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Mylan Launches Generic Cleocin® Solution

HERTFORDSHIRE, England and PITTSBURGH, June 3, 2016 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Clindamycin Palmitate Hydrochloride for Oral Solution USP, 75 mg/5 mL, which is a generic version of Pharmacia and Upjohn's Cleocin® Solution. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which is indicated for the treatment of serious infections caused by susceptible anaerobic bacteria and susceptible strains of streptococci, pneumococci and staphylococci when less toxic alternatives are inappropriate.(1)



Clindamycin Palmitate Hydrochloride for Oral Solution USP, 75 mg/5 mL, had U.S. sales of approximately \$30.9 million for the 12 months ending March 31, 2016, according to IMS Health.

Currently, Mylan has 253 ANDAs pending FDA approval representing \$108.2 billion in annual brand sales, according to IMS Health. Forty-three of these pending ANDAs are potential first-to-file opportunities, representing \$37.2 billion in annual brand sales, for the 12 months ending December 31, 2015, according to IMS Health.

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 1,400 generic and branded pharmaceuticals, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in approximately 165 countries and territories. Our global R&D and manufacturing platform includes more than 50 facilities, and we are one of the world's largest producers of active pharmaceutical ingredients. Every member of our nearly 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at mylan.com.

(1) *Clostridium difficile* associated diarrhea (CDAD) has been reported with use of nearly all antibacterial agents, including clindamycin and may range in severity from mild diarrhea to fatal colitis. Treatment with antibacterial agents alters the normal flora of the colon leading to overgrowth of *C. difficile*. Because clindamycin therapy has been associated with severe colitis which may end fatally, it should be reserved for serious infections where less toxic antimicrobial agents are inappropriate.

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