Alladapt Immunotherapeutics Receives FDA Fast Track Designation for ADP101 for the Treatment of Mono- and Multi-Food Allergies

– Fast Track Designation accelerates ADP101's development path for the treatment of mono- and multi-food allergy –

– Phase 1/2 Harmony data for ADP101 recently presented at the 2023 American College of Asthma, Allergy and Immunology (ACAAI) Meeting demonstrate dose-dependent, clinically meaningful desensitization responses and a favorable safety profile in pediatric patients allergic to qualifying foods –

MENLO PARK, Calif., Nov. 22, 2023 -- Alladapt Immunotherapeutics, Inc., a private, clinical-stage biopharmaceutical company developing prescription therapeutics to address IgE-mediated food allergy, today announced that ADP101, its investigational multi-food oral immunotherapy (mOIT) designed to simultaneously treat allergy to one or more of the world's most significant food allergens, received Fast Track Designation from the U.S. Food and Drug Administration (FDA). ADP101 is the most advanced multi-food OIT pharmaceutical candidate in development.

Ashley Dombkowski, Ph.D., Chief Executive Officer and Co-Founder of Alladapt, said, "The FDA's decision to grant ADP101 Fast Track Designation signifies an important milestone for people suffering from the substantial burden of food allergy, which requires constant, meticulous avoidance of all consumption or contact with allergens. Our team is thrilled to be at the forefront of developing a new treatment that addresses such a huge unmet need. We are excited to collaborate even more closely with the FDA as we move ahead to expedite development of this important therapy."

There are currently no FDA-approved OIT treatments for multi-food allergy or for allergy to foods other than peanut. In an independent study of patients who sought treatment for food allergic reactions in the emergency department over a 12-month period, 93% were either multi-allergic or allergic to foods other than peanut, with only 6.6% allergic to peanut alone.[1] This amplifies the need for interventions that can target a breadth and depth of allergens.

The Fast Track Designation grant letter provides FDA endorsement for expedited development of ADP101 as a treatment for food allergy, including the simultaneous treatment of multiple food allergies and the treatment of single food allergies, in children (4-17 years of age) with confirmed allergy to one or more of the following 15 foods contained in the drug product: almond, cashew, chicken egg, codfish, cow milk, hazelnut, peanut, pecan, pistachio, salmon, sesame seed, shrimp, soy, walnut and wheat.

FDA's Fast Track program is designed to expedite the development of new drugs intended to treat serious or life-threatening conditions. Fast Track allows more frequent meetings and written communications with FDA to discuss the drug's development plan, clinical trial design, and data

collection. Fast Track designated drugs can take advantage of Rolling Review, wherein a company can submit completed sections of its Biologic License Application (BLA) for review by FDA, rather than waiting until every section of the BLA is completed before the entire application can be reviewed. Such drugs are also eligible for Priority Review, if relevant criteria are met. This designation aims to bring important new drugs to patients earlier and address unmet medical needs.[2]

The Fast Track designation for ADP101 was supported by results from Alladapt's Phase 1/2 Harmony trial (NCT04856865) evaluating the efficacy and safety of ADP101 for inducing desensitization in patients with single or multiple food allergies. Study results presented at the 2023 European Academy of Allergy & Clinical Immunology Congress and the 2023 American College of Allergy, Asthma, and Immunology Annual Meeting demonstrated that ADP101 generated dose-dependent, clinically meaningful responses as a multi-OIT food allergy desensitization therapy, with a favorable safety and tolerability profile in pediatric patients allergic to one or more of the food sources in the product. Alladapt is also conducting the Encore Study, an open-label extension study of the Harmony study assessing long term use of ADP101 in mono- and multi-food allergic patients.

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.

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[1] Warren CM, Aktas ON, Manalo LJ, Bartell TR, Gupta RS. The epidemiology of multifood allergy in the United States: A population-based study. Ann Allergy Asthma Immunol. 2023;130(5):637-648.e5. doi:10.1016/j.anai.2022.12.031

[2] U.S. Food & Drug Administration. Fast Track. Updated January 4, 2018. Accessed November 21, 2023. https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track