# Mylan Receives Tentative FDA Approval for Generic Version of Singulair(R)

PITTSBURGH, May 29 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL) today announced that it has received tentative approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Montelukast Sodium Tablets, 10 mg (base).

Montelukast Sodium Tablets are the generic version of Merck and Co.'s Singulair®, which had total U.S. sales of approximately $2.6 billion for the 12 months ending March 31 for the same strength, according to IMS Health. This product is indicated for asthma and allergy treatment.

Currently, Mylan has 117 ANDAs pending FDA approval representing $82.1 billion in annual brand sales, according to IMS Health. Thirty-five of these pending ANDAs are potential first-to-file opportunities, which represent $16.7 billion in annual brand sales, according to IMS Health.

Mylan Inc., which provides products to customers in more than 140 countries and territories, ranks among the leading diversified generics and specialty pharmaceutical companies in the world. The company maintains one of the industry's broadest -- and highest quality -- product portfolios, supported by a robust product pipeline; owns a controlling interest in the world's third largest active pharmaceutical ingredient manufacturer; and operates a specialty business focused on respiratory and allergy therapies. For more information, please visit www.mylan.com.

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