FDA Approves New Drug to Treat Chronic Obstructive Pulmonary Disease

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SILVER SPRING, Md., March 1, 2011 /PRNewswire-USNewswire/ -- The U.S. Food and Drug Administration approved roflumilast, a pill taken daily to decrease the frequency of flare-ups (exacerbations) or worsening of symptoms from severe chronic obstructive pulmonary disease (COPD).

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COPD is a serious lung disease that makes breathing difficult. Symptoms can include breathlessness, chronic cough, and excessive phlegm. An exacerbation can last up to several weeks and result in lung function decline, increased risk of death, and may be associated with severe anxiety.

Cigarette smoking is the leading cause of COPD, according to the National Heart, Lung, and Blood Institute. COPD is the fourth leading cause of death in the United States.

Roflumilast, a new drug class for the treatment of COPD, is an inhibitor of an enzyme called phosphodiesterase type 4 (PDE-4). It is indicated for people with severe COPD to treat the symptoms of cough and excess mucus linked to bronchitis. Roflumilast is not intended to treat another form of COPD which involves primary emphysema.

"COPD is a serious disease that gets worse over time," said Curtis Rosebraugh, M.D., M.P.H., director of the Office of Drug Evaluation II in the FDA's Center for Drug Evaluation and Research. "New treatment options that reduce frequency of flare-ups or exacerbations are important in helping patients with COPD associated with chronic bronchitis and a history of exacerbations in managing this debilitating disease."

The safety and effectiveness of roflumilast was demonstrated in two Phase 3 clinical studies that included more than 1,500 patients ages 40 and older who received roflumilast. Those treated had a history of COPD associated with chronic bronchitis and had experienced an exacerbation of the disease during the 12 months prior to be
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