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With Life-Threatening Allergies Diagnosed in Infancy, kaléo Announces Availability of First and Only FDA-Approved Epinephrine Auto-Injector (EAI) for Infants and Toddlers Weighing 16.5 to 33 Pounds (7.5 to 15 kilograms)

- *AUVI-q® (epinephrine injection, USP) 0.1 mg auto-injector is specifically designed for infants and toddlers weighing 16.5 to 33 pounds (7.5 to 15 kilograms)*
- *Available in the United States by prescription for \$0 out-of-pocket for commercially insured patients through the AUVI-Q AffordAbility Program and Direct Delivery Service starting May 1st*

Richmond, VA (April 26, 2018) -- kaléo, a privately-held pharmaceutical company, today announced that AUVI-q® (epinephrine injection, USP) 0.1 mg will be available nationwide by prescription beginning May 1, 2018. AUVI-q 0.1 mg is indicated for the treatment of life-threatening allergic reactions, including anaphylaxis, in infants and toddlers weighing 16.5 to 33 pounds (7.5 to 15 kilograms). Featuring a shorter needle length and lower dose of epinephrine than other FDA-approved epinephrine auto-injectors (EAIs), AUVI-q 0.1 mg is the first and only FDA-approved EAI designed for this patient population. Like the rest of the AUVI-Q family, AUVI-q 0.1 mg features a voice instruction system that helps guide caregivers step-by-step through the injection process, as well as a needle that automatically retracts following administration.

“This day means a lot to me personally, as I suffer from life-threatening allergies and have a child who was diagnosed with life-threatening allergies as an infant,” said Eric S. Edwards, MD, PhD, Vice President of Innovation and Research & Development at kaléo. “Before the introduction of AUVI-q 0.1 mg, the youngest and most vulnerable population (16.5 to 33 pounds; 7.5 to 15 kilograms) did not have a treatment for anaphylaxis designed for them.”

Children are increasingly being treated for anaphylaxis. There was an estimated 130 percent increase in emergency room visits for anaphylaxis among children four years old and younger between 2005 and 2014.¹ For an infant or small child with a life-threatening allergy (LTA), even a small amount of an allergen such as a single peanut could cause a severe allergic reaction, which could potentially be fatal. It is estimated that nearly 39 percent of children with food allergies have a history of severe food-induced reactions.²

“Anaphylactic reactions can be frightening and serious, and when experienced by the very young, some of whom can’t communicate about what’s happening, these episodes can be particularly alarming,” according to Dr. Vivian Hernandez-Trujillo, pediatric allergist and fellow of the American Academy of Allergy, Asthma and Immunology, American College of Allergy, Asthma and Immunology, and American Academy of Pediatrics. “Now, caregivers can have AUVI-q 0.1 mg in hand to respond to an allergic emergency and safely administer epinephrine to infants and toddlers.”

Recent studies have revealed that delaying the introduction of some foods to children may actually increase their risk of developing food allergies.^{3,4} The National Institutes of Health (NIH) updated its allergy prevention guidelines, recommending parents introduce peanut-containing foods to certain infants as early as 4 to 6 months of age.⁵

“A diagnosis of a life-threatening allergy – especially in an infant or toddler – can have a major impact on the entire family. It is extremely important for parents and caregivers to be prepared in case of a severe allergic reaction,” said Kenneth Mendez, the President and CEO of the Asthma and Allergy Foundation of America (AAFA). “The availability of AUVI-q 0.1 mg as the first and only FDA-approved EAI designed for this patient population is positive news for our community.”

“I would have loved to have had the AUVI-q 0.1 mg available back when my son was an infant and was first diagnosed with an egg and wheat allergy,” said Dr. Todd Mahr, a pediatric allergist from La Crosse, Wisconsin, President-Elect of the American College of Allergy, Asthma and Immunology and immediate past-chair of the American Academy of Pediatrics’ Section on Allergy and Immunology. “Prior to this, there was no EAI specifically designed for infants and toddlers weighing 16.5 to 33 pounds (7.5 to 15 kilograms), so the AUVI-q 0.1 mg helps to address that significant unmet need.”

Each AUVI-q 0.1 mg prescription includes two auto-injectors and one Trainer for patients and caregivers to practice administration before an allergic emergency happens. The AUVI-q 0.1 mg will also include a 2 second countdown, like the 0.15 mg and 0.3 mg doses.

AUVI-Q is the number-one prescribed brand of epinephrine auto-injectors among allergists.⁶ “We are proud to now offer epinephrine solutions for a new member of the family,” said Phil Rackliffe, General Manager, Allergy and Pediatrics at kaléo. “We are committed to our collaborative approach to patient-inspired design in medicine.”

To learn more about AUVI-Q (0.3 mg, 0.15 mg and 0.1 mg), visit www.auvi-q.com, or follow AUVI-Q on Facebook or Twitter. For questions on how to get AUVI-Q, please call the AUVI-Q hotline at 1-877-30-AUVIQ.

