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Valeant Pharmaceuticals Announces Receipt Of U.S. FDA Complete Response Letter For Efinaconazole

May 28, 2013

LAVAL, Quebec, May 28, 2013 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) today announced that it has received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its New Drug Application (NDA) for efinaconazole for the treatment of onychomycosis. A CRL is issued by the FDA's Center for Drug Evaluation and Research when the review of a file is completed and questions remain that preclude the approval of the NDA in its current form. The questions raised by the FDA pertain only to Chemistry, Manufacturing and Controls (CMC) related areas of the container closure apparatus. As no efficacy or safety issues were raised by the FDA, Valeant believes that these items can be addressed and is working for a timely response to the FDA as soon as possible. Valeant remains committed to bringing efinaconazole to market as a potential new treatment for onychomycosis.

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, 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 our expectation to address matters raised in the Complete Response Letter, the approval of efinaconazole and the timing of any such approval. 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 approval of product candidates 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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