BAUSCH Health

Valeant Pharmaceuticals Announces Results Of Second Phase 3 Study For Psoriasis Treatment IDP-118

January 10, 2017

LAVAL, Quebec, Jan. 10, 2017 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) ("Valeant" or the "Company") today announced positive results from a second confirmatory pivotal Phase 3, multicenter double-blind, randomized, vehicle-controlled clinical study to assess the safety and efficacy of IDP-118 (halobetasol propionate and tazarotene) lotion in the treatment of plaque psoriasis.

Within the Phase 3 study of 203 adult subjects with moderate to severe psoriasis, IDP-118 showed statistical significance ($p < 0.001$) to vehicle with a treatment success rate at 8 weeks of 35.76% to 6.98%. The primary endpoint of the 12-week study (8 weeks of treatment followed by 4 weeks of follow-up) was achievement of a "clear" to "almost clear" score and at least a 2 grade improvement based on an Investigator Global Assessment (IGA) at 8 weeks, and clear to almost clear and at least 2 grade improvement in the IGA at weeks 12, 6, 4 and 2 as secondary endpoints.

"Investing in R&D and developing innovative products that improve people's lives continue to be priorities as we enter 2017," stated Joseph C. Papa, Chairman and Chief Executive Officer. "We are optimistic about the results of this confirmatory Phase 3 study, which demonstrate that the novel formulation in IDP-118, with its dual mechanism of action, can achieve greater efficacy at a much lower concentration while reducing irritation in patients who use a corticosteroid-retinoid combination to treat psoriasis."

While halobetasol propionate and tazarotene are both approved and used to treat plaque psoriasis, each has certain attributes that can influence the treatment duration owing to potential adverse events. Based on existing data from our clinical studies, the combination of these ingredients in IDP-118 with a dual mechanism of action potentially allows for expanded use of these active ingredients with reduced adverse events.

On December 8, Valeant announced the results of a prior Phase 3 study of 215 adult subjects with moderate to severe psoriasis. In this study, IDP-118 showed statistical significance ($p<0.001$) to vehicle with a treatment success rate at 8 weeks of 45.33% to 12.51%. The primary endpoint of the 12-week study (8 weeks of treatment with 4 weeks of follow-up) was achievement of a "clear" to "almost clear" score and at least 2 grade improvement based on an Investigator Global Assessment (IGA) at 8 weeks, and achieving clear to almost clear and at least 2 grade improvement in the IGA at weeks 12, 6, 4 and 2 as secondary endpoints.

The Phase 3 program was preceded by a successful Phase 2 study where the combination product IDP-118, with a treatment success rate of 52.5%, was superior to each of the actives halobetasol propionate and tazarotene as well as the vehicle, which demonstrates the IDP-118 formulation is superior to using the individual actives separately.

About Valeant

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, gastrointestinal disorders, eye health, neurology and branded generics. More information about Valeant can be found at www.valeant.com
.

Forward-looking Statements
This press release may contain forward-looking statements which 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, 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, unless required by law.

Contact Information:

Elif McDonald
elif.mcdonald@valeant.com

514-856-3855
877-281-6642 (toll free)

Media:
Renée Soto
or
Chris Kittredge/Jared Levy
Sard Verbinnen & Co.
212-687-8080

To view the original version on PR Newswire, visit:
http://www.prnewswire.com/news-releases/valeant-pharmaceuticals-announces-results-of-second-phase-3-study-for-psoriasis-treatment-idp-118-300388297.html

SOURCE Valeant Pharmaceuticals International, Inc.

908-569-3692