The sNDA for the AUVI-q 0.1 mg was granted Priority Review by the FDA, an expedited regulatory pathway reserved for products that may provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions when compared to available therapies.

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About Anaphylaxis

Anaphylaxis (pronounced ana-fuh-lak-sis) is a serious allergic reaction that happens quickly and may cause death. Anaphylaxis can occur as a result of exposure to allergens including tree nuts, peanuts, milk, eggs, fish, shellfish, soy, wheat, insect bites, latex and medication, among other allergens.

About AUVI-Q (0.3 mg, 0.15 mg and 0.1 mg)

AUVI-Q (epinephrine injection, USP) Auto-injector is a prescription medicine used to treat life-threatening allergic reactions, including anaphylaxis, in people who are at risk for or who have a history of serious allergic reactions. AUVI-Q contains epinephrine, a well-established, first-line

treatment for severe, life-threatening allergic reactions that occur as a result of exposure to allergens including food such as peanuts, tree nuts, fish, shellfish, dairy, eggs, soy and wheat; insect stings or bites; latex and medication, among other allergens and causes.

AUVI-Q is the only compact epinephrine auto-injector with a voice instruction system that helps guide patients and caregivers step-by-step through the injection process, and a needle that automatically retracts following administration. In anaphylaxis emergencies, it is often individuals without medical training who need to step in and deliver potentially life-saving epinephrine. AUVI-Q was designed through careful analysis of the situations where epinephrine auto-injectors are used and with significant input from the allergy community that relies on it incorporating Human Factors Engineering (HFE). HFE is about designing products or systems that are easy to operate and, most importantly, support correct use, with the goal to remove the potential for error. For more information about AUVI-Q (0.3 mg, 0.15 mg and 0.1 mg) visit www.auvi-q.com.

Indication

AUVI-Q® (epinephrine injection, USP) is a prescription medicine used to treat life-threatening allergic reactions, including anaphylaxis, in people who are at risk for or have a history of serious allergic reactions.

Important Safety Information

AUVI-Q is for immediate self (or caregiver) administration and does not take the place of emergency medical care. Seek immediate medical treatment after using AUVI-Q. Each AUVI-Q contains a single dose of epinephrine. **AUVI-Q should only be injected into your outer thigh, through clothing if necessary.** If you inject a young child or infant with AUVI-Q, hold their leg firmly in place before and during the injection to prevent injuries. Do not inject AUVI-Q into any other part of your body, such as into veins, buttocks, fingers, toes, hands, or feet. If this occurs, seek immediate medical treatment and make sure to inform the healthcare provider of the location of the accidental injection. Only a healthcare provider should give additional doses of epinephrine if more than two doses are necessary for a single allergic emergency.

Rarely, patients who use AUVI-Q may develop infections at the injection site within a few days of an injection. Some of these infections can be serious. Call your healthcare provider right away if you have any of the following symptoms at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have more or longer lasting side effects when you use AUVI-Q. Be sure to tell your healthcare provider about all the medicines you take, especially medicines for asthma. Also tell your healthcare provider about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson's disease, diabetes, heart problems or high blood pressure, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

Common side effects include fast, irregular or 'pounding' heartbeat, sweating, shakiness, headache, paleness, feelings of over excitement, nervousness, or anxiety, weakness, dizziness, nausea and vomiting, or breathing problems. These side effects usually go away quickly, especially if you rest. Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

Please see the full Prescribing Information and the Patient Information at www.auvi-q.com.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

About kaléo (kuh-LAY-oh)

Kaléo (ka-lay-o) is a Greek word meaning “to have a purpose or calling.” Kaléo is a pharmaceutical company dedicated to inventing, manufacturing and commercializing life-transforming products that empower patients and families to live fuller, bolder lives. Kaléo is a privately-held company headquartered in Richmond, Virginia. For more information, visit www.kaleo.com.

¹ Motosue, M. et al. Increasing ED visits for anaphylaxis 2005-2014 *The Journal of Allergy and Clinical Immunology: In Practice* (2017) 5:1, 171-175

² Gupta RS, Springston EE, Warriar MR, et al. The prevalence, severity, and distribution of childhood food allergy in the United States. *Pediatrics*. 2011;128(1):e9-17.

³ Du Toit G, Roberts G, Sayre P, et al. Randomized trial of peanut consumption in infants at risk for peanut allergy. *N Engl J Med*. 2015;372(9):803-813.

⁴ Magnusson J, Kull I, Rosenlund H, et al. Fish consumption in infancy and development of allergic disease up to age 12y. *Am J Clin Nutr*. 2013;97:1324-1330.

⁵ National Institute of Health, National Institute of Allergy and Infectious Diseases. Addendum Guidelines for the Prevention of Peanut Allergy in the United States.

<https://www.niaid.nih.gov/sites/default/files/peanut-allergy-prevention-guidelines-clinician-summary.pdf>. Accessed October 30, 2017.

⁶ Based on IMS prescription data September 2017 – December 2017