treated."

The Phase 1/2 Harmony study of ADP101 (NCT04856865) demonstrated clinically meaningful, dose-dependent responses in 61 pediatric patients with mono- and multi-food allergies:

- The primary endpoint was the proportion of participants tolerating a single dose of at least 600 mg (1044 mg cumulative) of protein from one or more qualifying foods without dose-limiting symptoms in a double-blind, placebo-controlled food challenge at study exit. After only 40 weeks on therapy, data from the intent-to-treat population revealed 55% of patients receiving high-dose ADP101 experienced desensitization to a single dose of 600mg (1044 mg cumulative) or more of protein from qualifying allergens, compared to 20% in the placebo group.
- Secondary endpoints revealed additional efficacy trends, with 56% of multi-allergic patients in the high-dose ADP101 arm achieving simultaneous desensitization to 600mg (1044 mg cumulative) or more of protein from two or more food allergens versus a 0% response rate among patients receiving placebo. Furthermore, 44% of patients receiving high-dose ADP101 were desensitized to 1000mg (2044 mg cumulative) or more of protein from two or more food allergens compared to a 0% response rate among patients on placebo. The majority of these responses were generated across unrelated, non-cross-reactive allergens.

Safety data indicated that ADP101 was well-tolerated; adverse events were mostly mild or moderate and rates diminished as patients moved from up-dosing into maintenance dosing. Severe anaphylactic events were infrequent and not related to ADP101. No study participants on ADP101 discontinued the study due to anaphylaxis. The administration of epinephrine for patients on active therapy occurred primarily during up-dosing and was associated with the management of mild or moderate reactions. The study discontinuation rate due to adverse events was 5% whether patients were on active therapy or placebo.

The poster is titled "Efficacy and Safety of ADP101 Multifood Oral Immunotherapy in Food-Allergic Patients in the Harmony Trial" (ID P180) and its associated abstract can be found online in a supplement to the November 2023 issue of Annals of Allergy, Asthma & Immunology, ACAAI's scientific journal, here. The poster presentation will take place in the ePoster Section of the Exhibit Hall on Nov. 10 at 3 p.m. PT.

Alladapt is also conducting the Encore Study, an open-label extension study of the Harmony study assessing long term use of ADP101. In addition to safety and tolerability data, Encore is assessing potential for improved response rates overall, a breadth of responses seen across allergens, and increases in the magnitude of desensitization experienced by patients over time. Data from Encore are expected to be reported on an annual basis with the first results anticipated in early 2024.

About the Harmony Study

The Phase 1/2 Harmony study is a randomized, double-blind, placebo-controlled trial designed to evaluate the efficacy and safety of ADP101 for inducing desensitization in patients with single or multiple food allergies. Eligible patients had a qualifying food allergy to 1-5 foods contained in ADP101, defined as dose-limiting symptoms on exposure to ≤100mg of protein on double-blind, placebo-controlled food challenge (DBPCFC) at screening. Per protocol, the trial enrolled 61 subjects aged 4-17 in a pediatric cohort, and 12 subjects aged 18-55 in an exploratory adult cohort. Subjects were randomized 2:2:1:1 to high-dose ADP101, low-dose ADP101, high-dose placebo and low-dose placebo. Previously presented topline study data can be found here.

About Alladapt Immunotherapeutics

Alladapt Immunotherapeutics, Inc., is a private, clinical-stage biopharmaceutical company developing prescription therapeutics targeting food allergy. In the U.S. alone, there are over 32 million people with food allergy, a prevalence similar to that of asthma or diabetes. Despite the severity and widespread presence of food allergy, the current standard of care for this serious immunologic disease is meticulous avoidance of the food allergen and emergent use of epinephrine in case of reactions caused by accidental exposure.

ADP101, the Company's lead product candidate, is an investigational oral immunotherapy representing the nine food groups responsible for the vast majority of significant food allergic reactions globally. The Company has generated positive data in the Phase 1/2 Harmony study, a randomized, double-blind, placebo-controlled study evaluating the efficacy and safety of ADP101 for the simultaneous treatment of one or more severe food allergies in children and adults. The Encore open label extension study assessing long term use of ADP101 is ongoing, as well.

Alladapt was co-founded in 2018 by biotechnology entrepreneur, Ashley Dombkowski, Ph.D., and allergist, clinician and protein biochemist, Kari Nadeau, M.D., Ph.D. Dr. Nadeau currently serves as the Chair of the Department of Environmental Health at Harvard School of Public Health and John Rock Professor of Climate and Population Studies. Food allergen specific OIT conducted by Dr. Nadeau and other food allergy experts is an approach that has shown consistent promising results through administration of increasing amounts of an allergen to individuals with food allergy to raise their reactive threshold and decrease the severity of allergic responses to the allergenic food. Allergen immunotherapy for environmental allergy and insect venom allergy is an established interventional precedent that is considered both effective and disease modifying. Oral Immunotherapy for the treatment of food allergy may offer similar mechanistic promise for delivering not only desensitization but long-term disease modifying benefits.

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

Investor Contact:

John Woolford
ICR Westwicke
John.Woolford@westwicke.com

Media Contact:

Jon Yu
ICR Westwicke
AlladaptPR@westwicke.com