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**ORTHO DERMATOLOGICS RECEIVES U.S. FDA APPROVAL FOR EXPANDED USE OF LUZU®  
(LULICONAZOLE) CREAM, 1%, IN PEDIATRIC PATIENTS WITH  
ATHLETE’S FOOT, JOCK ITCH AND RINGWORM**

RALEIGH, N.C., FEBRUARY 22, 2018 – Ortho Dermatologics, a division of Valeant Pharmaceuticals North America, LLC (NYSE: VRX and TSX: VRX) (“Valeant”), today announced that the U.S. Food and Drug Administration (FDA) approved the supplemental New Drug Application (sNDA) to expand the use of LUZU® (luliconazole) cream, 1% for the topical treatment of patients 12 and older with athlete's foot (interdigital tinea pedis) and jock itch (tinea cruris) and patients two and older with ringworm (tinea corporis), caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*. These conditions are very common skin diseases caused predominantly by dermatophyte fungi.<sup>1</sup> LUZU was initially approved as a treatment for adults in 2013.

“Though anyone at any age can get infected with athlete’s foot, jock itch and ringworm, because they are very contagious,<sup>2,3,4</sup> treatment options are limited for children,” said Bill Humphries, executive vice president of Dermatology, Ortho Dermatologics. “We are pleased that the FDA recognized the benefits of treatment with LUZU for pediatric patients. This new indication furthers our commitment to address common skin conditions in our younger patients.”

LUZU is the first topical azole antifungal agent originally approved to treat tinea cruris and tinea corporis with a one-week, once-daily treatment regimen, with results available three weeks post-treatment. Other approved treatments require at least two weeks of treatment.

The FDA approval to expand the indication for LUZU is based on two postmarketing requirement studies conducted in subjects 12 to <18 years of age with interdigital tinea pedis and tinea cruris and in subjects two to <18 years of age with tinea corporis. One study evaluated the pharmacokinetics under maximal use conditions in pediatric subjects ages 12 to <18 years with interdigital tinea pedis or tinea cruris. Another study evaluated the safety, efficacy and pharmacokinetics of LUZU when applied topically once daily for seven days in pediatric subjects two years to <18 years of age with tinea corporis.

**About LUZU (luliconazole) Cream, 1%**

LUZU® (luliconazole) cream, 1% is indicated for the topical treatment of interdigital tinea pedis, tinea cruris and tinea corporis caused by the organisms *Trichophyton rubrum* and *Epidermophyton floccosum*. LUZU has been extensively studied in the United States, with three positive pivotal studies that were the basis for approval. These studies were conducted in 423 subjects with either tinea pedis or tinea cruris.<sup>5</sup>

## About Ortho Dermatologics

Ortho Dermatologics is one of the largest prescription dermatology businesses in the world dedicated to helping patients in the treatment of a range of therapeutic areas including actinic keratosis, acne, atopic dermatitis, cold sores, athlete's foot, nail fungus and other dermatoses. The Ortho Dermatologics portfolio includes several leading acne, anti-fungal and anti-infective products. More information can be found at [www.ortho-dermatologics.com](http://www.ortho-dermatologics.com).

## Indication

**LUZU (luliconazole) Cream, 1%** is a prescription medicine used on the skin (topical) to treat athlete's foot between the toes (interdigital tinea pedis), jock itch (tinea cruris) and ringworm (tinea corporis).

## Important Safety Information

LUZU Cream is for use on skin only. Do not get LUZU Cream near or in your eyes, mouth or vagina.

Before using LUZU Cream, tell your doctor about any medical conditions you have, including if you are pregnant or planning to become pregnant, or are breastfeeding or planning to breastfeed. It is not known whether LUZU Cream will harm your unborn baby or if it passes into breast milk.

Tell your doctor about all of the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Use LUZU Cream exactly as directed by your doctor. Wash your hands after applying it.

LUZU Cream may cause skin reactions or irritation at the treatment site. Tell your doctor if you have skin reactions at the treatment sites.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [fda.gov/medwatch](http://fda.gov/medwatch) or call 1-800-FDA-1088.

Click [here](#) for Full Prescribing Information.

## 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 Valeant'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. Ortho Dermatologics' affiliated entities undertake 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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LUZU is a trademark of Ortho Dermatologics' affiliated entities.

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<sup>1</sup> Noble, SL et al. Diagnosis and Management of Common Tinea Infections. *Am Fam Physician*. 1998 Jul 1;58(1):163-174.

<sup>2</sup> Mayo Clinic. (2016). Jock Itch. Retrieved from <https://www.mayoclinic.org/diseases-conditions/jock-itch/symptoms-causes/syc-20353807>. Accessed February 13, 2018.

<sup>3</sup> Mayo Clinic. (2017). Ringworm. Retrieved from <https://www.mayoclinic.org/diseases-conditions/ringworm-body/symptoms-causes/syc-20353780>. Accessed February 13, 2018.

<sup>4</sup> Mayo Clinic. (2014). Athlete's Foot. Retrieved from <https://www.mayoclinic.org/diseases-conditions/athletes-foot/symptoms-causes/syc-20353841>. Accessed February 13, 2018.

<sup>5</sup> LUZU [prescribing information]. Bridgewater, NJ: Valeant Pharmaceuticals.