MSD

News Release

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Media Contact: Tommy Ringart
(Tel):

Merck Statement Regarding the June 2008 Update to the Prescribing Information for PROPECIA (finasteride, 1mg) in the European Union

SWEDEN, XX JULY 2009 – The following statement issued by Merck Sharp & Dohme (MSD) pertains to the June 2008 update to the prescribing information for PROPECIA® (finasteride, 1mg).

MSD is confident in the efficacy and safety of PROPECIA, a medicine that has been prescribed to millions of patients with male pattern hair loss since its approval in 199X. Nothing is more important to Merck than the safety of its medicines and vaccines.

The prescribing information for PROPECIA was updated in June 2008 to include persistence of erectile dysfunction following the discontinuation of PROPECIA based on a limited number of post-marketing reports. This update was made in conjunction with the standard marketing authorization renewal process in the European Union (EU) in 2008. The revision was applied to the prescribing information in Austria, Denmark, Finland, France, Germany, Greece, Italy, Luxembourg, Netherlands, Iceland, Portugal, Spain, and Sweden.

In controlled clinical studies of PROPECIA, drug-related sexual undesirable effects were more common among finasteride-treated men than placebo-treated men, with frequencies of 3.8% vs 2.1%, respectively, during the first 12 months. The incidence of these effects decreased to 0.6% in finasteride-treated men over the following four years. Approximately 1% of men in each treatment group discontinued due to drug related sexual adverse experiences in the first 12 months, and the incidence declined thereafter.

There have been post-marketing reports of erectile dysfunction which persisted after discontinuation of PROPECIA. The fact that an adverse event has been reported does not reflect a conclusion that the post-marketing event is caused by PROPECIA. In general, a post-marketing adverse event may be caused by underlying disease, genetic condition, the medication, concomitant medications or background event that may occur coincidentally in any population.

After a thorough review of the data from the controlled clinical trials of PROPECIA, and a careful assessment of post-marketing adverse events, MSD believes that the data supports the continued use of PROPECIA in appropriate patients with male pattern hair loss. MSD will continue to communicate with patients and health care providers about PROPECIA in ways that will help inform their decisions about appropriate treatment choices.

Patients with male pattern hair loss should talk with their doctors if they have any questions about the benefits and risks of PROPECIA. They can also visit INSERT LOCAL WEBSITE ADDRESS for more information. Patients should not stop taking the medication without first discussing with their doctor.

Background on post-marketing adverse event reports

MSD continually reviews post-marketing reports as part of its ongoing commitment to monitor the safety profile of its medications. MSD submits these reports to regulatory agencies around the world for their review. In addition to reports that MSD receives directly from healthcare providers and patients or their caregivers, we review information published in the medical literature and gather adverse event reports through data obtained directly by regulatory agencies worldwide. Each report is individually reviewed. MSD encourages healthcare providers and consumers to report any adverse experience associated with any MSD medication or vaccine.

About PROPECIA

PROPECIA (finasteride 1 mg, MSD) is indicated for early stages of androgenetic alopecia in men only. PROPECIA is contraindicated in women when they are or may potentially be pregnant, because it may cause abnormalities of the external genitalia of a male fetus. Women should not handle crushed or broken tablets when they are or may potentially be pregnant because of the possibility of absorption of finasteride. PROPECIA tablets have a coating that will prevent contact with the active ingredient during normal handling, provided the tablets have not been broken or crushed.

About MSD

Merck & Co., Inc., Whitehouse Station, N.J., U.S.A., which operates in many countries as Merck Sharp & Dohme (MSD), is a global research-driven pharmaceutical company dedicated to putting patients first. Established in 1891, Merck currently discovers, develops, manufactures and markets vaccines and medicines to address unmet medical needs. The Company devotes extensive efforts to increase access to medicines through far-reaching programs that not only donate Merck medicines but help deliver them to the people who need them. Merck also publishes unbiased health information as a not-for-profit service. For more information, visit www.merck.com.

Forward-looking statement

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements are based on management's current expectations and involve risks and uncertainties, which may cause results to differ materially from those set forth in the statements. The forward-looking statements may include statements regarding product development, product potential or financial performance. No forward-looking statement can be guaranteed and actual results may differ materially from those projected. Merck undertakes no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise. Forward-looking statements in this press release should be evaluated together with the many uncertainties that affect Merck's business, particularly those mentioned in the risk factors and cautionary statements in Item 1A of Merck's Form 10-K for the year ended Dec. 31, 2007, and in any risk factors or cautionary statements contained in the Company's periodic reports on Form 10-Q or current reports on Form 8-K, which the Company incorporates by reference.

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