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Mylan to Launch First Generic to EpiPen® Auto-Injector at a List Price of \$300 per Two-Pack Carton, a More than 50% Discount to the Brand Product

HERTFORDSHIRE, England and PITTSBURGH, Aug. 29, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that its U.S. subsidiary will launch the first generic to EpiPen® Auto-Injector (epinephrine injection, USP) at a list price of \$300 per generic EpiPen® two-pack carton, which represents a discount of more than 50% to the Mylan list price, or wholesale acquisition cost ("WAC"), of the branded medicine. The authorized generic will be identical to the branded product, including device functionality and drug formulation. Mylan expects to launch the product in several weeks, pending completion of labeling revisions. Upon launch, the product will be available as a two-pack carton in both 0.15 mg and 0.30 mg strengths. Mylan also intends to continue to market and distribute branded EpiPen®.



Mylan CEO Heather Bresch commented, "We understand the deep frustration and concerns associated with the cost of EpiPen® to the patient, and have always shared the public's desire to ensure that this important product be accessible to anyone who needs it. Our decision to launch a generic alternative to EpiPen® is an extraordinary commercial response, which required the cooperation of our partner. However, because of the complexity and opaqueness of today's branded pharmaceutical supply chain and the increased shifting of costs to patients as a result of high deductible health plans, we determined that bypassing the brand system in this case and offering an additional alternative was the best option. Generic drugs have a long, proven track record of delivering significant savings to both patients and the overall healthcare system. The launch of a generic EpiPen®, which follows the steps we took last week on the brand to immediately reduce patients' out-of-pocket costs, will offer a long-term solution to further reduce costs and ease the burden and complexity of the process on the patient."

Bresch continued, "Ensuring access to medicine is absolutely the core of Mylan's mission and has been since our founding 55 years ago. Mylan currently markets approximately 600 products in the U.S., saving our healthcare system hundreds of millions of dollars annually. We also are committed partners to the allergy community and take our responsibilities to serving these patients very seriously. Today's action further demonstrates this commitment."

To enhance affordability for the broadest patient population possible, both the augmented patient assistance program and the \$300 savings card announced last week will remain in place for the brand product. The \$300 My EpiPen Savings Card® acts as cash at the pharmacy and is available at epipen.com/savings. People interested in learning more about the patient assistance program should contact Mylan's Customer Relations team at 800-395-3376. Mylan also will continue its *EpiPen4Schools*® program.

In addition, Mylan intends to initiate a direct ship program in conjunction with the launch of the generic at the \$300 generic list price. Mylan also continues to fight for enhanced access to epinephrine auto-injectors through other measures, such as inclusion of the product on the federal and private insurance preventive drug lists, which could potentially eliminate all co-pays.

Importantly, Mylan remains fully committed to continuing to meet the needs of this under-served patient population. This includes investing in education and awareness about anaphylaxis, a life-threatening allergic reaction. These efforts have proven vital to ensuring patients are aware of their risk, prepared in the event anaphylaxis occurs, and have access to

epinephrine auto-injectors whenever and wherever they need them, at an affordable cost.

About EpiPen[®] (epinephrine injection, USP) Auto-Injector

EpiPen[®] (epinephrine injection, USP) and EpiPen Jr[®] (epinephrine injection, USP) Auto-Injectors are used for the emergency treatment of life-threatening allergic reactions. Each EpiPen 2-Pak[®] and EpiPen Jr 2-Pak[®] contains two single auto-injectors, instructions for use and a training device, with no drug product or needle, to help patients become familiar with the administration technique. EpiPen[®] Auto-Injector should be administered immediately at the first sign of an anaphylactic reaction. EpiPen[®] Auto-Injector is not a substitute for emergency medical treatment. Patients should seek emergency medical attention immediately following administration. For more information about EpiPen[®] Auto-Injector, visit epipen.com.

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 2,700 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 40,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com

Indications

EpiPen[®] (epinephrine injection, USP) 0.3 mg and EpiPen Jr[®] (epinephrine injection, USP) 0.15 mg Auto-Injectors are for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise, or unknown triggers; and for people who are at increased risk for these reactions. EpiPen[®] and EpiPen Jr[®] are intended for immediate administration as emergency supportive therapy only. Seek immediate emergency medical help right away.

Important Safety Information

Use EpiPen[®] or EpiPen Jr[®] Auto-Injectors right away when you have an allergic emergency (anaphylaxis). **Get emergency medical help right away.** You may need further medical attention. Only a healthcare professional should give additional doses of epinephrine if you need more than two injections for a single anaphylactic episode. EpiPen[®] or EpiPen Jr[®] should **only** be injected into the middle of your outer thigh (upper leg), through clothing if necessary. Do not inject into your veins, buttocks, fingers, toes, hands or feet. Hold the leg of young children firmly in place before and during injection to prevent injuries. In case of accidental injection, please seek immediate medical treatment.

Rarely, patients who have used EpiPen[®] or EpiPen Jr[®] may develop an infection at the injection site within a few days. Some of these infections can be serious. Call your healthcare professional right away if you have any of the following at an injection site: redness that does not go away, swelling, tenderness, or the area feels warm to the touch.

Tell your healthcare professional about all of your medical conditions, especially if you have asthma, a history of depression, thyroid problems, Parkinson's disease, diabetes, high blood pressure or heart problems, have any other medical conditions, are pregnant or plan to become pregnant, or are breastfeeding or plan to breastfeed. Be sure to also tell your healthcare professional all the medicines you take, especially medicines for asthma. **If you have certain medical conditions, or take certain medicines, your condition may get worse or you may have longer lasting side effects when you use EpiPen[®] or EpiPen Jr[®].**

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

Please see the full [Prescribing Information](#) and [Patient Information](#).

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.

For additional information, please contact us at 800-395-3376.

EpiPen[®], EpiPen Jr[®], EpiPen 2-Pak[®], EpiPen Jr 2-Pak[®], *EpiPen4Schools*[®] and My EpiPen Savings Card[®] are registered trademarks owned by Mylan Inc.

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