



August 7, 2012

## **Mylan Specialty and Pfizer Announce Licensing Agreement for EpiPen® Injection 0.3/0.15mg in Japan**

### **Agreement to deliver important treatment option for life-threatening allergic reactions in Japan**

BASKING RIDGE, N.J. and NEW YORK, Aug. 7, 2012 /PRNewswire/ -- Mylan Specialty L.P., a subsidiary of Mylan Inc. (Nasdaq: MYL), and Pfizer Inc. (NYSE: PFE) today announced a license agreement, under which Pfizer will obtain the exclusive rights to market and sell EpiPen® Injection 0.3/0.15mg in Japan. These products, known in the U.S. as EpiPen® (epinephrine) 0.3mg and EpiPen Jr® (epinephrine) 0.15mg Auto-Injectors, are for self-administration for the emergency treatment of life-threatening allergic reactions (anaphylaxis) caused by allergens, exercise or unknown triggers. EpiPen Injection is the only approved epinephrine auto-injector in Japan.

"We are very excited to extend our partnership with Pfizer to this important market," said Mylan Chief Executive Officer Heather Bresch. "Last year, we announced that the Japanese Ministry of Health, Labour and Welfare approved National Health Insurance price listing for EpiPen Injection. We have built on this positive momentum by recently launching our next-generation EpiPen Injection in Japan. We look forward to achieving success with Pfizer as our partner that furthers our commitment to better serve the people of Japan who suffer from life-threatening allergies."

Under the terms of the agreement, the exclusive rights to market and sell the next-generation EpiPen Injection in Japan will be transferred to Pfizer from Mylan Seiyaku. The next-generation EpiPen Injection and EpiPen Auto-Injector are currently available in Japan, the U.S., Canada, South Africa, Australia and certain European countries.

"Pfizer and Mylan share a deep commitment to serve the people of Japan who are at risk for anaphylaxis," said Ichiro Umeda, President Pfizer Japan. "This agreement will help us to better address this important public health issue in Japan — from improving awareness and preparedness, to expanding access to treatment — through Pfizer's existing commercial infrastructure and market expertise."

The financial terms of the agreement were not disclosed.

### **About Anaphylaxis and Food Allergies**

Anaphylaxis is a life-threatening allergic reaction that is rapid in onset and may cause death, either through swelling that shuts off airways or through a significant drop in blood pressure.<sup>1</sup> Anaphylaxis can be triggered by certain foods, insect stings, medications, latex, exercise or other allergens.<sup>1</sup>

A food allergy is a medical condition in which the immune system incorrectly identifies a food protein as a threat and attempts to protect the body against it by releasing chemicals into the blood. The release of these chemicals results in the symptoms of anaphylaxis.<sup>2</sup> According to Japan's "Food Allergy Management Guideline 2008," the foods that most commonly cause anaphylaxis in Japan include hen's eggs, cow's milk products, wheat, shellfish, fruits, buckwheat, fish and peanuts.<sup>3</sup>

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

EpiPen® (epinephrine) 0.3 mg and EpiPen Jr® (epinephrine) 0.15 mg Auto-Injectors are approved in the U.S. 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 [click here](#) to view the EpiPen Auto-Injector prescribing information.

Please [click here](#) for the EpiPen Auto-Injector patient insert.

For more information about EpiPen Auto-Injector, please visit [www.epipen.com](http://www.epipen.com).

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

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

## References

1. Simons FER. Anaphylaxis. *J Allergy Clin Immunol*. 2010;125(2)(suppl 2):S161-S181.
2. Boyce JA, Assa'ad A, Burks AW, et al. Guidelines for the diagnosis and management of food allergy in the United States: report of the NIAID-Sponsored Expert Panel. *J Allergy Clin Immunol*. 2010;126(6 suppl):S1-S58.
3. Ebisawa M. Management of Food Allergy in Japan "Food Allergy Management Guideline 2008 (Revision from 2005)" and "Guidelines for the Treatment of Allergic Diseases in Schools." *Allergology International*. 2009 Nov; 58(4):1-9.

*This press release includes statements that constitute "forward-looking statements," including with regard to the license agreement. 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: the impacts of competition; failure to achieve anticipated sales; changes in economic and financial conditions of the companies' businesses; uncertainties and matters beyond the control of management; and the other risks detailed in the companies' filings with the Securities and Exchange Commission. The companies undertake no obligation to update these statements for revisions or changes after the date of this release.*

## 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 [www.mylanspecialty.com](http://www.mylanspecialty.com).

## About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in health care. 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 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 1,100 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately one-third of HIV/AIDS patients in developing countries depend. We also operate one of the largest active pharmaceutical ingredient manufacturers and currently market products in approximately 150 countries and territories. Our workforce of more than 18,000 people is dedicated to improving the customer experience and increasing pharmaceutical access to consumers around the world. But don't take our word for it. See for yourself. See inside. [mylan.com](http://mylan.com)

## About 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 [www.pfizer.com](http://www.pfizer.com).

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