Dear Friend,

This looks to be another pivotal year in the research arena, and I am pleased to be sharing some of the latest high-impact research news.

I recently attended the annual scientific meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) meeting in Los Angeles, where eagerly awaited results from the LEAP-On study, funded by FARE and the National Institute of Allergy and Infectious Diseases, were presented. You’ll read more about the findings in this newsletter, but I will take a moment here to say we are proud to have supported a study that is likely to play a critical role in the prevention of peanut allergy for future generations.

The LEAP studies represent important work in the area of prevention. We are also continuing to focus research efforts in the area of treatment. Earlier this year, we attended a meeting of the Allergic Products Advisory Committee at the FDA’s Center for Biologics Evaluation and Research, where committee members discussed safety data and clinical trial endpoints for licensure of food allergy immunotherapy products. I spoke to the committee about the incredible unmet need for food allergy therapeutics, which is probably the greatest dichotomy between need and research activity I have observed in pharmaceutical development.

FARE believes that by defining a consistent and well-documented regulatory process for the approval of new therapeutics for food allergy, the FDA will help to encourage the development of these important products. We will continue our efforts to help advance the pace of research and new treatments.

We are also excited to be hosting our annual Research Retreat in McLean, Va. this spring where we will meet with directors of the FARE Clinical Network centers of excellence and hear reports on the progress made by the recipients of the FARE Investigator in Food Allergy awards.

In closing, I am hopeful about the year ahead. Together, we will continue to advance food allergy research and improve the lives of the 15 million Americans with food allergies.

Sincerely,

James R. Baker, Jr., MD
Chief Executive Officer

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**LEAP-On Study Finds Early Introduction of Peanuts Provides Lasting Protection Against Allergy**

A new study funded by FARE and the National Institute of Allergy and Infectious Diseases (NIAID) provides strong evidence that introducing peanuts early in life is protective against developing peanut allergy, according to the results of LEAP-On, published in the New England Journal of Medicine on March 4. Researchers presented their findings at the annual scientific meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI), which was held in Los Angeles on March 4-7. The continuation of last year’s groundbreaking LEAP Study, these findings showed that even after abstaining from peanuts for a full year, nearly all children in the trial who were at high risk for developing a peanut allergy, one group was fed peanuts early in life while the other group completely avoided peanuts until the age of 5.

The children were considered high risk because they either had an egg allergy or severe eczema. Findings published last year showed that early introduction reduced the rate of peanut allergy among at-risk infants by 80 percent. In LEAP-On, researchers sought to determine whether the children in the consumption group would develop peanut allergy if they subsequently avoided peanuts for 12 months.

They learned there was no significant increase in the prevalence of peanut allergy associated with abstaining from eating peanuts for a year. At age 6, the prevalence of peanut allergy was 4.8 percent among those in the consumption group, up from 3.6 percent at age 5.

“We expect that findings from the LEAP-On study will serve to reinforce the work that has already begun in rewriting guidance for clinicians from the NIAID regarding the role of early introduction of peanut in the prevention of peanut allergy,” said James R. Baker, Jr., MD, CEO and chief medical officer of FARE. “These guidelines, when finalized, will address the circumstances under which peanut should be introduced into an infant’s diet, including timing and whether the child should first undergo diagnostic tests.”
This year’s annual scientific meeting of the American Academy of Allergy, Asthma & Immunology (AAAAI) featured hundreds of research presentations. FARE once again had a strong presence at this event, providing information to allergists about patient resources as an exhibitor, attending scientific presentations and co-authoring and supporting a number of abstracts.

Here are highlights from two studies that received funding from FARE.

Long-term Follow-Up of MOIT

In this study from Stanford University, researchers reported long-term follow-up data for patients who were desensitized after multiple oral immunotherapy to try to better understand long-term effects after completion of various clinical trials. Overall, they learned that patients regularly consumed home doses that maintained desensitization.

“We repeated food challenges and all subjects in both groups remained desensitized to at least 2 g of each of their food allergens, even those who chose to consume smaller home doses as little as three times per week,” said Kari Nadeau, MD, PhD, of the Sean N. Parker Center for Allergy & Asthma Research at Stanford University School of Medicine.

