

# Mylan and Pfizer Announce Epinephrine Auto-injector Settlement Agreement

PITTSBURGH and NEW YORK, Feb. 16, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) and Pfizer Inc. (NYSE: PFE) today announced that Meridian Medical Technologies, a Pfizer subsidiary, has entered into a settlement agreement with Intelliject and Sanofi-Aventis that will resolve pending patent litigation related to Intelliject's 505(b)(2) new drug application (NDA) for its epinephrine auto-injector known as e-cue<sup>™</sup>, which will be manufactured and marketed by Sano**f** ventis. According to the terms of the settlement, Intelliject and Sanofi-Aventis may launch e-cue no earlier than Nov. 15, 2012, subject to receipt of final approval from the U.S. Food and Drug Administration.

Meridian manufactures EpiPen® Auto-Injector and Mylan Specialty markets and distributes the product in the United States.

Mylan Chief Executive Officer Heather Bresch commented, "We are pleased with this settlement, and are confident that the EpiPen® Auto-Injector will continue to be a market leader, given the proud, 20-year heritage of this important treatment for anaphylaxis. Anaphylaxis poses a life-threatening risk for many, and yet there continues to be low awareness of the signs, symptoms or steps that can be taken to be prepared to respond when anaphylaxis occurs - including ensuring immediate access to epinephrine auto-injectors. That is why we believe that, in addition to our significant efforts in this area, people with life-threatening allergic reactions will benefit from more voices in the fight to raise anaphylaxis awareness, preparedness and access to treatment."

Additional terms of the agreement are confidential, and the agreement itself is subject to review by the U.S. Department of Justice and the Federal Trade Commission.

#### **About EpiPen Auto-Injector**

EpiPen® (epinephrine) 0.3mg and EpiPen Jr® (epinephrine) 0.15 mg Auto-Injectors are for the emergency treatment of severe allergic reactions (anaphylaxis). As with any medication, EpiPen Auto-Injector has an expiration date printed directly on the side of the auto-injector and end side of the carton and should be replaced when the unit expires. The product should be stored at room temperature, protected from light and never refrigerated or kept where it might be exposed to extreme temperatures, such as in the glove compartment of a car.

#### Indications

EpiPen® and EpiPen Jr® (0.3 and 0.15 mg epinephrine) 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 self-administration as emergency supportive therapy only. Seek immediate emergency medical treatment after use.

### **Important Safety Information**

EpiPen® Auto-Injectors contain a single dose of epinephrine, which you inject into your outer thigh. DO NOT INJECT INTRAVENOUSLY. DO NOT INJECT INTO YOUR BUTTOCK, as this may not be effective. In case of accidental injection, please seek immediate medical treatment. Epinephrine should be used with caution if you have heart disease or are taking certain medicines that can cause heart-related (cardiac) symptoms.

If you take certain medicines, you may develop serious life-threatening side effects from the epinephrine in

**EpiPen Auto-Injectors.** Be sure to tell your doctor all the medicines you take, especially medicines for asthma. Side effects may be increased in patients with certain medical conditions, or who take certain medicines. These include asthma, allergies, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure and heart disease. The most common side effects may include increase in heart rate, stronger or irregular heartbeat, sweating, nausea and vomiting, difficulty breathing, paleness, dizziness, weakness or shakiness, headache, apprehension, nervousness or anxiety. These side effects usually go away quickly, especially if you rest.

Please <u>click here</u> to view the EpiPen prescribing information.

Please <u>click here</u> for the EpiPen patient insert.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit <u>www.fda.gov/medwatch</u> or call 1-800-FDA-1088.

# **About Mylan Specialty**

Mylan Specialty, a subsidiary of Mylan Inc. (Nasdaq: MYL), is a specialty pharmaceutical company focused on the development, manufacturing and marketing of prescription drug products for the treatment of respiratory diseases, severe allergic reactions and psychiatric disorders. The company puts patients first and facilitates efficient, cost-effective partnerships with customers. For more information, please visit <u>www.mylanspecialty.com</u>.

# **About Mylan**

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 150 countries and territories. The company maintains one of the industry's broadest and highest quality product portfolios supported by a robust product pipeline; operates one of the world's largest active pharmaceutical ingredient manufacturers; and runs a specialty business focused on respiratory, allergy and psychiatric therapies. For more information about Mylan, please visit <u>www.mylan.com</u>. For more information about generic drugs, please visit <u>www.ChoosingGenerics.com</u>.

# Pfizer Inc: Working together for a healthier world®

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at <u>www.pfizer.com</u>.

Mylan Forward-Looking Statement: This press release includes statements that constitute "forward-looking statements," including with regard to the settlement and the marketing of the product. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: any legal or regulatory challenges to the settlement; strategies by competitors or other third parties to delay or prevent product introductions; risks inherent in legal and regulatory processes; and the other risks detailed in the company's periodic filings with the Securities and Exchange Commission. The company undertakes no obligation to update these statements for revisions or changes after the date of this release.

PFIZER DISCLOSURE NOTICE: The information contained in this release is of February 16, 2012. Pfizer assumes no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.

This release contains forward-looking information that involves substantial risks and uncertainties regarding the settlement agreement and the marketing of the EpiPen Auto-Injector. Actual results may differ materially from those expressed in or implied by such forward-looking statements. Such risks and uncertainties include, among other things, the possibility of legal or regulatory challenges to the settlement agreement and the impact of competitive pressures on the marketing of the EpiPen Auto-Injector.

A further list and description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2010 and in its reports on Form 10-Q and Form 8.

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