FDA Accepts for Filing Mylan's ANDA for Generic Copaxone(R)

PITTSBURGH, Sept 14, 2009 /PRNewswire-FirstCall via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today announced that the U.S. Food and Drug Administration (FDA) has accepted for filing Mylan Pharmaceutical Inc.'s abbreviated new drug application (ANDA) for Glatiramer Acetate Injection (20 mg/mL), a generic version of Teva's Copaxone(R), a product indicated for the treatment of multiple sclerosis.

As previously announced, Mylan entered into a license and supply agreement with NATCO Pharma Ltd. (NATCO) which granted Mylan exclusive distribution rights for Glatiramer Acetate pre-filled syringes in the U.S. and all major markets in Europe, Australia, New Zealand, Japan and Canada. The agreement also includes an option to potentially expand into additional territories.

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 the world's third largest active pharmaceutical ingredient manufacturer; and runs a specialty business focused on respiratory and allergy therapies. For more information, please visit www.mylan.com.

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