



Mylan Rebukes and Cites Flaws in Bayer-Sponsored Mylan-Nifedipine Extended Release Bioequivalence Study in Canada

TORONTO, Mar 9, 2010 (Canada NewsWire via COMTEX News Network) -- Mylan (Nasdaq: MYL) today reported that it has identified multiple flaws within a purported bioequivalence study sponsored by Bayer Inc. of Canada. The study compared Bayer's antihypertensive Adalat(R) XL(R) tablets, 60 mg, marketed in Canada, to Mylan's approved generic version, Mylan-Nifedipine Extended Release tablets, 60 mg, marketed in Canada.

Mylan-Nifedipine Extended Release has been sold in Canada since January 2009, after meeting Health Canada's stringent requirements for marketing approval. These requirements included multiple bioequivalence studies in full compliance with Health Canada guidance. These studies demonstrated bioequivalence in all cases, and approval by Health Canada confirmed that Mylan's product is therapeutically equivalent to the brand version. Mylan's product is listed as a benefit in all provincial drug formularies. More than 25 million doses of Mylan-Nifedipine Extended Release, 60 mg, were sold in 2009.

Mylan Vice President of Pharmacokinetics and Drug Metabolism Russell Rackley, Ph.D. commented: "Bayer's study of Mylan's Mylan-Nifedipine Extended Release is misleading. It makes therapeutically irrelevant inferences, utilizes inferior design elements and does not meet Health Canada Guidelines in several areas."

Marvin C. Meyer, Ph.D., Professor Emeritus, University of Tennessee at Memphis and consultant to Mylan, has submitted a formal rebuttal to the International Journal of Clinical Pharmacology and Therapeutics entitled "Critical Questions Concerning the Validity of the Bayer Study Report of 'Differences in bioavailability between 60 mg of nifedipine osmotic push-pull systems after fasted and fed administration.'" Peer review and publication is pending.

Given the flaws in the Bayer-sponsored study, Mylan encourages health care providers to reject its therapeutically inaccurate conclusions and be assured that Mylan's product meets all of Health Canada's stringent guidelines for bioequivalence.

Mylan Inc. ranks among the leading generic and specialty pharmaceutical companies in the world and provides products to customers in more than 140 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, please visit www.mylan.com.

SOURCE: Mylan Pharmaceuticals ULC

Kathleen Stelmach, Torchia Communications, (416) 341-9929, ext. 227,
kathleen@torchiacom.com

Copyright (C) 2010 CNW Group. All rights reserved.

News Provided by COMTEX