Mylan CEO Heather Bresch Testifies Before Congress in Support of Generic Drug User Fee Program and Urges Update of Federal Food, Drug and Cosmetic Act of 1938 to Create a Level Playing Field for Manufacturers

PITTSBURGH, Feb. 9, 2012 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) CEO Heather Bresch today testified before the U.S. House of Representatives Energy and Commerce Committee at a hearing hosted by the subcommittee on Health entitled "Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages."

In her testimony, Bresch commented: "Every consumer should have the peace of mind in knowing that every prescription, brand or generic, dispensed in the United States, is held to the same standard of quality regardless of whether the product or its ingredients originated in the U.S. or outside its borders. With a mission to protect and promote the public health, the U.S. Food and Drug Administration ("FDA") has a critical responsibility, along with industry, to ensure the safety, efficacy and security of the U.S. drug supply. Unfortunately, FDA is still operating as a domestic agency, under a 1938 law that has remained largely unchanged despite globalization of the industry, which has left it without the resources or legal authority to regulate the global drug supply that now serves the U.S. market. Just as the pharmaceutical industry has become global, in order to meet its mission, so too must FDA."

Drug products, both branded and generic, originate in factories all over the world, moving into the American marketplace through supply chains that can involve numerous players. It is estimated that up to 40% of finished drugs consumed by U.S. patients are manufactured abroad and 80% of the active ingredients and bulk chemicals used in drugs come from foreign countries.[1] According to FDA, the number of foreign drug facilities supplying the U.S. has grown by 185% between 2001 and 2008, while at the same time FDA inspection rates have decreased by nearly 57%.[2]

Bresch further commented: "Mylan is pleased to have played a leading role in developing and negotiating a comprehensive user fee program for generic drugs ("GDUFA"), along with our colleagues across the generic and active pharmaceutical ingredient industries. Through GDUFA, the generic industry, which accounts for 78% of all prescriptions dispensed in the U.S., has stepped up to the plate to help provide FDA with resources to address the industry-wide challenges caused by the global drug supply and the corresponding increase in FDA's workload. Through GDUFA, the generic industry will provide FDA with approximately $1.5 billion in new funding over the next five years. In return, FDA has agreed to more timely review of generic drug applications, increased transparency, and biennial Good Manufacturing Practice (GMP) surveillance inspections of all generic finished dosage form ("FDF") and active pharmaceutical ingredient ("API") manufacturers— both foreign and domestic — on a risk adjusted basis.[3]"

"However, for GDUFA to truly be successful and to achieve the lasting change that we at Mylan and those across our industry wish to see, the currently outdated U.S. law [the Federal Food, Drug and Cosmetic Act of 1938 ("FDCA")] must be amended to reflect the 21st century needs of FDA in regulating the nation's global drug supply. For example, current law requires that U.S.-based manufacturers be inspected by FDA every two years, but does not require the same of foreign manufacturers. This significant disparity in the degree of FDA oversight creates an unlevel playing field by reducing the ability of American businesses to compete since complying with quality systems and FDA regulations represents approximately 25% of a drug manufacturer's operating costs.[4] U.S.-based facilities participating in both the U.S. and global pharmaceutical market should not be competitively disadvantaged and effectively encouraged to move jobs outside the U.S. as a result of an antiquated law that is impeding FDA from carrying out its oversight responsibilities over all players supplying the U.S. pharmaceutical market."

"Inspection parity will also benefit foreign facilities, as well as small and first-time entrants to the industry, which are currently disadvantaged by delays in gaining approval for new products — brand or generic — due to a lack of a recent inspection history, which is required before a new product can be approved."

"Mylan urges Congress to pass GDUFA, as unanimously ratified by industry, and update the FDCA. By taking these steps, we can further reduce government and taxpayer health care spending through more timely access to affordable generic medicine; ensure American competitiveness by addressing the unlevel playing field currently faced by U.S. manufacturers through inspection rates that are four times that of foreign competitors; and equip FDA with the authority it needs to carry out its mission of protecting the drug supply in today's highly globalized industry," Bresch's testimony concluded.

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 www.mylan.com. For more information about generic drugs, please visit www.ChoosingGenerics.com.

[1] U.S. Government Accountability Office*. Drug Safety: FDA Has Conducted More Foreign Inspections and Begun to Improve Its Information on Foreign Establishments, but More Progress Is Needed* (Publication No. GAO-10-961). (September 2010).

[2] Deborah M. Autor, Deputy Commissioner, U.S. Food and Drug Administration, *Ensuring the Safety, Efficacy, and Quality of Drugs*, A Roundtable on Ensuring the Safety of the U.S. Drug Supply, Mar 14-15, 2011.

[3] *See* GDUFA goals letter for further explanation of risk basis. *See also* GPhA's testimony before the Senate HELP Committee, dated Sept. 17, 2011. (A "risk-based" model for inspections prioritizes inspections according to a company's safety and compliance track record. This system would ensure that questionable or problematic facilities receive a comprehensive review and evaluation sooner. Facilities with strong records of compliance and positive inspections would be placed further down on the inspection schedule, allowing the agency to prioritize its immediate attention on companies that have never had an inspection or that have a history of compliance issues.)

[4] Pew Health Group, After Heparin: Protecting Consumers from the Risks of Substandard and Counterfeit Drugs, at 27.

SOURCE Mylan Inc.