BAUSCH Health

Valeant Pharmaceuticals Receives U.S. FDA Clearance For Restylane® Silk

June 16, 2014

LAVAL, Quebec, June 16, 2014 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) today announced that that the U.S. Food and Drug Administration (FDA) has issued marketing clearance for *Restylane® Silk* Injectable Gel with 0.3% Lidocaine, a device indicated for submucosal implantation for lip augmentation and dermal implantation for correction of perioral rhytids in patients over the age of 21.

"We are pleased to have received marketing clearance from the FDA for *Restylane® Silk* so quickly after the approval of Julbia," said J. Michael Pearson , chairman and chief executive officer. "Our R&D team is hitting on all cylinders and demonstrating that Valeant has a successful, output-focused R&D model that concentrates on areas of expertise where we are confident that our investments will pay off."

Information about Restylane® Silk Injectable Gel with 0.3% Lidocaine

Restylane® Silk is a crystal clear injectable gel composed of hyaluronic acid, a natural substance that already exists in the body. *Restylane® Silk* is non-animal based and free from animal protein. Allergy pretesting is not necessary. *Restylane® Silk* contains 0.3% lidocaine, which was added to reduce the discomfort associated with the treatment.

A clinical study was conducted with *Restylane® Silk* to evaluate the safety and effectiveness of injections to enhance lip fullness and to improve the wrinkles around the lips. The study included 221 mostly female subjects and evaluated subjects with light and dark skin. Subjects with very dark skin were not studied.

Ninety-eight percent (98%) of subjects reported improvement in their lip fullness 14 days after injection and 76% of the subjects still had lip improvement 6 months after their injection.

The majority of adverse events were mild in intensity and the most common symptoms were lip swelling, contusion, and lip pain. The incidence of adverse event decreased significantly after the second treatment.

Restylane Silk is contraindicated for patients with severe allergies manifested by a history of anaphylaxis or history or presence of multiple severe allergies; patients with a history of allergies to gram positive bacterial proteins; patients with bleeding disorders; for implantation in anatomical spaces other than the dermis or submucosal implantation for lip augmentation and should not be used in patients with previous hypersensitivity to local anesthetics of the amide type, such as lidocaine.

Complete information on *Restylane® Silk,* can be found at www.valeant.com
.

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 Valeant has a successful, output-focused R&D model and that we are confident that our investments will pay off. 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

SOURCE Valeant Pharmaceuticals International, Inc.