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KALÉO ANNOUNCES U.S. AVAILABILITY AND PRICING TO PATIENTS OF AUVI-Q® (Epinephrine Injection, USP) AUTO-INJECTOR, FOR LIFE-THREATENING ALLERGIC REACTIONS

- AUVI-Q will be available by prescription nationwide on February 14, 2017.
- Kaléo launches AUVI-Q *AffordAbility*, a first-of-its-kind access program and commitment for AUVI-Q:
 - More than 200 million Americans with commercial insurance, including those with high-deductible plans, will be able to obtain AUVI-Q for \$0 out-of-pocket.
 - AUVI-Q will be available free of charge to patients with a household income of less than \$100,000 who do not have government or commercial insurance.
 - The cash price for AUVI-Q is \$360, and will be available to those patients without government or commercial insurance.

RICHMOND, VA. (January 19, 2017) – Kaléo, a privately-held pharmaceutical company, today announced the AUVI-Q® (epinephrine injection, USP) Auto-injector will be available by prescription starting February 14th, and announced AUVI-Q *AffordAbility*, a first-of-its-kind access program for AUVI-Q. Through this new program, patients with commercial insurance, even those with high-deductible plans, will have an out-of-pocket cost of \$0. For patients who do not have government or commercial insurance, and have a household income of less than \$100,000, AUVI-Q will be available free of charge. In addition, the cash price for AUVI-Q is \$360 and will be available to those patients without government or commercial insurance. Each AUVI-Q prescription includes two Auto-injectors and one Trainer for AUVI-Q.

“We met with patients and physicians and listened to the very real challenges in the current healthcare environment with obtaining access to affordable medicines,” said Spencer Williamson, President and CEO of kaléo. “As a result, starting February 14, for more than 200 million Americans with commercial insurance, including those with high-deductible plans, the out-of-pocket cost for AUVI-Q will be \$0.”

AUVI-Q is a FDA-approved 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. It is an epinephrine auto-injector with innovative features such as voice instructions that help guide a user with step-by-step instructions through the epinephrine delivery process and an automatic retractable needle system, a first for epinephrine auto-injectors, that injects the epinephrine and retracts the needle back into the device within seconds.

“We know how important it is that severely allergic patients have an epinephrine auto-injector that can be with them at all times and used correctly, even without training, during a panic-stricken allergic emergency,” said Eric Edwards M.D., Ph.D, Vice President of Product Strategy at kaléo. “We are excited to make AUVI-Q, an epinephrine auto-injector with innovative features, available for millions of patients living with severe, life-threatening allergies.”

AUVI-Q *AffordAbility* is a first-of-its-kind program and commitment for AUVI-Q, designed to provide affordable access to this potentially life-saving epinephrine auto-injector for eligible patients. This new program removes potential and previously experienced insurance barriers, restrictions and delays, even for those commercially-insured patients with high-deductible plans. AUVI-Q will also be available via a direct delivery service, that can ensure the best expiration dating for AUVI-Q. For live assistance in filling an AUVI-Q prescription, any patient, physician or pharmacist will be able to call 1-877-30-AUVI-Q.

Identical twin brothers, Eric and Evan Edwards, the inventors of AUVI-Q, grew up with life-threatening allergies. They know what it is like to live in fear of that life-or-death moment, both as patients and parents of food-allergic children. Their goal was to develop an epinephrine auto-injector that contained innovative features, such as a voice instruction system that helps guide patients and caregivers step-by-step through the injection process. Eric and Evan Edwards believe and trust in AUVI-Q, not only for themselves, but also for their children and other families who may have to depend on it to administer epinephrine during an allergic emergency.

To learn more about AUVI-Q, please visit www.auvi-q.com.

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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.

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 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 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 click here to 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. Kaléo is a privately-held company headquartered in Richmond, Virginia. For more information, visit www.kaleopharma.com.