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Mylan Supports Generic Drug Industry's Call on FDA to Uphold Consistent, Proven International Standard for Biosimilar Naming

-To avoid frivolous brand tactics and confusion in the marketplace, company urges use of identical, non-proprietary names to promote ongoing efforts to expand access and ensure patient safety-

PITTSBURGH, Sept. 23, 2013 /PRNewswire/ -- Mylan Inc. (Nasdaq: MYL) today expressed support for the Generic Pharmaceutical Association's (GPhA) filing of an official Citizen Petition with the Food and Drug Administration (FDA) detailing the industry's position on biosimilar naming. The petition recommends that all biosimilars approved by the agency share the same international non-proprietary name (INN) as the biologic products to which they refer. A drug's INN serves to clearly and universally state a medicine's main substance or ingredient — for example, Lipitor®'s INN, or generic name, is Atorvastatin Calcium. An approved biosimilar product will have been shown through rigorous physicochemical and functional testing to be as close to the reference product as the reference product is to itself from lot to lot, but with more affordability. It is therefore critical for the medical community to continue identifying biosimilars using the same naming convention as other medicines available to patients today.

Mylan CEO Heather Bresch commented: "Mylan's mission to set new standards in health care and expand access to high quality medicine is aligned with GPhA's Citizen Petition to FDA regarding the use of consistent international standards for biosimilar naming. The use of consistent INN's ensures patient safety as it helps to protect patients from concerns such as double dosing where two highly similar products may be prescribed."

The importance of consistent INN's to patient safety can be illustrated by the more than 150 different biologic INN's with over 250 different trade names on the market today. If each biologic were to have just four biosimilar options (i.e. fewer competitors than the average path taken by small molecules which have an average of 12 manufacturers per product), 600 new INN's would be added to the biologic products presently available. The unnecessary increase in unique product names could serve to confuse health care providers, put patient outcomes at risk and only further delay access to these critical products.

Bresch continued: "The use of a consistent INN naming standard has been in place for more than 50 years and is used in scores of countries around the world. Multiple biologics have already been approved in the U.S. using the same INN, and continuing to use this proven naming methodology represents an important step to ensure that patients in the U.S. and elsewhere can benefit from expanded access to more affordable biologic medicines."

Mylan urges the wide variety of impacted stakeholders to continue working together to maintain and expand access to high quality medicines in the U.S., including biosimilar drugs that share the same INN name as their reference product.

For more information about GPhA's Citizen Petition, please access the [full letter](#). For more information about biosimilars, visit: <http://www.gphaonline.org/issues/biosimilars>.

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 approximately 1,100 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

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