Mylan Receives Approvals for Generic Versions of Hyzaar® and Cozaar®

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PITTSBURGH, Oct. 15 /PRNewswire-FirstCall/ -- Mylan Inc. (Nasdaq: MYL [1]) today announced that its subsidiary Mylan Pharmaceuticals Inc. received final approvals from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Applications (ANDAs) for the generic versions of Hyzaar® Tablets, 50 mg/12.5 mg and 100 mg/25 mg, and Cozaar® Tablets, 25 mg, 50 mg and 100 mg, both antihypertensives. Merck and Co. Inc.'s Hyzaar® is known generically as Losartan Potassium and Hydrochlorothiazide (HCTZ) Tablets and Merck Research Laboratories' Cozaar® is known generically as Losartan Potassium Tablets.

Losartan Potassium and HCTZ Tablets, 50 mg/12.5 mg and 100 mg/25 mg, had U.S. sales of approximately $570 million and Losartan Potassium Tablets had U.S. sales of approximately $940 million for the 12 months ending June 30, 2010, according to IMS Health. Both products are available for immediate shipment. Mylan Pharmaceuticals received final FDA approval and launched the 100 mg/12.5 mg strength of Losartan Potassium and HCTZ Tablets on April 6, 2010.

Currently, Mylan has 151 ANDAs pending FDA approval representing $92.9 billion in annual sales, according to IMS Health. Forty-two of these pending ANDAs are potential first-to-file opportunities, representing $21.9 billion in annual brand sales, for the 12 months ending June 30, 2010, according to IMS Health.

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 informatio
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