Valeant Pharmaceuticals Announces FDA Approval Of Jublia® for the Treatment of Onychomycosis

June 09, 2014

LAVAL, Quebec, June 9, 2014 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) today announced that that its wholly owned subsidiary, Valeant Pharmaceuticals North America LLC, received notice that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Jublia® (efinaconazole 10% topical solution), the first topical triazole approved for the treatment of onychomycosis of the toenails.

"We acquired Jublia® through our purchase of Dow Pharmaceutical Sciences in 2008 and advanced Jublia® from pre-IND stage through Clinical Phases 1, 2 and 3," said J. Michael Pearson, chairman and chief executive officer. "We are working quickly to get this important product launched in the U.S. and Canada in the third quarter of 2014. We anticipate favorable managed care coverage in the U.S., similar to other branded antifungal agents, with peak sales of $300-$800 million in the U.S. alone and we are also working with other regulatory agencies around the world on further approvals. This is the fourth product, sourced from our acquisition of Dow Pharmaceutical Sciences, for which we have received FDA approval – the other three being 1% clindamycin and 5% benzoyl peroxide gel (IDP 111), Acanya® and Retin-A Micro (tretinoin) Gel microsphere 0.08%. We have also filed a new treatment for acne, Onexton™, which has a PDUFA date of November 30, 2014. All these compounds came through our Dow acquisition, bringing with it the full set of R&D capabilities from preclinical through regulatory."

Onychomycosis is a common and destructive nail infection that is currently undertreated largely because of the limitations of available treatments. Currently, over-the-counter or prescription topical treatments provide limited efficacy and are often administered in conjunction with frequent debridement, or the scraping, cutting or removal of the nail. Prescription oral treatments are limited by drug interactions and serious safety concerns.

"Onychomycosis is not only embarrassing and uncomfortable, but can lead to permanent nail damage and limited mobility in the general population," said American Podiatric Medical Association Executive Director and CEO Glenn B. Gastwirth, DPM. "We welcome the approval of Jublia® and encourage people with onychomycosis of the toenails to discuss their condition with their podiatrist, or other healthcare professional to find a treatment that's right for them."

The licensor and business partner for efinaconazole, Kaken Pharmaceutical, has also agreed to supply Valeant with the finished dosage form of Jublia for the U.S. market.

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).

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 Onychomycosis

Onychomycosis is a common nail infection caused predominantly by dermatophyte fungi that typically occurs under the toenail, though fingernails may also be affected. Approximately 35 million Americans suffer from onychomycosis, most of whom are men between 50 and 70 years of age. The fungi that cause onychomycosis live in warm, moist environments, including swimming pools and showers, and may invade the skin through tiny cuts or small separations between the nail and nail bed.

The condition typically begins as a small white or yellow spot beneath the nail, and causes nail discoloration, thickening and/or distortion, pain, detachment of the nail from the nail bed and irregular surface changes. Once onychomycosis begins, it can persist indefinitely if not treated and may cause permanent nail damage. Currently 85 percent of onychomycosis patients are untreated.

[Source:
http://www.mayoclinic.org/diseases-conditions/nail-fungus/basics/definition/con-20019319
]

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 can be found at

www.valeant.com

.

Forward-looking Statements

This press release contains forward-looking statements regarding, among other things, that Jublia® is a milestone in the treatment of onychomycosis, that Jublia® is an effective treatment of onychomycosis and the potential launch of Jublia®. 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 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. 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, except as required by law.

Contact Information:
Laurie W. Little
Valeant Pharmaceuticals International, Inc.
949-461-6002
laurie.little@valeant.com

Valeant Pharmaceuticals International, Inc.

Logo -
http://photos.prnewswire.com/prnh/20101025/LA87217LOGO

SOURCE Valeant Pharmaceuticals International, Inc.