Mylan Announces FDA Approval Of APOKYN NDA; A Novel Treatment in Parkinson's Disease

PITTSBURGH--(BUSINESS WIRE)--April 22, 2004--Mylan Laboratories Inc. (NYSE: MYL) announced that its branded-drug subsidiary, Bertek Pharmaceuticals Inc., received notice from the Food and Drug Administration (FDA) following their priority review that APOKYN™ (apomorphine hydrochloride injection) has been approved as the first and only therapy in the United States for the acute, intermittent treatment of hypomobility, "off" episodes ("end-of-dose wearing off" and unpredictable "on/off" episodes) associated with advanced Parkinson's disease.

"This is a significant day for the Parkinson's community and another milestone in Mylan's mission to develop pharmaceutical products that address unmet medical needs," said Robert J. Coury, Mylan Vice Chairman and CEO.

The FDA approval clears the way for Bertek to market APOKYN and provides a new therapy for "off" episodes, one of the most debilitating aspects suffered by patients with Parkinson's disease. The approval includes post marketing study commitments, but will not impact market introduction of this important product. The product will be available by July 2004 and distributed through a limited specialty pharmacy network. APOKYN has orphan drug status, a federal designation to indicate the drug's exclusive use in treating a condition affecting fewer than 200,000 people in the United States. APOKYN will be the third orphan drug marketed by Mylan and Bertek.

About APOKYN

APOKYN provides patients with an effective treatment to use during an 'off' episode. "Off" episodes are debilitating periods of partial loss of movement or total immobility experienced by patients with advanced Parkinson's disease. As Parkinson's disease progresses, patients begin to experience immobilizing "off" episodes despite treatment with drugs used to increase or replace dopamine. APOKYN is not used to prevent "off" episodes and it does not replace other Parkinson's disease medications, but rather treats an existing "off" episode when it occurs. As an acute, rescue treatment, APOKYN helps patients experiencing a debilitating "off" episode to walk, talk or move around easier. The intensity, duration and frequency of "off" episodes vary for each sufferer. Patients with Parkinson's disease lose motor control during "off" episodes, making routine tasks such as walking and even speaking extremely difficult. Patients with Parkinson's or their caregivers administer the medication via injection under the skin.

"These debilitating effects are known all too well by patients experiencing 'off' episodes," said Dr. Mark Stacy, director of the Movement Disorders Section at Duke University Medical Center. "With the FDA approval of APOKYN, I can now offer patients an effective treatment to relieve them from these immobilizing 'off' episodes."

In clinical trials conducted by Bertek, APOKYN was effective in improving an overall measurement of patient movement. "The data from clinical trials show that APOKYN, when used in conjunction with standard pharmacological therapies for Parkinson's disease, has the ability to provide relief from an 'off' episode," said Dr. James H. Sherry, Vice President of Clinical Affairs at Bertek Pharmaceuticals Inc. "This is a new way for Parkinson's patients to reduce some of the burden of their disease."

The effectiveness of APOKYN for the acute treatment of "off" episodes associated with advanced Parkinson's disease was established in three randomized controlled clinical trials. Patients who received APOKYN demonstrated statistically significant improvement in their Unified Parkinson's disease Rating Scale part III (UPDRS) motor score at 20-minutes following the administration of the drug compared to a placebo injection. The UPDRS is used by researchers and clinicians around the world to measure disease severity in patients.

Important Information

APOKYN should not be used by patients who are being treated with certain drugs to treat nausea and vomiting or irritable bowel syndrome. These medications (including, for example, ondansetron, granisetron, dolasetron, palonesetron, and alosetron) called 5HT3 antagonists or blockers. In addition, APOKYN should not be used by patients who have an allergic reaction to the drug or its ingredients (notably sodium metabisulfite). APOKYN should be injected under the skin only, and not into a vein. Because APOKYN can cause severe nausea and vomiting, it is taken with an oral medicine that helps to prevent these effects. APOKYN may lower blood pressure (orthostatic hypotension), cause fainting, and increase the risk of falling. At recommended doses minimal increases in QTC were observed. Caution should be used when prescribing apomorphine with drugs that prolong the QT/QTC interval. Some patients treated with APOKYN may get sleepy during the day or fall asleep without warning while doing everyday activities. The most common side effects of APOKYN are yawning, dyskinesias, nausea and/or vomiting, sleepiness, dizziness, runny nose, hallucinations, fluid retention, chest pain, increased sweating, flushing, and

an unusually pale complexion.

About Bertek

Bertek Pharmaceuticals Inc., based in Research Triangle Park, N.C., develops and licenses proprietary pharmaceuticals, with a current focus on dermatology, neurology and cardiology. For more information, visit www.bertek.com.

About Mylan

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.

This press release includes statements that constitute "forward-looking statements," including with regard to the availability and use of APOKYN. These statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Because such statements inherently involve risks and uncertainties, actual future results may differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to: delays in the product launch, including due to matters outside of the Company's control; the Company's exposure to lawsuits and contingencies associated with its business; other uncertainties and matters beyond the control of management and the other risks detailed in the Company's periodic filings with the Securities and Exchange Commission. The Company undertakes no obligation to update these statements for revisions or changes after the date of this release.

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