

Actavis and Valeant Announce FDA Approval for Metronidazole 1.3%

March 25, 2014

DUBLIN and LAVAL, Quebec, March 25, 2014 /PRNewswire/ -- Actavis plc (NYSE: ACT) and Valeant Pharmaceuticals International, Inc. (NYSE: VRX) (TSX: VRX) today announced that the U.S. Food and Drug Administration (FDA) has approved the New Drug Application (NDA) for Metronidazole 1.3% Vaginal Gel, an antibiotic for the treatment of bacterial vaginosis (BV). Actavis acquired the rights to Metronidazole 1.3% from Valeant Pharmaceuticals International in April 2013.

Bacterial vaginosis is an infection caused by an imbalance in the normal bacteria in the vagina. It is the most common vaginal infection in women ages 15 to 44^[1]. Metronidazole 1.3% provides a convenient, single-dose treatment for BV that is packaged in a pre-filled disposable applicator. The U.S. BV market is valued at approximately \$140 million annually, according to IMS Health.

"The approval of Metronidazole 1.3% is a significant milestone for Actavis and provides an important new option with a single-dose treatment for women suffering from BV," said Fred Wilkinson, President, Actavis Global R&D. "The expected launch of the product later this year will establish a promising long-term opportunity for Actavis and support the continued growth of our industry-leading Women's Health franchise."

"Valeant is pleased that another internal R&D compound has been approved by the FDA and will soon be available," said Tage Ramakrishna, M.D. and Chief Medical Officer, Valeant Pharmaceuticals. "Metronidazole 1.3% gives health care providers and women a new safe and effective treatment for bacterial vaginosis."

Under the terms of the agreement with Valeant, Actavis will acquire the rights to Metronidazole 1.3% for up to \$57 million in up front payments, milestone payments and certain guaranteed royalty payments during the first three years of commercialization depending on market conditions. Actavis will also pay ongoing royalties to Valeant after the first three years of commercialization.

The approval of Metronidazole 1.3% was based on the results of a Phase III randomized, double-blind, placebo-controlled, multicenter clinical trial, which found that the higher concentration Metronidazole 1.3% was well tolerated, safe and efficacious. Metronidazole 1.3% provides an alternative treatment option to MetroGel-Vaginal[®] (metronidazole vaginal gel 0.75%) for patients with bacterial vaginosis.

Indication and Usage

Metronidazole vaginal gel 1.3% is a nitroimidazole antimicrobial indicated for the treatment of bacterial vaginosis in non-pregnant women.

Metronidazole vaginal gel 1.3% should be administered once intravaginally at bedtime. Not for ophthalmic, dermal or oral use.

Selected Safety Information

Metronidazole vaginal gel 1.3% is contraindicated in patients with a history of hypersensitivity to

metronidazole, parabens, other ingredients of the formulation, or other nitroimidazole derivatives. Metronidazole vaginal gel 1.3% should not be used concomitantly with or within 2 weeks of disulfiram treatment. Patients should not to consume alcoholic beverages and preparations containing ethanol or propylene glycol during and for at least 24 hours after treatment with Metronidazole vaginal gel 1.3%

Convulsive seizures and peripheral neuropathy have been reported in patients treated with oral or intravenous metronidazole. Treatment should be discontinued promptly if abnormal neurologic signs develop. Metronidazole may interfere with certain serum chemistry laboratory values.

Prolonged anticoagulant effects of warfarin and other coumarin anticoagulants have been reported with co-administration of oral metronidazole. Elevated plasma lithium concentrations have been reported with oral metronidazole.

The most common adverse reactions observed in the clinical study (incidence =1%) were vulvovaginal candidiasis, headache, vulvovaginal pruritus, nausea, diarrhea, and dysmenorrhea.

The product and brand names mentioned herein are trademarks, registered trademarks and/or service marks of their respective owners.

About Actavis

Actavis plc (NYSE: ACT) is a global, integrated specialty pharmaceutical company focused on developing, manufacturing and distributing generic, brand and biosimilar products. Actavis has global headquarters in Dublin, Ireland and U.S. administrative headquarters in Parsippany, New Jersey, USA.

Actavis develops and manufactures generic, brand, branded generic, legacy brands and Over-the-Counter (OTC) pharmaceutical products and has commercial operations in approximately 60 countries. The Company's North American branded pharmaceuticals business is focused principally in the Women's Health, Urology, Gastroenterology and Dermatology therapeutic categories with a strong pipeline of products in various stages of development. Actavis also has a portfolio of five biosimilar products in development in Women's Health and Oncology. Actavis Global Operations has more than 30 manufacturing and distribution facilities around the world, and includes Anda, Inc., a U.S. pharmaceutical product distributor.

For press release and other company information, visit Actavis' Web site at <http://www.actavis.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

Actavis Forward-Looking Statement

Statements contained in this press release that refer to future events or other non-historical facts are forward-looking statements that reflect Actavis' current perspective of existing trends and information as of the date of this release. Except as expressly required by law, Actavis disclaims any intent or obligation to update these forward-looking statements. Actual results may differ materially from Actavis' current expectations depending upon a number of factors affecting Actavis' business. These factors include, among others, the impact of competitive products and pricing; market acceptance of and continued demand for Actavis' products, including

Metronidazole 1.3%; difficulties or delays in manufacturing; the difficulty of predicting the timing or outcome of FDA or other regulatory agency approvals or actions, if any; patents and other intellectual property rights held by the Company and the ability to successfully enforce such rights against third parties; and other risks and uncertainties detailed in Actavis' periodic public filings with the Securities and Exchange Commission, including but not limited to Actavis plc's Annual Report on Form 10-K for the year ended December 31, 2013. Except as expressly required by law, Actavis disclaims any intent or obligation to update these forward-looking statements.

Valeant Forward-Looking Statement

This press release may contain forward-looking statements, including, but not limited to, statements regarding a new safe and effective treatment for health care providers and women.

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, 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.

[i]

<http://www.cdc.gov/std/bv/stdfact-bacterial-vaginosis.htm>

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