BAUSCH Health

FDA Approves Ortho Dermatologics' Labeling For JUBLIA® (efinaconazole) Topical Solution, 10%, In Patients As Young As Six Years Old

April 29, 2020

LAVAL, Quebec, April 29, 2020 /PRNewswire/ -- Bausch Health Companies Inc. (NYSE/TSX: BHC) and its dermatology business, Ortho Dermatologics, one of the largest prescription dermatology health care businesses, today announced the U.S. Food and Drug Administration (FDA) has approved a supplemental New Drug Application (sNDA) for JUBLIA® (efinaconazole) topical solution, 10%, a treatment for onychomycosis, a fungal infection of the toenails, which extends the age range included in the product's label to children six years of age and older.[1] JUBLIA was first approved in June 2014 in patients 18 years and older.



"Onychomycosis is increasingly being seen in pediatrics - representing 15 percent of all nail dystrophies in children,"[2] said Bill Humphries, president, Ortho Dermatologics. "With nearly six years of real-world use since its initial approval to treat adults in 2014, JUBLIA has a demonstrated safety and efficacy profile, and we are pleased the FDA has recognized it as a valuable treatment option for children with toenail fungal infections."

The safety, pharmacokinetics and efficacy of JUBLIA in patients ages six to 16 years old were evaluated in a multicenter, open-label, single-arm Phase 4 study that enrolled 62 patients with mild-to-severe onychomycosis. The primary objectives were to evaluate the safety of JUBLIA over the 52 weeks of the study in pediatric subjects with at least mild onychomycosis of the toenails, as well as the pharmacokinetics of JUBLIA at four weeks in pediatric subjects 12 to 16 years with moderate-to-severe onychomycosis of the toenails. Efficacy assessments included mycologic cure

(fungus-free), complete cure (completely clear nails and fungus-free), and clinical efficacy (<10 percent toenail involvement).[3]

In the study, JUBLIA was shown to be well tolerated in the pediatric population. The most common treatment-related side effect was ingrown nails. The systemic exposure to JUBLIA in this pediatric population was comparable to that previously reported in adults. The efficacy assessments showed that by week 52, 65 percent of patients achieved mycologic cure, with a 36.7 percent mycologic cure rate observed as early as week 12. A total of 40 percent of patients had complete cure by week 52, and half of patients achieved clinical efficacy by the study conclusion.[3]

"Aside from being a cause of discolored toenails, onychomycosis may cause patients to experience nail discomfort in their shoes and during general activity. In certain populations, it can also potentially lead to a secondary infection," said Tracey Vlahovic, DPM, clinical professor, Department of Podiatric Medicine, and adjunct professor, Department of Microbiology, Temple University School of Medicine. "The expanded labeling for JUBLIA further demonstrates the safety and efficacy of this treatment option, which I look forward to adding to my treatment regimen for pediatric patients."

Onychomycosis is a chronic fungal nail infection caused predominantly by dermatophyte fungi that typically occurs under the toenail, though fingernails may also be affected. The condition typically begins as a small white or yellow spot beneath the nail, and causes nail discoloration, thickening and/or distortion, pain, detachment of the nail from the nail bed and irregular surface changes. Once onychomycosis begins, it can persist indefinitely if not treated and may cause permanent nail damage.

Through the company's access program, most eligible, commercially insured patients will pay as little as $0 for both the 4 and 8 mL sizes of JUBLIA.

For more information on JUBLIA, visit
www.jubliarx.com
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Important Safety Information for JUBLIA® (efinaconazole) Topical Solution, 10%,

INDICATION
JUBLIA® (efinaconazole) Topical Solution, 10% is a prescription medicine used to treat fungal infections of the toenails.

IMPORTANT SAFETY INFORMATION

- JUBLIA is for use on nails and surrounding skin only. Do not use JUBLIA in your mouth, eyes, or vagina. Use it exactly as instructed by your doctor.
- The safety and efficacy of JUBLIA have not been established in children under six years old.
- Before you use JUBLIA, tell your doctor about all your medical conditions, including if you are or plan to become pregnant, are breastfeeding, or plan to breastfeed, because it is not known whether JUBLIA can harm an unborn fetus or nursing infant.
- Tell your doctor about all medications you are taking, and whether you have any other nail infections.
- JUBLIA is flammable. Avoid heat and flame while applying JUBLIA to your toenail.
- JUBLIA may cause irritation at the treated site. The most common side effects include: ingrown toenail, redness, itching, swelling, burning or stinging, blisters, and pain. Tell your doctor about any side effects that bother you or do not go away.

To report SUSPECTED ADVERSE REACTIONS, contact Ortho Dermatologics at 1-800-321-4576 or the FDA at 1-800-FDA-1088 or visit
www.fda.gov/medwatch
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Please click
here
for full Prescribing Information, including Patient Information.

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About Ortho Dermatologics
Ortho Dermatologics is one of the largest prescription and aesthetic dermatology businesses dedicated to helping patients in the treatment of a range of therapeutic areas, including psoriasis, actinic keratosis, acne, atopic dermatitis and other dermatoses. The Ortho Dermatologics portfolio also includes several leading medical device systems for aesthetic applications, such as skin tightening and resurfacing, laser hair removal and preventative therapeutic skin care treatments. More information can be found at
www.ortho-dermatologics.com
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About Bausch Health
Bausch Health Companies Inc. (NYSE/TSX: BHC) is a global company whose mission is to improve people's lives with our health care products. We develop, manufacture and market a range of pharmaceutical, medical device and over-the-counter products, primarily in the therapeutic areas of eye health, gastroenterology and dermatology. We are delivering on our commitments as we build an innovative company dedicated to advancing global health. More information can be found at
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Forward-looking Statements
This news 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," "believes," "estimates," "potential," "target," or "continue" and variations or similar expressions. These statements are based upon the current expectations and beliefs of Bausch Health 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 Bausch Health's most recent annual or quarterly report and detailed from time to time in Bausch Health's other filings with the U.S. 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. Bausch Health undertakes no obligation to update any of these forward-looking statements to reflect events or circumstances after the date of this news release or to reflect actual outcomes, unless required by law.

References
1. Prescribing Information. JUBLIA® (efinaconazole) topical solution, 10%.
2. Rodriguez-Pazos L, et al. *Mycoses*. 2011;54(5):450-453.
3. Data on file. Bausch Health US, LLC.

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JUB.0066.USA.20

Investor Contact:	**Media Contact:**
Arthur Shannon	Lainie Keller
arthur.shannon@bauschhealth.com	lainie.keller@bauschhealth.com
(514) 856-3855	(908) 927-1198
(877) 281-6642 (toll free)	

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SOURCE Bausch Health Companies Inc.

Investor Inquiries
ir@bauschhealth.com
877-281-6642
514-856-3855 (Canada)

Media inquiries
Corporate.communications@bauschhealth.com
848-264-0934

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