

Dey Pharma Commemorates 14th Annual Food Allergy Awareness Week

Week promotes broader education of food allergies, a growing public health issue

BASKING RIDGE, N.J., May 10, 2011 /PRNewswire/ -- Dey Pharma, L.P., a subsidiary of Mylan Inc. (Nasdaq: MYL), is pleased to recognize the 14th annual Food Allergy Awareness Week (FAAW), May 8-14. Created by the Food Allergy and Anaphylaxis Network (FAAN) in 1997, FAAW aims to educate others and raise awareness about food allergies, a medical condition which affects one in 25 Americans.(1,2) Food allergies are the most common trigger of anaphylaxis,(3) a severe allergic reaction that can be fatal within minutes.(4,5)

Heather Bresch, Mylan's President commented: "It is alarming that many people are unaware that a food allergy can potentially be a life-threatening medical condition. For some food allergy sufferers, even trace amounts of a food allergen can cause a reaction.(6) Further, even those who have food allergies may not realize that mild allergic reactions may be followed by a severe reaction after a second exposure to the same allergen.(7) Raising awareness and broadening education about the prevalence and risk of food allergies is a critical mission for Dey and Mylan and we are committed to helping people, especially children, who face daily challenges in managing their food allergies, better inform and protect themselves. That is why we are so honored to participate in FAAN's 14th Annual Food Allergy Awareness Week."

The opportunity to further educate about food allergies and anaphylaxis is particularly relevant this year with the recent introduction of the 2010 Guidelines for the Diagnosis and Management of Food Allergy in the United States. The new guidelines were developed by an expert panel sponsored by the National Institute of Allergy and Infectious Diseases (NIAID); a division of the Centers for Disease Control and Prevention (CDC). While designed for health care professionals, the NIAID guidelines provide a number of recommendations important for patients and caregivers on management of food allergies:

- The most common food allergens are eggs, milk, peanuts, tree nuts, soy, wheat, crustacean shellfish and fish(8)
- The severity of an allergic reaction to food is based on many factors, which means the severity of any future reaction cannot be accurately predicted by the severity of a past reaction(8)
- Epinephrine is the drug of choice for anaphylaxis and should be administered as first-line therapy(8)
- Epinephrine should be available at all times to patients at risk(6)
- If a person is experiencing anaphylaxis, they should administer epinephrine and immediately seek medical attention by calling 9-1-1(8)
- A delay in or lack of administering epinephrine has been repeatedly implicated in anaphylaxis fatalities; the use of antihistamines is the most common reason reported for not using epinephrine(8)

Bresch continued: "Tragic and preventable anaphylaxis-related events occur across the U.S. year-round due to a lack of awareness of the causes (or triggers) of anaphylaxis and failure to recognize the signs and symptoms. Being prepared with immediate access to an epinephrine auto-injector is critical to a positive outcome when a potentially life-threatening allergic reaction occurs. Through the introduction of the NIAID guidelines and important events like Food Allergy Awareness Week, we are hopeful that deaths from food-related anaphylaxis can be reduced."

About Anaphylaxis

Anaphylaxis is a severe allergic reaction that involves a number of body systems and can be fatal within minutes, either through swelling that shuts off airways or through a significant drop in blood pressure.(4,5) Anaphylaxis can be triggered by certain foods, insect stings, medications, latex or other allergens.(5) Twelve million Americans -- 4% of the population -- have a food allergy that may put them at risk for anaphylaxis.(6) There are approximately 50 to 2,000 episodes of anaphylaxis per every 100,000 people globally, translating to a 0.05% to 2.0% lifetime prevalence of anaphylaxis.(7) The precise incidence of anaphylaxis is unknown because this serious, life-threatening condition is believed to be underreported.(7) Failure to inject epinephrine promptly is associated with fatal anaphylaxis.(5)

About EpiPen Auto-Injector

EpiPen® and EpiPen Jr (0.3 and 0.15 mg epinephrine) 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.

Dey Pharma, L.P., the distributor of EpiPen Auto-Injector, offers patient support through a program that has a free membership at www.myepipen.com. This program provides helpful tips, resources and an expiration reminder program.

Indication

EpiPen and EpiPen Jr (0.3 and 0.15 mg epinephrine) Auto-Injectors are for the emergency treatment of severe 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 designed for immediate use in an emergency, to treat a severe allergic reaction fast and give you time to get to a hospital or medical center. EpiPen and EpiPen Jr are not a substitute for emergency medical treatment.

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.

For full prescribing information, please <u>click here</u> or visit <u>www.epipen.com</u>.

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 Dey

Dey Pharma, L.P., 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.dev.com.

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, please visit www.mylan.com.

EpiPen® is a registered trademark of Mylan Inc. licensed exclusively to its wholly-owned subsidiary, Dey Pharma, L.P.

References

- 1. Sicherer SH, Simons FE. Quandaries in prescribing an emergency action plan and self-injectable epinephrine for first-aid management of anaphylaxis in the community. *J Allergy Clin Immunol.* 2005;115(3):575-583.
- 2. Neugut Al, Ghatak AT, Miller RL. Anaphylaxis in the United States: an investigation into its epidemiology. *Arch Intern Med.* 2001;161(1):15-21.
- 3. American College of Allergy, Asthma and Immunology. Anaphylaxis Overview. Available at http://www.acaai.org/allergist/allergies/Anaphylaxis/Pages/default.aspx.
- 4. Sampson HA, Munoz-Furlong A, Campbell RL, et al. Second symposium on the definition and management of

- anaphylaxis: summary report -- Second National Institute of Allergy and Infectious Disease/Food Allergy and Anaphylaxis Network symposium. *J Allergy Clin Immunol.* 2006;117(2):391-397.
- 5. Simons FER. Anaphylaxis. J Allergy Clin Immunol. 2010;125(suppl 2):S161-S181.
- 6. Munoz-Furlong A, Weiss C. Characteristics of food-allergic patients placing them at risk for a fatal anaphylactic episode. *Curr Allergy Asthma Rep.* 2009;9(1):57-63.
- 7. Lieberman P, Camargo CA, Bohlke K, et al. Epidemiology of anaphylaxis: findings of the American College of Allergy, Asthma and Immunology Epidemiology of Anaphylaxis Working Group. *Ann Allergy Asthma Immunol.* 2006;97(5):596-602.
- 8. Boyce, 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 Dec:126(6):S1-58.

SOURCE Mylan Inc.

News Provided by Acquire Media