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Mylan Invalidates Allergan's Patents on Restasis®

HERTFORDSHIRE, England, and PITTSBURGH, Oct. 16, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced that the United States District Court for the Eastern District of Texas has issued a 135-page decision finding all asserted claims of the patents relating to Restasis® invalid based on obviousness. The Court, recognizing that Allergan's patent protection for Restasis ended in 2014, concluded that "Allergan is not entitled to renewed patent rights for Restasis in the form of a second wave of patent protection." The invalidated patents are United States Patent Numbers 8,629,111; 8,648,048; 8,685,930 and 9,248,191. Mylan received a covenant not to sue on the remaining two Orange Book patents, U.S. Patent Numbers 8,633,162 and 8,642,556, shortly before the trial began.



The Court's decision also will be binding against the Saint Regis Mohawk Tribe, which the Court added to the lawsuit. In ultimately allowing the Tribe to join the lawsuit, the Court expressed its concerns that "sovereign immunity should not be treated as a monetizable commodity that can be purchased by private entities as part of a scheme to evade their legal responsibilities. It is not an inexhaustible asset that can be sold to any party that might find it convenient to purchase immunity from suit. Because that is in essence is [sic] what the agreement between Allergan and the Tribe does, the Court has serious reservations about whether the contract between Allergan and the Tribe should be recognized as valid, rather than being held void as being contrary to public policy."

Mylan CEO Heather Bresch commented, "We couldn't be more pleased with today's federal court ruling invalidating the Restasis patents. For decades, our investments and perseverance continue to pay off as we have led the charge in challenging the unnecessary roadblocks often put up by brand pharmaceutical companies, whether it's through the regulatory pathway or around its intellectual property, which often delay access to affordable generic medicines to patients.

Bresch continued, "We look forward to continuing to work with the FDA to expeditiously bring our more affordable, generic Restasis product to patients."

The admitted purpose of the Allergan/Saint Regis Mohawk Tribe transaction was to employ Native American sovereign immunity to cut-off pending IPR proceedings before the Patent Trial and Appeal Board (PTAB) and to prevent the PTAB from canceling Allergan's invalid patents. The Court's decision emphasized the duplicitousness of Allergan's changing course with respect to the Patent Office, explaining that the company "invoked the benefits of the patent system" but now seeks "the right to continue to enjoy the considerable benefits of the U.S. patent system without accepting the limits that Congress has placed on those benefits."

Forward-Looking Statements

This press release includes statements that constitute "forward-looking statements," including with regard to the status of litigation and that Mylan has been working with FDA for years to gain approval for generic Restasis and is proud that Mylan's investment and perseverance will contribute to bringing this product to patients. 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: any changes in or difficulties with Mylan's or its partners' ability to develop, manufacture, and commercialize products; any regulatory, legal, or other impediments to Mylan's or its partners' ability to bring products to market, including generic Restasis; Mylan's and its partners' ability to protect intellectual property and preserve intellectual property rights; the effect of any changes in Mylan's or its partners' customer and supplier relationships and customer purchasing patterns; other changes in third-party relationships; the impact of competition; changes in the economic and financial conditions of the businesses of Mylan or its partners; the scope, timing, and outcome of any ongoing legal proceedings, including any appeal of the Court's decision invalidating the Restasis patents, and the impact of any such proceedings on Mylan's or its partners' business; actions and decisions of healthcare and pharmaceutical regulators, and changes in healthcare and pharmaceutical laws and regulations, in the United States and abroad; risks associated with international operations; other uncertainties and matters beyond the control of management; and the other risks detailed in Mylan's filings with the Securities and Exchange Commission. Mylan undertakes no obligation to update these statements for revisions or changes after the date of this release.

About Mylan

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. 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 7,500 marketed products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at Mylan.com.

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