



March 1, 2014

## **Mylan Specialty to Present Poster Presentations about an Individual's Risk of Anaphylaxis at Upcoming Medical Meeting**

**Two poster presentations will highlight initial findings from The Anaphylaxis Risk Assessment (TARA) study, one of the largest U.S. managed care retrospective database reviews to date**

PITTSBURGH, March 1, 2014 /PRNewswire/ -- Mylan Specialty will present initial data from The Anaphylaxis Risk Assessment (TARA) study at the 2014 Annual Meeting of the American Academy of Allergy, Asthma and Immunology (AAAAI) held in San Diego, Calif., Feb. 28 - March 4. TARA aims to uncover factors associated with an individual's risk for experiencing a life-threatening allergic reaction (anaphylaxis) and involved a retrospective claims analysis of more than 28,000 medical records from a large managed care database associated with Optum.

"As leaders in the space, Mylan Specialty continually works to advance the understanding of anaphylaxis," said Roger Graham, President, Mylan Specialty. "Collectively, these data shed light on anaphylaxis risk factors and support the need for future research toward a clinically useful risk assessment tool for anaphylaxis."

Details for the TARA study poster sessions are as follows:

- **Methodology for Identifying Patients Presenting with Anaphylaxis Using Administrative Claims Data**  
*Poster 94, March 1, 2014; 12:45 p.m. EST*
- **Factors Associated With Increased Risk of Anaphylaxis**  
*Poster 73, March 1, 2014; 12:45 p.m. EST*

Additional presentations, supported by Mylan Specialty, include studies examining factors linked to untimely refills of epinephrine auto-injector prescriptions and a report of individual state pharmacist guidelines regarding substitution of epinephrine auto-injector prescriptions.

- **Factors Associated with a Lower Probability of Refilling an EpiPen<sup>®</sup> Auto-Injector in a Timely Manner**  
*Poster 88, March 1, 2014; 12:45 p.m. EST*
- **Confusion With Substituting Epinephrine Auto-Injectors: A Focus on Medication Counseling, Dispensing, and Patient Education**  
*Poster 96, March 1, 2014; 12:45 p.m. EST*

Full session details and data abstracts for the 2014 Annual Meeting can be found on the AAAAI website at <http://annualmeeting.aaaai.org/>; full-text abstracts are published in an online supplement of *The Journal of Allergy and Clinical Immunology* (JACI).

### **About the TARA Study**

The Anaphylaxis Risk Assessment (TARA) study is a retrospective claims analysis that used medical and pharmacy claims data from 2011 and 2012 for commercial enrollees in a large U.S. health plan associated with Optum. Data from adult and pediatric patients with claims-based evidence of anaphylaxis during emergency department or in-patient visits were identified and compared with data from controls with no evidence of anaphylaxis. A 12-month baseline period was used to assess patients' characteristics including history of allergies and conditions related to anaphylaxis, comorbidities and health care resource utilization and costs. Patient demographics and baseline characteristics were also compared between anaphylaxis cases and controls.

### **About Anaphylaxis**

Anaphylaxis is a life-threatening allergic reaction that has many possible triggers, occurs quickly, without warning, and must be treated immediately with epinephrine. Symptoms may include hives or redness of the skin, tightness in the throat, nausea, dizziness, breathing problems, a decrease in blood pressure and/or fainting. Anaphylaxis can be caused by triggers such as food, stinging and biting insects, medicines, latex or even exercise. Epinephrine is the only first-line treatment for anaphylaxis. According to the food allergy guidelines developed by the National Institute of Allergy and Infectious Diseases, if experiencing anaphylaxis, a person should use an epinephrine auto-injector and seek immediate emergency medical attention. Epinephrine is a naturally-occurring hormone, also known as adrenaline, and it should be available at all times to patients at risk. Delays in

epinephrine administration have been associated with negative health consequences, even possibly death.

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

EpiPen and EpiPen Jr Auto-Injectors are used for the emergency treatment of life-threatening allergic reactions. Each EpiPen 2-Pak<sup>®</sup> and EpiPen Jr 2-Pak<sup>®</sup> 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. EpiPen Auto-Injector has been the No. 1 dispensed epinephrine auto-injector for more than 25 years and has three-step easy-to-follow instructions for use. For more information about EpiPen Auto-Injector, please visit [www.EpiPen.com](http://www.EpiPen.com).

### **Indications**

EpiPen<sup>®</sup> (epinephrine) 0.3 mg and EpiPen Jr<sup>®</sup> (epinephrine) 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 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 INTO YOUR VEIN, BUTTOCK, FINGERS, TOES, HANDS OR FEET.** 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.

Tell your doctor if you have certain medical conditions such as asthma, depression, thyroid disease, Parkinson's disease, diabetes, high blood pressure and heart disease, 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 doctor 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 take the EpiPen or EpiPen Jr Auto-Injector.**

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.

Talk to your healthcare professional to see if EpiPen or EpiPen Jr Auto-Injector is right for you.

Please [click here](#) for Full Prescribing Information.

Please [click here](#) for Patient Information.

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.

### **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, life-threatening allergic reactions and psychiatric disorders. For more information, please visit [mylanspecialty.com](http://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 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 1,300 generic pharmaceuticals and several brand medications. In addition, we offer a wide range of antiretroviral therapies, upon which approximately 40% 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 140 countries and territories. Our workforce of more than 20,000 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)

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