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Valeant Pharmaceuticals Announces Approval Of Jublia® For The Treatment Of Onychomycosis In Canada

October 03, 2013

LAVAL, Quebec, Oct. 3, 2013 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) announced today that its wholly owned subsidiary, Valeant Canada LP, has received notice that the New Drug Submission for Jublia® has been approved from the Canadian regulatory authority, Health Canada. Jublia® (efinaconazole 10% topical solution) is indicated for the treatment of mild to moderate onychomycosis, a common and destructive nail infection caused predominantly by dermatophyte fungi. The only currently approved topical treatments are lacquers with limited efficacy. Oral treatments are limited by drug interactions and numerous safety concerns including the potential for acute liver injury. Laser treatments only improve the appearance of the nail.

"Jublia® represents the first new topical onychomycosis treatment approved in more than a decade, and we are very excited to bring this new treatment option to patients in Canada," said J. Michael Pearson, chairman and chief executive officer. "An effective topical therapy like Jublia® is a logical treatment option to avoid drug interactions and systemic side effects, and we believe Jublia® will position us well to address a growing unmet need."

"There is a pressing need for an effective topical therapy for mild to moderate onychomycosis, especially in individuals who cannot tolerate or are not candidates for an oral antifungal," stated Dr. Aditya K. Gupta, M.D., Ph.D., F.A.A.D., F.R.C.P(C), Professor, Department of Medicine, University of Toronto, Canada. "The Phase III clinical trial data for Jublia® show that it is an effective and safe topical antifungal therapy for mild to moderate onychomycosis. Jublia® is likely to become widely prescribed by dermatologists, family physicians and other healthcare providers for the treatment of onychomycosis"

Information about Jublia® (efinaconazole 10% topical solution)

Jublia® (efinaconazole 10% topical solution), is the first topical triazole antifungal agent developed for distal lateral subungual onychomycosis (DLSO). Canadian approval is the first regulatory approval world-wide.

Being a solution, Jublia® is applied daily to the nail with a novel bottle that has a built-in flow-through brush applicator. It dries quickly and there is no need to remove excess product. There are no concerns for systemic side effects such as drug-drug interactions or acute liver injury.

Jublia® has been extensively studied prior to its approval. The two positive pivotal studies that were the basis for approval were published last year in the prestigious *Journal of the American Academy of Dermatology.* These international studies were conducted in 1,655 subjects with onychomycosis, including subjects in Canada.

For the pivotal studies, the primary endpoint was complete cure at Week 52, which required that the target nail show no clinical involvement and no evidence of fungus present by both KOH

testing and a negative fungal culture. In Study 1, 17.8% of subjects treated with Jublia® were completely cured, compared to only 3.3% of subjects treated with vehicle. In Study 2, 15.2% of subjects treated with Jublia® were completely cured, compared to only 5.5% of subjects treated with vehicle.

Adverse events that were reported were generally mild and transient and were similar between subjects treated with Jublia® and vehicle. The most commonly reported adverse events in patients treated with Jublia® were application site dermatitis and application site vesicles.

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 of Jublia® in Canada, the ability of Jublia to position the Company to meet unmet needs and the prescribing practices of healthcare practitioners. Jublia has not been approved by the U.S. Food and Drug Administration. 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 associated with the launch of a new product 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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