Merck to Continue Work with FDA for OXYTROL® as an Over-the-Counter Treatment for Overactive Bladder in Women

Terms:
Company Statements

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WHITEHOUSE STATION, N.J., Nov. 9, 2012 - Today, Merck (NYSE: MRK), known as MSD outside the United States and Canada, confirmed that the U.S. Food and Drug Administration's (FDA) Nonprescription Drug Advisory Committee proposed that the FDA consider labeling modifications as part of their review of OXYTROL (oxybutynin transdermal system) as an over-the-counter (OTC) treatment for overactive bladder (OAB) in women. The proposed brand name for the OTC product is OXYTROL FOR WOMEN. The panel members generally agreed that OXYTROL has demonstrated a favorable safety profile since it was first approved by the FDA as a prescription treatment in 2003. The FDA generally follows advisory committee recommendations, although it is not bound to do so.

Overactive bladder is a physically and emotionally draining condition affecting over 20 million women in the U.S. Rather than seek treatment, the majority of women choose to self-manage their condition with coping strategies that include pads, dark clothing, mapping out the nearest toilets, and avoiding social interactions outside the home.

“Access to an effective, over-the-counter treatment could significantly improve how women manage this condition, and help to treat the symptoms that current coping strategies cannot,” said Bridgette P. Heller, Executive Vice President and President, Merck Consumer Care. “We will continue to work closely with the FDA to address any questions the FDA might have in order to bring OXYTROL FOR WOMEN over-the-counter.”

OXYTROL is currently the only transdermal system (patch) available to treat OAB with a prescription. OXYTROL has been available by prescription since 2003. The active ingredient, oxybutynin, has been used to treat OAB for more than 30 years.

Merck licensed the exclusive rights to market, distribute and sell OXYTROL as a potential OTC treatment for OAB from Watson Pharma Inc. (NYSE: WPI).

Important Safety Information

The most commonly reported adverse events were application site reactions, dry mouth, constipation, diarrhea, dysuria, and abnormal vision. OXYTROL is contraindicated in patients with urinary retention, gastric retention, or uncontrolled narrow-angle glaucoma and in patients who are at risk for these conditions. OXYTROL is also contraindicated in patients who have demonstrated hypersensitivity to oxybutynin or other components of the product. OXYTROL should be administered with caution in the following patients: those with hepatic or renal impairment; clinically significant bladder outflow obstruction; gastrointestinal obstructive disorders because of the risk of gastric retention; patients with gastroesophageal reflux. Please see Prescribing Information.

About Merck Consumer Care

Today's Merck is a global healthcare leader working to help the world be well. Merck Consumer Care is a subsidiary of Merck & Co., Inc. Each day, millions count on one or more of our industry-leading brands that help prevent or treat various common conditions. These include household names such as CLARITIN® for allergies, COPPERTONE® for sun care, DR. SCHOLL’S® for foot care, and many more. For more information, visit www.merck.com and connect with us on Twitter, Facebook and YouTube.

Merck Forward-Looking Statement

This news release includes "forward-looking statements" within the meaning of the safe harbor provisions of the United States Private Securities Litigation Reform Act of 1995. Such statements may include, but are not limited to, statements about the benefits of the merger between Merck and Schering-Plough, including future financial and operating results, the combined company's plans, objectives, expectations and intentions and other statements that are not historical facts. Such statements are based upon the current beliefs and expectations of Merck's management and are subject to significant risks and uncertainties. Actual results may differ from those set forth in the forward-looking statements.

The following factors, among others, could cause actual results to differ from those set forth in the forward-looking statements: the possibility that all of the expected synergies from the merger of Merck and Schering-Plough will not be realized, or will not be realized within the expected time period; the impact of pharmaceutical industry regulation and healthcare legislation in the United States and internationally; Merck's ability to accurately predict future market conditions; dependence on the effectiveness of Merck's patents and other protections for innovative products; and the exposure to
litigation and/or regulatory actions.

Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events or otherwise. Additional factors that could cause results to differ materially from those described in the forward-looking statements can be found in Merck's 2011 Annual Report on Form 10-K and the company's other filings with the Securities and Exchange Commission (SEC) available at the SEC's Internet site (www.sec.gov).