



## **Mylan Receives Approval for Fludarabine Phosphate Injection, USP**

PITTSBURGH, Oct 04, 2010 /PRNewswire via COMTEX News Network/ -- Mylan Inc. (Nasdaq: MYL) today announced that its subsidiary Bioniche Pharma received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for Fludarabine Phosphate Injection USP, 25 mg/mL, packaged in 50 mg/2 mL Single-dose Vials. The product was determined to be bioequivalent and, therefore, therapeutically equivalent to Teva Parenteral's Fludarabine Phosphate Injection USP, 25 mg/mL, a chemotherapy medication for B-cell chronic lymphocytic leukemia (CLL).

Fludarabine Phosphate Injection USP, 25 mg/mL had U.S. sales of approximately \$15 million for the 12 months ending June 30, 2010, according to IMS Health.

Bioniche Pharma is part of Mylan Institutional, a newly created platform that provides differentiated pharmaceutical products to institutional customers throughout North America. Mylan Institutional's product offering includes the specialty injectables of Bioniche Pharma with the unit dose capabilities of Mylan's UDL Laboratories. Mylan Institutional's customers include group purchasing organizations, wholesalers, hospitals, surgical and radiology services, home infusion service providers, long-term care facilities, correctional facilities, specialty pharmacies, veterinary clinics and retail outlets.

Currently, Mylan has 150 ANDAs pending FDA approval representing \$94.2 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 information, please visit [www.mylan.com](http://www.mylan.com).

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