Socioeconomic Disparities in the Economic Impact of Childhood Food Allergy

In this study led by Ruchi Gupta, MD, MPH, with Northwestern Medicine and Lurie Children’s Hospital, a FARE Clinical Network center of excellence, researchers examined the socioeconomic disparities for families with food allergies. They found that families with children with food allergies in the lowest income stratum spend two and a half times more on emergency department and hospitalization costs, and less on specialists and out-of-pocket medication costs.

FARE funded this study to understand the disparities in the economic burden of childhood food allergy, said James R. Baker, Jr, MD, CEO.

“This data shows the remarkable direct and out-of-pocket costs related to food allergies, which families have to bear,” Baker said. “This reinforces that food allergies are an important economic issue as well as a medical problem.”

Aimmune and DBV Present at AAAAI

Two companies that have both received breakthrough therapy designation from the FDA presented new findings at this year’s AAAAI meeting.

Aimmune Therapeutics

Aimmune reported data from ARC002, an open-label Phase 2 trial of AR101, a peanut allergen formulation for oral immunotherapy use in the treatment of peanut allergy. In this trial involving participants ages 4-21, former placebo subjects up-dosed to 300 mg of peanut protein over a period of 22 weeks and then underwent double-blind placebo-controlled food challenge after two more weeks of therapy. In this group, 20 of 26 of the placebo subjects passed the challenge at 443 mg of peanut and entered the open-label continuation trial, during which they received 12 weeks of treatment with AR101.

In the group that had previously undergone therapy with AR101, 21 out of 29 participants also entered the open-label continuation trial. Researchers reported that 100 percent of participants in both groups tolerated 443 mg of peanut protein, 90 percent tolerated 1,043 mg of peanut protein and 60 percent tolerated 2,043 mg of peanut protein. The highest amount is equivalent to about seven or eight peanuts. Two participants required single doses of epinephrine during the double-blind placebo-controlled food challenge. None required epinephrine during the double-blind placebo-controlled food challenge that followed up-dosing. Five patients stopped the trial, primarily due to gastrointestinal side effects.

Results from the open label phase of this trial indicate that AR101 is safe and effective, according to researchers.

“These data suggest that treatment with AR101 could provide effective protection against accidental ingestion for the majority of peanut allergic individuals,” said J. Andrew Bird, MD, assistant professor at the University of Texas Southwestern Medical Center. “Accidental exposures to peanut typically involve ingestion of less than one peanut and often just traces of peanut, and we have shown that the levels of desensitization achieved in the post-therapy food challenges after 12 weeks of low-dose maintenance in ARC002 protect against ingestion of more than one peanut for 85 percent of participants in the study.”

For information on Aimmune’s clinical trial, visit clinicaltrials.gov and search “Aimmune.”

DBV Technologies

Favorable safety and efficacy data was also reported by DBV Technologies regarding OLFUS-VIPES, the ongoing, open label, two-year follow-up study of VIPES, the Phase IIb clinical trial of Viaskin® Peanut, also known as the peanut patch.

Out of 207 participants who completed the VIPES randomized controlled trial, 171 entered the open label continuation. These participants had previously received either placebo or one of three 12-month dose regimens.

Hugh A. Sampson, primary investigator of the OLFUS-VIPES study, director of the Jaffe Food Allergy Institute at the Kravis Children’s Hospital at Mount Sinai and chief scientific officer for DBV Technologies, reported that 80 percent of children ages 6 to 11 responded to Viaskin Peanut 250 µg in the trial. Two years into the trial, the average cumulative reactive dose among this group was 1,883 mg of peanut protein compared with 84 mg at baseline. (One peanut contains approximately 250 mg of peanut protein.)

According to a press release from DBV Technologies about this research, a doubling in response rates at 1,000 mg or more during the oral food challenge was observed during the second year of treatment in children dosed with Viaskin Peanut 250 µg, which increased to 60 percent.

“Data from OLFUS-VIPES support an increase in treatment response over time. Patients were highly motivated and we saw excellent treatment compliance and no treatment-related dropouts,” Sampson said. “I believe this is a unique feature of Viaskin Peanut, which continues to show a strong safety profile. We also continue to observe a significant increase in the level of peanut protein consumed by patients that have been treated for two years.”

There were no reactions that required epinephrine, nor were any treatment-related serious adverse events observed during the trial. Most adverse events were considered to be mild or moderate, mainly related to skin symptoms.

For information on DBV’s clinical trial, visit clinicaltrials.gov and search “Viaskin.” •