

# Valeant Announces Successful Results From Phase III Onychomycosis Trials

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MISSISSAUGA, Ontario, Dec. 16, 2011 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) today announced successful results from two large international Phase 3 studies of its topical investigational drug {efinaconazole (IDP-108)} product for the treatment of mild to moderate onychomycosis of the toenail. In both the studies, the investigational drug product was found to be statistically superior ( $p < 0.001$ ) to placebo for all primary and secondary endpoints. It was found to be generally safe and well tolerated.

Efinaconazole is an investigational antifungal drug belonging to the triazole family. The investigational drug product has not been found by the U.S. Food and Drug Administration (FDA) to be safe or effective for the treatment of mild to moderate onychomycosis of the toenail and may not be sold or promoted in the United States unless the FDA has approved a new drug application. Similar restrictions apply in other countries.

Valeant holds an exclusive license from Kaken Pharmaceutical Co., Ltd., to commercialize efinaconazole in North America, Central America, South America and the European Union.

## About Onychomycosis

Onychomycosis (also known as "dermatophytic onychomycosis" and "tinea unguium") is a fungal infection that affects the nail and nail bed. The prevalence of onychomycosis is about 6-8% in the adult population. It is the most common disease of the nail and constitutes about a half of all nail abnormalities. Without treatment, the nails thicken and cause localized pressure-related pain. Dermatophytes are the primary fungi that cause onychomycosis.

## About Valeant

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

## Forward-looking Statements

To the extent any statements made in this document contain information that is not historical, these statements are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, and may be forward-looking information as defined under applicable Canadian securities legislation (collectively, "forward-looking statements").

These forward-looking statements relate to, among other things, the successful approval and commercialization of IDP-108. 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 successful approval and commercialization of IDP-108, and the risk factors as detailed from time to time in Valeant's reports filed with the Securities and Exchange Commission ("SEC") and the Canadian Securities Administrators ("CSA").

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