



## **Mylan Laboratories and Watson Pharmaceuticals Announce Receipt of 'Approvable' Letter for EMSAM**

PITTSBURGH & CORONA, Calif.--(BUSINESS WIRE)--Feb. 2, 2004--Mylan Laboratories Inc. (NYSE:MYL) and Watson Pharmaceuticals, Inc. (NYSE:WPI) announced today that Somerset Pharmaceuticals, Inc. has received an "Approvable" letter from the U.S. Food and Drug Administration (FDA) for EMSAM™ (selegiline transdermal system), the company's transdermal therapy for which they are seeking an indication for the treatment of major depressive disorder. Somerset is a joint venture between Mylan and Watson.

The FDA's letter indicates that Somerset has submitted sufficient data to support the efficacy of EMSAM (20mg, 30 mg & 40mg) in the acute and maintenance treatment of major depressive disorder. Somerset has initiated discussions with the FDA to review and clarify its comments. These comments include that Somerset conduct Phase 4 post-marketing pharmacokinetic and safety studies as well as additional pharmacology/toxicology studies. In addition, Somerset will initiate discussions with the FDA regarding proposed labeling, including FDA's request to include labeling addressing tyramine dietary restrictions while taking EMSAM.

"We will work diligently with the FDA on the specific additional requirements needed to obtain approval of our EMSAM™ product," said Mel Sharoky, M.D., Somerset's president and chief executive officer. "With over 2,000 depressed patients exposed to EMSAM, we are encouraged by the product's safety data and view EMSAM as an important advance in the treatment of depression. At the same time, Somerset will continue its discussions to out license EMSAM with a potential partner."

Mylan Laboratories Inc.

Mylan Laboratories Inc. is a leading pharmaceutical company with four subsidiaries, Mylan Pharmaceuticals Inc., Mylan Technologies Inc., UDL Laboratories Inc. and Bertek Pharmaceuticals Inc., that develop, manufacture and market an extensive line of generic and proprietary products.

For more information about Mylan, visit [www.mylan.com](http://www.mylan.com).

Watson Pharmaceuticals, Inc.

Watson Pharmaceuticals, Inc., headquartered in Corona, CA, is a leading specialty pharmaceutical company that develops, manufactures, markets and distributes branded and generic pharmaceutical products. Watson pursues a growth strategy combining internal product development, strategic alliances and collaborations and synergistic acquisitions of products and businesses.

For press releases and other company information, visit Watson Pharmaceuticals' Web site at <http://www.watsonpharm.com>.

The parties caution that this press release may contain forward-looking statements, including with regard to EMSAM's safety and its role in the treatment of depression. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Actual future results may differ materially from those expressed or implied by such forward-looking statements due to such factors including, but not limited to, the results of the Phase 4 pharmacokinetic and safety studies and the additional pharmacology/toxicology studies, changing market conditions, the availability and cost of raw materials, the impact of competitive products and pricing, the timely development, FDA approval, and market acceptance of Somerset's and its competitors' products, the outcome of litigation and other risks detailed from time to time in the Securities and Exchange Commission filings of Mylan Laboratories Inc. and Watson Pharmaceuticals, Inc. Except as required by law, the parties undertake no obligation to update these statements for revisions or changes after the date of this release.

CONTACT: Mylan Laboratories Inc.  
Kris King, 724-514-1800  
or  
Watson Pharmaceuticals, Inc.  
Patty Eisenhour, 909-493-5611

SOURCE: Mylan Laboratories Inc.