AllerGenis and Partners Present Positive Precision Medicine Data on Tracking Peanut-Allergy Desensitization Therapy at ACAAI Virtual 2020 Annual Scientific Meeting

- *Each year in the U.S. 200,000 people require emergency medical care for allergic reactions to food.*
- *Annual incidence of accidental exposures resulting in allergic reactions is more than 10% in peanut-allergic children, highlighting the need for successful desensitization therapies and tools to confirm their effectiveness.*
- *Precision medicine tools are required to monitor response to treatment, as existing tools (sIgE, sIgG4, and components) are insufficient in this context.*
- *This work was conducted using samples from children who participated in the PEPITES study, which was designed to assess the safety and efficacy of epicutaneous immunotherapy for peanut allergy using investigational DBV712 250 µg in peanut-allergic children aged four to 11 years.*
- *In this analysis, it was demonstrated that Epitope Mapping using the BBEA assay (the AllerGenis platform) was highly accurate (95%) in predicting treatment response, and specifically, determining progress towards desensitization of children who participated in the PEPITES study who received treatment with investigational DBV712 250 µg.*

HATFIELD, Pa.—November 13, 2020—AllerGenis LLC, a data-driven precision diagnostics company focused on food allergies today announced that positive new data about an innovative approach to track the progress of peanut allergy desensitization utilizing AllerGenis' Epitope Mapping Platform in children undergoing epicutaneous immunotherapy for peanut allergy (DBV712 250 µg) being developed by DBV Technologies, will be presented at the American College of Allergy and Asthma & Immunology (ACAAI) virtual 2020 Annual Scientific Meeting. The presentation, a partnership with DBV Technologies, is titled, "Specific Peanut Epitopes as a Biomarker for Desensitization During Epicutaneous Immunotherapy," and will be given by David Fleischer, MD, Professor of Pediatrics and Section Head, Children's Hospital Colorado, at 3:33 p.m. CST on Saturday, November 14. Access full abstract here.

The results to be presented at ACAAI are based on samples from subjects who participated in the Efficacy and Safety of Viaskin Peanut in Children with Immunoglobulin E (IgE)-Mediated Peanut Allergy (PEPITES) study (NCT02636699). This was a Phase 3, double-blind, randomized controlled trial of children aged four to 11 years with peanut allergies who were treated with DBV712 250 µg or placebo for 12 months. Daily treatment with investigational DBV712 250 µg (approximately 1/1000 one peanut) was shown to result in a statistically significant increase in desensitization in peanut-allergic children aged four to 11 years compared with placebo.

"The ACAAI presentation describes a highly specific and accurate – with 95% accuracy – precision diagnostic approach to monitor the progress of epicutaneous peanut desensitization therapy by epitope mapping, which represents a significant step forward in this area," said David Fleischer, MD, of Children's Hospital of Colorado. "This has potential to improve on existing biomarkers, such as total peanut-IgE and total peanut-IgG4, that have not been proven to be adequate for quantifying the success of desensitization during immunotherapy."

Peanut allergy affects around 1.6 million children and adolescents in the United States,[1] and is a leading cause of allergy-related death as well as the main cause of food-induced anaphylaxis.[2] Up to 2.2% of the pediatric population has been diagnosed with a peanut allergy, with prevalence increasing from 0.4% in 1997 to 2.2% in 2016.[1,3] Annual incidence of accidental exposure resulting in allergic reaction is over 10% in peanut-allergic children, and only 20% of children with peanut allergy outgrow this condition.[4]

"These results suggest the potential for a novel way to accurately track the treatment progress of peanut-allergic children undergoing desensitization using DBV's investigational DBV712 250 µg for the treatment of peanut allergy in children aged four to 11," noted Jim Garner, AllerGenis CEO. "This type of tracking has the potential to be helpful to emerging therapies."

Study authors are David Fleischer, MD, Professor of Pediatrics and Section Head, Children's Hospital Colorado; Dianne E Campbell, MD, PhD ,Vice President, Medical Affairs and Clinical Development DBV Technologies; Bob Getts, PhD, Chief Science Officer, AllerGenis; Paul Kearney, PhD, Head of Product and Clinical Development, AllerGenis; Todd D Green, MD, Vice President, Clinical Development and Medical Affairs, DBV Technologies; and, Hugh A Sampson, MD, of the Elliot and Roslyn Jaffe Food Allergy Institute of the Icahn School of Medicine at Mount Sinai and Chief Scientific Officer, DBV Technologies.

About AllerGenis

Established in 2017 and located in Hatfield, PA, AllerGenis develops precision, data-driven diagnostics to help healthcare providers more accurately and safely diagnose, assess, and monitor patients with food allergies. The company was founded out of a collaboration between Genisphere, provider of the 3DNA® platform for targeted drug delivery, and Hugh Sampson MD, of the Icahn School of Medicine at Mount Sinai. Mount Sinai Health System has licensed its proprietary epitope mapping platform to AllerGenis, which the company is using to create the largest food allergy knowledge base populated by individual patient epitope signatures derived from epitope mapping, clinical history, and patient-reported outcomes to gain clinical insights. For more information, visit www.allergenis.com.

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