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KALÉO ANNOUNCES 2017 U.S. RETURN OF AUVI-Q® (EPINEPHRINE INJECTION, USP) AUTO-INJECTOR FOR LIFE-THREATENING ALLERGIC REACTIONS

- Kaléo, the inventor of AUVI-Q, commits to making the innovative epinephrine auto-injector with industry-first features available in the first half of 2017 as an alternative for the life-threatening allergy community
- New, revamped manufacturing and quality system helps ensure reliable and accurate epinephrine dose delivery

RICHMOND, VA. (October 26, 2016) – Kaléo, a privately-held pharmaceutical company, today announced that it will reintroduce AUVI-Q® (epinephrine injection, USP) auto-injector to the U.S. market in the first half of 2017. AUVI-Q 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.

“Today’s news represents an important milestone for the life-threatening allergy community, which has suffered from a lack of epinephrine auto-injector options for far too long,” said Evan Edwards, Vice President of Product Development & Industrialization at kaléo. “As the inventors of AUVI-Q, my brother and I have dedicated our lives to researching and developing an innovative epinephrine auto-injector that would do for severe allergy sufferers what the AEDs did for cardiac arrest in the community; namely a product that could assist and guide even an untrained user through a life-threatening emergency.”

AUVI-Q is a compact epinephrine auto-injector with industry-first features, including a voice prompt system that guides a user with step-by-step instructions through the delivery process, and a needle that automatically retracts following administration. AUVI-Q is engineered to help patients and their caregivers to confidently administer epinephrine in life-threatening allergic emergencies.

After regaining the rights to AUVI-Q, kaléo conducted a thorough manufacturing assessment and invested in new technology and quality systems to ensure accurate, reliable and consistent delivery from the product. AUVI-Q is manufactured on an intelligent, high-tech, 100% automated robotic production line with more than 100 automated quality checks on each AUVI-Q, ensuring a streamlined and consistent production process.

“For the millions affected by life-threatening food allergies, an epinephrine auto-injector serves as a lifeline,” said James R. Baker, Jr., MD, CEO and Chief Medical Officer at Food Allergy Research and Education (FARE). “These lifesaving devices must be accessible and affordable, and Americans should have options when it comes to selecting the right auto-injector for their family.”

Eric Edwards M.D., Ph.D, Vice President, Product Strategy at kaléo, added, “As a patient and parent of children with life-threatening allergies, I know how the moment of an allergic emergency can unfold- with panic and fear- and that is why I believe and trust in AUVI-Q, not only for myself, but also for my children and other families who might have to depend on it. Driven by this reality, kaléo strives for flawless manufacturing to ensure each AUVI-Q is built to exceptional quality standards.”

Kaléo is aware of the epinephrine auto-injector access and affordability challenges confronting patients and is working to engage with various stakeholders, including wholesalers, insurance companies, pharmacies and pharmacy benefit managers, to ensure that all patients regardless of insurance coverage, have affordable access to AUVI-Q.

“We believe that patients should have options when it comes to epinephrine auto-injectors for life-threatening allergic reactions,” said Spencer Williamson, President and CEO of kaléo. “When a health care practitioner prescribes AUVI-Q, determining that it is best for a patient, we believe that the patient should be able to obtain the product without insurance barriers or being subjected to a high out-of-pocket cost. As we prepare to make AUVI-Q available once again in the United States, our priority is to return AUVI-Q to the market as an epinephrine auto-injector alternative that all patients can afford.”

“We are very excited about patients once again having a choice in epinephrine auto-injectors,” said Eleanor Garrow-Holding, President and CEO of the Food Allergy & Anaphylaxis Connection Team (FAACT). “As food allergy advocates and families personally affected by food allergies, we understand that each person with food allergies has individual needs and comfort levels. Those living with life-threatening allergies deserve innovative products and choices that meet their individual needs. As such, we are grateful that patients will have options when selecting their potentially life-saving epinephrine auto-injector.”

The latest updates regarding the return of AUVI-Q will be available to members of the public who register online at www.auvi-q.com.

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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

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.

Invented by twin brothers Eric and Evan Edwards, a physician and engineer who each suffer from life-threatening allergies, AUVI-Q is a compact epinephrine auto-injector with industry-first features, including a voice prompt system that guides a user with step-by-step instructions through the epinephrine delivery process, and a needle that automatically retracts following administration. In emergencies such as anaphylaxis, it is often individuals without medical training who need to step in and deliver potentially life-saving rescue therapy. AUVI-Q was designed – through careful analysis of the situations where epinephrine is used and with significant input from the allergy community that relies on it – to reflect 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.

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 use. 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 with AUVI-Q, hold their leg firmly in place before and during the injection to prevent injuries. Do not inject into veins, buttocks, fingers, toes, hands, or feet. If you accidentally inject AUVI-Q into any other part of your body, seek immediate medical treatment.

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 is a pharmaceutical company dedicated to building innovative solutions for serious and life-threatening medical conditions. Our mission is to provide innovative solutions that empower patients to confidently take control of their medical conditions. We believe patients and caregivers are the experts on how their medical condition impacts their lives, and are an integral part of our product development process. Each kaléo product combines an established drug with an innovative delivery platform with the goal of achieving superiority and cost effectiveness. Kaléo is a privately-held company headquartered in Richmond, Virginia. For more information, visit www.kaleopharma.com.