Mylan Announces Tentative FDA Approval for Paroxetine Hydrochloride Extended-Release Tablets

PITTSBURGH, May 31 /PRNewswire-FirstCall/ -- Mylan Laboratories Inc. (NYSE: MYL) today announced that Mylan Pharmaceuticals Inc. has received tentative approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Paroxetine Hydrochloride Extended-release Tablets, 12.5 mg and 25 mg.

Mylan's ANDA is eligible to receive final approval on June 29, 2007, concurrent with the expiration of the pediatric exclusivity associated with U.S. patent 4,721,723.

Paroxetine Hydrochloride Extended-release Tablets are the generic version of GlaxoSmithKline's Paxil CR®. Paroxetine Hydrochloride Extended-release Tablets had U.S. sales of approximately $307 million for the 12 months ending March 31, 2007, for the same strengths.

Mylan Laboratories Inc. is a leading pharmaceutical company with three principal subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc. and UDL Laboratories Inc., and a controlling interest in Matrix Laboratories Limited, India. Mylan develops, licenses, manufactures, markets and distributes an extensive line of generic and proprietary products.

For more information about Mylan, please visit www.mylan.com.

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