# Valeant Pharmaceuticals Announces Relaunch Of Generic Ofloxacin Otic Solution

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LAVAL, Quebec, Aug. 8, 2016 /PRNewswire/ -- Valeant Pharmaceuticals International, Inc. (NYSE: VRX and TSX: VRX) today announced the relaunch of its generic ofloxacin otic solution to treat bacterial ear infections. The product was temporarily discontinued in April 2015 due to an issue concerning the active pharmaceutical ingredient supplier, which has been resolved.

Ofloxacin otic is a quinolone antibiotic solution used to treat outer ear infections in adults and children, chronic middle ear infections in adults and children with perforated eardrums, and acute middle ear infections in children with ear tubes. The product targets bacteria that cause the infection.

"We are pleased to relaunch this important product that improves the lives of a large population of children and adults who suffer from ear infections," said Joseph C. Papa, chairman and chief executive officer of Valeant. "Given the limited number of alternative products on the market, our team invested significant time and resources working with our active pharmaceutical ingredient supplier and the FDA to resolve this issue as quickly as possible. This relaunch demonstrates the strength of our generic portfolio, as well as our dedication to delivering effective and affordable treatments to patients."

The ofloxacin otic solution began shipping to customers on August 1, 2016 and will be available at most major retailers across the U.S.

#### **About Ofloxacin Otic**

Ofloxacin otic solution 0.3% is indicated for the treatment of infections in the following specific conditions:

- Otitis Externa in adults and pediatric patients > 6 months of age due to *E. coli, Pseudomonasaeruginosa*, and *Staph. aureus*.
- Chronic Suppurative Otitis Media in patients > 12 years of age with perforated tympanic membranes due to *Proteus mirabilis*, *Pseudomonas aeruginosa* and *Staph. Aureus*.
- Acute Otitis Media in pediatric patients > 1year of age with tympanostomy tubes due to Haemophilus influenza, Moraxella catarrhalis, Pseudomonas aeruginosa, Staph. Aureus and Strep. Pneumoniae.

## **Safety Information**

Adverse reactions in patients with non-intact tympanic membranes include diarrhea, nausea, vomiting, dry mouth, headache, vertigo, otorrhagia, tinnitus and fever. Prolonged use may result in over-growth of nonsuceptible organisms, including fungi. Serious and occasionally fatal hypersensitivity (anaphylactic) reactions, some following the first dose, have been reported in patients receiving quinolones.

## **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

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## **Forward-looking Statements**

This press release may contain forward-looking statements, including, but not limited to, statements regarding strength of our generic portfolio and delivering effective and affordable treatments to patients. 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, unless required by law.

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