Alladapt Immunotherapeutics Announces Topline Pediatric Data from Phase 1/2 Harmony Study Evaluating ADP101 for the Treatment of Patients with Mono- and Multi-Food Allergy, as Presented at the European Academy of Allergy and Clinical Immunology Hybrid Congress

-Results from primary analysis conducted in pediatric patients demonstrate dose-dependent and clinically meaningful responses in addition to a favorable safety and tolerability profile-

-Harmony, which was designed with a "low and slow" patient-centric up-dosing protocol, is the first clinical study to successfully evaluate a pharmaceutical-grade oral immunotherapy in both mono- and multi-allergen settings-

-Results from Harmony support goal to progress ADP101 to Phase 3 development -

MENLO PARK, Calif., June 13, 2023— Alladapt Immunotherapeutics, Inc., a private, clinical-stage biopharmaceutical company developing prescription therapeutics to address IgE-mediated food allergy, today announced topline results from the Phase 1/2 Harmony study evaluating the efficacy and safety of ADP101 for the treatment of food allergy. The findings—which demonstrated dose-dependent, clinically meaningful responses, and a favorable safety and tolerability profile in pediatric patients with mono- and multi-food allergies—were presented in an oral session and a flash talk at the European Academy of Allergy and Clinical Immunology (EAACI) Hybrid Congress June 9-11, 2023 in Hamburg, Germany.

ADP101 is an investigational, potentially best-in-class, pharmaceutical-grade, multi-allergen oral immunotherapy (OIT) designed to simultaneously desensitize patients allergic to one or more of the most common allergenic foods including egg, milk, tree nuts, peanut, fin fish, shrimp, wheat, soy, and sesame.

"We believe these encouraging topline results from our Harmony study support ADP101's potential to be a safe and effective treatment option for children with one or more of the world's most common food allergies," said Ashley Dombkowski, Ph.D., Chief Executive Officer of Alladapt. "From the outset, a patient-centric approach to dosing has been vitally important to us, and as a result, our clinical team carefully designed the Harmony study to incorporate a 'low and slow' up-dosing protocol, with the intentional absence of an initial dose escalation day, to help minimize adverse reactions and the burden on the patient and the treating physician. Additionally, ADP101 is designed such that the pace of dosing enables physicians to customize a schedule that fits their patients' needs—which we believe may greatly improve the overall patient experience and thus adherence. With this milestone, we are one step closer to our goal of delivering a pharmaceutical-grade, broadly applicable OIT to patients and providers. On behalf of our entire team, I am grateful for our clinical trial sites, our development partners, and the patients and families who participated in our Harmony study."

Phase 1/2 Harmony Study Pediatric Data Highlights:

The study demonstrated clinically meaningful results and a dose-dependent response across multiple efficacy endpoints, with reported p-values comparing high-dose active treatment versus placebo. Desensitization to 600mg or more of protein from 1 or more qualifying allergens at 40 weeks was

observed in 20.0%, 38.1% and 55.0% in those receiving placebo (pooled), low-dose ADP101 and high-dose ADP101, respectively (p=0.048, α=0.025). In a pre-specified supplemental analysis in the intent-to-treat population, taking into account COVID-19 site closures and other administrative challenges, desensitization at the 600mg level of protein was demonstrated in 21.5%, 40.5% and 58.0% of patients, respectively (p=0.013). Additionally, efficacy trends favoring high-dose ADP101 were noted across secondary efficacy endpoints:

- Desensitization of 1 or more foods at the 1000mg of protein or higher threshold was observed in 15.0%, 23.8% and 50.0% in placebo, low-dose ADP101 and high-dose ADP101, respectively (p=0.041).
- Desensitization of 2 or more foods at the 600mg of protein or higher threshold was observed in 0%, 22.2% and 55.6% of the same dose groups (p=0.006).
- Desensitization of 2 or more foods at the 1000mg of protein or higher threshold was observed in 0%, 11.1% and 44.4% of the same dose groups (p=0.021).

The study also showed desensitization potential to multiple food allergens simultaneously, with high-dose ADP101 showing a strong response that persisted at the 1000mg or higher threshold. The multiple allergen desensitization trends were broadly observed across foods and occurred in individual patients across unrelated food groups.

Secondary safety endpoints also showed that ADP101 was well-tolerated, with most treatment emergent adverse events classified as mild or moderate and occurring during the up-dosing treatment period. In the dose-maintenance phase, no adverse events were reported with a frequency >15% in any treatment group. There were no severe anaphylactic events or discontinuations for anaphylaxis attributed to ADP101. No life-threatening or fatal events occurred during the Harmony study. Epinephrine was primarily used for mild or moderate events and usage occurred with decreased frequency in the maintenance phase. There were no discontinuations following epinephrine use in the ADP101 active treatment arms. There was no evidence of treatment-associated sensitization to new allergens during the study.

Commented Warner Carr, M.D., Allergy & Asthma Associates of Southern California, and a primary investigator in the Harmony study: “There is an urgent need for FDA approved food allergy interventions. Oral immunotherapy has the potential to fundamentally modify a patient’s immune system at the molecular level, which over time, could lead to meaningful and improved levels of protection from accidental exposures. In addition to its potential as a standalone OIT, if approved, I believe ADP101 could also be explored as the backbone of combination therapy with a range of immune-modulating biologics.”

Added Dana McClintock, M.D., Alladapt’s Chief Medical Officer: “Based on these Harmony data, we are now looking ahead to a Phase 3 program to support regulatory approval of ADP101. Food allergy is a largely invisible, chronic disease that places a severe immunological and psychological burden on patients and their families. With limited treatment options, clinicians are actively seeking effective, practical interventions that could be broadly accessed by as many of their patients as possible. As we progress our clinical program, we intend to continue partnering with the food allergy community to ensure these needs are well reflected in our program.”

Alladapt intends to submit the full Harmony study results for peer-reviewed publication and anticipates initiating the Phase 3 program focused on the pediatric population in 2024. The Harmony study also

evaluated 12 adult allergy patients as an exploratory cohort. The Encore Open-Label Extension study following Harmony is currently ongoing.

The data presentations may be found on EAACI's website.

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.

About Alladapt Immunotherapeutics
Alladapt Immunotherapeutics, Inc. is a private, clinical-stage biopharmaceutical company developing prescription therapeutics targeting food allergy. 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 recently completed its Harmony study, a Phase 1/2, 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. Encore, an open-label extension study of the Harmony study, is currently ongoing.

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. This work, combined with research on disease mechanisms, pathways, and protein structures, led the founders to envision biopharmaceutical interventions capable of addressing food allergy due to a wide-ranging set of foods. For more information, please visit the Company's website at www.alladapt.com.

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