BAUSCH Health

Valeant Pharmaceuticals Announces U.S. Approval Of Luzu® Cream, 1%

November 15, 2013

LAVAL, Quebec, Nov. 15, 2013 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) announced today that its wholly owned subsidiary, Valeant Pharmaceuticals North America LLC, has received notice that the New Drug Application for Luzu® (luliconazole) Cream, 1% has been approved by the United States Food and Drug Administration (FDA). Luzu® Cream, 1% is indicated for the topical treatment of athlete's foot (interdigital tinea pedis), jock itch (tinea cruris), and ringworm (tinea corporis), caused by the organisms Trichophyton rubrum and Epidermophyton floccosum, in patients 18 years of age and older. These are very common skin diseases caused predominantly by dermatophyte fungi.

"We are pleased to receive FDA approval for Luzu® earlier than expected," said J. Michael Pearson, chairman and chief executive officer. "This is the first safe and effective product indicated for daily use over a one week period. This will be a welcome alternative to current options that require two weeks of treatment, and we believe Luzu® will position us well to address this growing unmet need."

Information about Luzu® (luliconazole) Cream, 1%

Luzu® (luliconazole) Cream, 1% is the first topical azole antifungal agent approved to treat tinea cruris and tinea corporis with a one-week, once-daily treatment regimen. All other approved treatments require two weeks of treatment. Interdigital tinea pedis is approved with a two-week, once-daily treatment. US approval is the first regulatory approval in North America. Luliconazole has been approved in Japan since 2005.

Luzu® has been extensively studied in the US, with three positive pivotal studies that were the basis for approval. These studies were conducted in 679 subjects with either tinea pedis or tinea cruris.

For the two pivotal studies in tinea pedis with a treatment duration of two weeks, the primary endpoint was stringently defined as complete clearance 4-weeks post-treatment, which means that the skin showed no clinical involvement and no evidence of fungus. In Study 1, 26% of subjects treated with Luzu® were completely cleared, compared to only 2% of subjects treated with vehicle. In Study 2, 14% of subjects treated with Luzu® were completely cleared, compared to only 3% of subjects treated with vehicle.

For the pivotal study in tinea cruris, complete clearance was assessed 3-weeks post-treatment. After 1 week of treatment, 21% of subjects treated with Luzu® were completely cleared, compared to only 4% of subjects treated with vehicle.

The most common adverse events were mild application site reactions, reported in less than one percent of subjects for both Luzu® and vehicle.

About Valeant Pharmaceuticals International, Inc.

Valeant Pharmaceuticals International, Inc. (NYSE/TSX: VRX) is a multinational specialty pharmaceutical company that develops, manufactures and markets a broad range of pharmaceutical products primarily in the areas of dermatology, eye health, neurology, and branded generics. More information about Valeant Pharmaceuticals International, Inc. can be found at
www.valeant.com
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Forward-Looking Statements

This press release may contain forward-looking statements, including, but not limited to, statements regarding the launch and role of Luzu® in the U.S. Forward-looking statements may generally be identified by the use of the words "anticipates," "expects," "intends," "plans," "should," "could," "would," "may," "will," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of management and are subject to certain risks and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. These risks and uncertainties include, but are not limited to, the uncertainty of product launches and the risks and uncertainties discussed in the Company's most recent annual or quarterly report and detailed from time to time in Valeant's other filings with the Securities and Exchange Commission and the Canadian Securities Administrators, which factors are incorporated herein by reference. Readers are cautioned not to place undue reliance on any of these forward-looking statements. These forward-looking statements speak only as of the date hereof. Valeant undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this press release or to reflect actual outcomes.

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