

Asthma and Allergy Foundation of America Elevates Patient Voice in ICER Review of New Peanut Allergy Treatments

Affirms Burden of Food Allergies on Families, Patients, and Caregivers

June 14, 2019 – **Washington, DC** – On June 11 in Oakland, CA the Institute for Clinical and Economic Review (ICER) and its California Technology Assessment Forum (CTAF) met to assess the clinical effectiveness and value of treatments for peanut allergy. The review examined two new technologies to induce immune tolerance — Viaskin® Peanut (DBV Technologies) and AR101 (Aimmune Therapeutics) — as well as non-commercialized oral immunotherapy (OIT). ICER invited the Asthma and Allergy Foundation of America (AAFA) to share AAFA's recent research results that describe the burden of food allergies on patients and caregivers. ICER's final evidence report and meeting summary will be released on July 11.

AAFA wishes to respond to concern from the allergy community regarding restricted access to new treatments for peanut allergy and the outcome of ICER's findings. Patients should know that ICER's panel review does not impact an approval or denial from the Food and Drug Administration (FDA). "Because these therapies are still in clinical trials, ICER's review of these therapies was premature. This was an academic exercise and a way for ICER to advance its agenda as a watchdog group," stated Kenneth Mendez, AAFA's CEO and president who attended the meeting and presented AAFA's research. "Until the FDA approves these therapies, the findings of the CTAF panel should not impact whether the drugs are available to patients."

AAFA wants to reassure people living with peanut allergy that FDA approval is still possible for these new treatments. Here are three positive outcomes of the ICER meeting and analysis:

- ICER's review clearly confirmed the significant burden peanut allergies present on families, patients and caregivers. AAFA appreciates ICER bringing these facts to light through joint survey work and inviting AAFA to share patient-centered research with the CTAF voting panel. AAFA presented survey results from its "My Life With Food Allergies" — a significant, first of its kind study with patient reported outcomes from over 3,000 patients and caregivers.
- Because of information provided by AAFA, ICER adjusted the economic model to reflect the significant value these new peanut therapies can provide to improve the quality of life for families with peanut allergies.
- The CTAF voting panel acknowledged AAFA's position that there are important contextual considerations: these new therapies will allow successful treatment of many patients where one did not exist previously, and the relief these new therapies can provide families and caregivers.

"We are concerned that ICER's early review may squelch innovation for promising new therapies, or worse, hope in the patient community for new treatments," Mendez stated. "However, we agree with ICER that we need more quality of life data to accurately quantify the burden of peanut and other food allergies on patients and caregivers."



The FDA gave AR101 the Fast Track and Breakthrough Therapy Designations, which speeds review. The decision on AR101 is expected later this year. The Viaskin patch developed by DBV Technologies also received Fast Track Designation, but the company's biologics license application was withdrawn late last year after the FDA requested additional data. DBV expects to resubmit the application in the second half of 2019.

If these therapies are approved by the FDA, as with any medication, it will be important for patients and caregivers to work with their healthcare provider to understand if it is the right treatment for them and any associated risks of the treatment. AAFA looks forward to continued exploration of innovative ways to treat food allergies — a chronic and potentially life-threatening disease affecting about 32 million people in the United States.

About AAFA

Founded in 1953, AAFA is the oldest and largest non-profit patient organization dedicated to saving lives and reducing the burden of disease for people with asthma, allergies and related conditions through research, education, advocacy and support. AAFA provides practical information and community-based services through its digital communities and national network of local chapters and educational support groups. Through its Kids with Food Allergies division, AAFA offers the most extensive online support community for families raising children with food allergies. AAFA also helps consumers identify products suitable for those with asthma and allergies through the asthma & allergy friendly® Certification Program. For more information, visit www.aafa.org.

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