



## News Release

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### FOR IMMEDIATE RELEASE

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### **FDA Approves OXYTROL<sup>®</sup> FOR WOMEN, the First Over-the-Counter Treatment for Overactive Bladder in Women**

#### ***New Over-the-Counter Option for More Than 20 Million Women with Overactive Bladder***

WHITEHOUSE STATION, N.J., January 25, 2013 – Merck (NYSE: MRK), known as MSD outside the United States and Canada, announced today that the U.S. Food and Drug Administration (FDA) has approved OXYTROL FOR WOMEN (oxybutynin transdermal system, 3.9 mg/day), the first and only over-the-counter (OTC) treatment for overactive bladder in women. OXYTROL FOR WOMEN addresses an important unmet need for overactive bladder, or OAB, a condition that affects more than 20 million American women. Despite the fact that OAB is a treatable medical condition, more than 80 percent of women with OAB do not seek treatment.

OAB is characterized by a number of symptoms that can be physically burdensome and emotionally draining, including a strong urge to urinate right away and the need to urinate more often than usual, with or without leakage. The majority of women who suffer develop the condition between the ages of 45 and 60 years old. According to the National Association for Continence, although OAB is a treatable medical condition, most women do not discuss their symptoms with a doctor and assume that the symptoms are a normal part of aging. Rather than seek treatment, many women try to manage their condition with coping strategies that include wearing pads and/or dark clothing, mapping out the nearest toilets, and avoiding social interactions outside the home.

"The approval of OXYTROL FOR WOMEN as an OTC treatment option is an exciting development for the millions of women who struggle to deal with OAB every day," said Eman Elkadry, M.D., Clinical Instructor Harvard Medical School; Boston Urogynecology Associates at Mount Auburn Hospital. "This effective, over-the-counter treatment offers women an option to

independently manage their condition and achieve a newfound sense of control. The approval also provides recognition that this is a real medical disorder that can be addressed."

The FDA approval of the prescription to OTC switch was based on data from several well-designed studies that demonstrated a woman's ability to correctly recognize OAB symptoms, understand key safety messages on the label, judge if the product is right, or wrong, for her, and appropriately use OXYTROL FOR WOMEN in an unsupervised setting. The FDA considers this a partial switch, as OXYTROL will remain available by prescription only for the treatment of OAB in men. The approval follows an FDA Advisory Committee meeting that occurred in November 2012.

"Merck is dedicated to increasing access to safe and effective treatments to help people better manage their health conditions and improve the quality of their lives," said Bridgette P. Heller, Executive Vice President and President, Merck Consumer Care. "We are proud to bring OXYTROL FOR WOMEN over-the-counter and provide a treatment option that can help women with OAB recognize and treat their symptoms."

Merck anticipates that OXYTROL FOR WOMEN will be available to customers in fall 2013.

Please visit [www.OxytrolForWomen.com](http://www.OxytrolForWomen.com) for more information.

### **About OXYTROL® FOR WOMEN**

OXYTROL® FOR WOMEN is the only over-the-counter treatment available for overactive bladder in women. The OXYTROL FOR WOMEN patch provides transdermal delivery of oxybutynin, an active ingredient used to treat OAB for more than 30 years. Each OXYTROL FOR WOMEN patch delivers 3.9 mg of oxybutynin per day for a continuous four days and nights.

Merck licensed the exclusive rights to market, distribute and sell OXYTROL as an OTC treatment for OAB from Actavis, Inc. (NYSE: ACT), formerly known as Watson Pharmaceuticals, Inc.

OXYTROL® (oxybutynin transdermal system) is a registered trademark of Watson Pharma, Inc.

### **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<sup>®</sup> for allergies, COPPERTONE<sup>®</sup> for sun care, DR. SCHOLL'S<sup>®</sup> for foot care, and many more. For more information, visit [www.merck.com](http://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 health care 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](http://www.sec.gov)).

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