

Valeant Pharmaceuticals Announces Publication of Efinaconazole Phase III Results

November 26, 2012

MONTREAL, Nov. 26, 2012 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) announced today that the *Journal of the American Academy of Dermatology* has published the positive results from our two pivotal, international, multicenter, randomized, double-blind, vehicle-controlled studies that were conducted in 1,655 subjects with onychomycosis. Onychomycosis is a common nail infection caused predominantly by dermatophyte fungi, resulting in nail destruction and deformity. The only approved topical treatments are lacquers with very limited efficacy. Oral treatments, while more efficacious, are limited by drug interactions and numerous safety concerns including the potential for acute liver injury. Valeant investigated the safety and efficacy of efinaconazole 10% topical solution (efinaconazole), the first triazole antifungal agent developed for distal lateral subungual onychomycosis (DLSO).

The study's primary endpoint was stringently defined as the complete cure rate at Week 52, which means that the target nail showed 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 efinaconazole were completely cured, as compared to only 3.3% of subjects treated with vehicle and in Study 2, 15.2% of subjects treated with efinaconazole were completely cured, as compared to only 5.5% of subjects treated with vehicle. Using the secondary endpoint of complete or almost complete cure, defined as $\leq 5\%$ clinical involvement and 100% mycologic cure, the success rates for efinaconazole increased to 26.4% and 23.4%, respectively. The adverse events that were reported were generally mild and transient and were similar between subjects treated with efinaconazole solution 10% and vehicle.

"We are pleased to share the positive results from the two Phase III studies of efinaconazole with the publication by a leading dermatology journal," stated J. Michael Pearson, chairman and chief executive officer. "While oral treatment of onychomycosis has been the standard of care, drug interactions and risk of acute liver injury may limit their use especially in older adults where disease is most prevalent, those on multiple drug regimens, or for patients or doctors who prefer topical therapies. As no new onychomycosis treatments have been introduced for over 10 years, we believe in the authors' conclusion that this may be the first topical treatment option for DLSO that can be considered a viable alternative to oral treatments."

"This is a very exciting time for patients with the pending launch of the first new topical anti-fungal treatment approved in more than a decade," said Boni Elewski, MD Professor of Dermatology, University of Alabama. "Onychomycosis is a common infection that, left untreated, can later appear not only on other toes and fingers, but also on friends and family, too. It is estimated that one in ten Americans suffer from onychomycosis, which causes the nail to thicken and can be quite painful, making this condition more than just a cosmetic problem. Furthermore, as some research indicates that up to half of patients over the age of 70 suffer from this progressive disease. An effective topical therapy like efinaconazole is a logical treatment option to avoid drug interactions and systemic side effects, as these patients undoubtedly take other oral medications."

For the complete article, please go to

Trial Design

The two large, international, multicenter, randomized, double-blind, vehicle-controlled studies were conducted in subjects with onychomycosis affecting at least one great toenail. The toenail was required to have at least 20-50% of clinical involvement. Study 1 had 870 subjects and Study 2 had 785. They were randomized in a 3:1 ratio to efinaconazole topical solution 10% or to vehicle. Treatment was applied once-daily for 48 weeks, with post-treatment follow-up occurring at Week 52. Debridement was not performed in the studies.

The primary endpoint was stringently defined as the complete cure rate at Week 52, which means that the target nail showed no clinical involvement and no evidence of fungus present by both KOH testing and by a negative fungal culture.

In both studies, the primary endpoint of complete cure was statistically significant ($P < .001$) in favor of efinaconazole topical solution 10%. In Study 1, 17.8% of subjects treated with efinaconazole were completely cured compared to only 3.3% of subjects treated with vehicle. In Study 2, 15.2% of subjects treated with efinaconazole were completely cured compared to only 5.5% of subjects treated with vehicle. Although no head-to-head studies have been conducted, these results are comparable to that reported with oral treatment of onychomycosis.

Both studies also found that mycologic cure rates were also statistically significant ($P < .001$) in favor of efinaconazole topical solution 10%. In Study 1, 55.2% of subjects treated with efinaconazole demonstrated mycologic cure compared to only 16.8% of subjects treated with vehicle. In Study 2, 53.4% of subjects treated with efinaconazole demonstrated mycologic cure compared to only 16.9% of subjects treated with vehicle. Given that healthy toenails can take 78 weeks to grow completely, it is not surprising that mycologic cure rates are greater than complete cure rates. In addition, more patients treated with efinaconazole (Study 1: 26.4% and Study 2: 23.4%) achieved a complete or almost complete cure ($\leq 5\%$ clinical involvement and mycologic cure) compared with vehicle (Study 1: 7.0% and Study 2: 7.5%; both $P < .001$).

The adverse events that were reported were generally mild and transient and were similar between subjects treated with efinaconazole solution 10% and vehicle. Local site reactions were infrequently reported (e.g., dermatitis), and appeared to be more likely to occur with efinaconazole treatment (2%).

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 neurology, dermatology and branded generics. More information about Valeant Pharmaceuticals International, Inc. can be found at www.valeant.com

About The Journal of the American Academy of Dermatology

As the official publication of the American Academy of Dermatology, the Journal is dedicated to the clinical and continuing education needs of the entire dermatologic community and is internationally known as the leading journal in the field. Original, peer-reviewed articles cover clinical and investigative studies, treatments, new diagnostic techniques, and other topics relating

to the prevention, diagnosis, and treatment of disorders of the skin. Included are CME articles based on the Core Curriculum of the American Academy of Dermatology.

The *Journal* is ranked 3rd of 43 journals in the Dermatology category in the 2009 Journal Citation Reports®, published by Thomson Reuters, and has an Impact Factor of 4.081. *The Journal of the American Academy of Dermatology* is also recommended for purchase in the Brandon-Hill study, Selected List of Books and Journals for the Small Medical Library.

Forward-Looking Statements

These forward-looking statements relate to, among other things, the efficacy of efinaconazole, the approval, if any, of efinaconazole by FDA or other similar regulatory agencies and the role of efinaconazole as a treatment for onychomycosis. Forward-looking statements can generally be identified by the use of words such as "believe," "anticipate," "expect," "estimate," "intend," "continue," "plan," "project," "will," "may," "should," "could," "would," "target," "potential" and other similar expressions. In addition, any statements that refer to expectations, projections or other characterizations of future events or circumstances are forward-looking statements. Actual results may differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from these expectations include, among other things, the decisions by FDA or other similar regulatory agencies, the efficacy of efinaconazole and the market acceptance of efinaconazole, and the risk factors as detailed from time to time in Valeant's reports filed with the Securities and Exchange Commission and the Canadian Securities Administrators. Valeant cautions that the foregoing list of important factors that may affect future results is not exhaustive. When relying on Valeant's forward-looking statements to make decisions with respect to Valeant, investors and others should carefully consider the foregoing factors and other uncertainties and potential events. Valeant undertakes no obligation to update or revise any forward-looking statement, except as required by law.

Contact Information:

Laurie W. Little
949-461-6002
laurie.little@valeant.com

SOURCE Valeant Pharmaceuticals International, Inc.



Investor Inquiries

ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries

Corporate.communications@bauschhealth.com
908-569-3692

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