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**ORTHO DERMATOLOGICS ANNOUNCES LAUNCH OF MOBILE APP DESIGNED TO HELP PATIENTS ADHERE TO TREATMENT WITH JUBLIA® (EFINACONAZOLE 10% TOPICAL SOLUTION) FOR TOENAIL FUNGUS**

RALEIGH, N.C., JULY 11, 2018 – Ortho Dermatologics today announced the launch of JubliApp™ mobile app designed to help encourage patients to adhere to treatment with JUBLIA® (efinaconazole 10% topical solution), a topical azole used to treat fungal infections of the toenails.

“Ortho Dermatologics wants to reach patients where they are, and more and more people are using mobile apps to maintain their health,” said Bill Humphries, Executive Vice President and Company Group Chairman, Ortho Dermatologics. “We want to use this innovative approach to ensure patients have the tools they need to help them maximize their treatment regimen.”

JubliApp was designed to help patients reach their treatment goals through their daily administration of JUBLIA. The app offers treatment reminders, efficacy tracking, and a game to keep patients engaged while the daily application is drying, helping to make the 48-week long therapy less intimidating. JubliApp also has several other key features to keep patients on track with their treatment, including:

- Reminding patients on a daily basis to apply the treatment and notifying them on a monthly basis when they will need to refill their prescription
- Taking and comparing side-by-side photos of toenails to track the results of the treatment over time; patients can also share the photos with their healthcare professional (HCP) to monitor progress
- Identifying which toenails have been affected by toenail fungus (TNF)
- Ensuring patients allow the daily treatment the time needed to dry by encouraging them to play the *Mission Plu-Toe* game after application—then notifying them when drying time is up
- Sharing weekly progress reports, which track whether the patient applied the daily treatment, played the game, or took a photo of the affected toenails

“Since we only see patients a handful of times a year, it’s often difficult to ensure they are being adherent to a long-course treatment like JUBLIA,” said Dr. Tracey Vlahovic, DPM, Professor, Department of Podiatric Medicine at Temple University. “By giving patients the ability to send physicians their progress photos at the touch of a button, we’re able to give them real-time guidance to provide their best chance for complete clearance.”

To download the app, visit the App Store on an iOS device or Google Play on an Android mobile device and search “JubliApp” or “Jublia” and click “Get” to download.

### **About JUBLIA® (efinaconazole 10% topical solution)**

Jublia® (efinaconazole 10% topical solution), was the first topical azole antifungal agent developed for distal lateral subungual onychomycosis (DLSO).

Being a solution, Jublia® is applied daily to the nail with a novel bottle that has a built-in flow-through brush applicator. It dries quickly and there is no need to remove excess product. There are no known drug interactions, and liver monitoring is not required. Jublia is for use on nails and surrounding skin only. Jublia should not be used in the mouth, eyes, or vagina.

Jublia® was extensively studied prior to its approval. The two positive pivotal studies that were the basis for approval were published in 2013 in the prestigious *Journal of the American Academy of Dermatology*. These international studies were conducted in 1,655 subjects with onychomycosis, including subjects in Canada.

For the pivotal studies, the primary endpoint was complete cure at Week 52, which required that the target nail show no clinical involvement and no evidence of fungus present by both KOH testing and a negative fungal culture. In Study 1, 17.8% of subjects treated with Jublia® were completely cured, compared to only 3.3% of subjects treated with vehicle. In Study 2, 15.2% of subjects treated with Jublia® were completely cured, compared to only 5.5% of subjects treated with vehicle.

Adverse events that were reported were generally mild and transient and were similar between subjects treated with Jublia® and vehicle. The most commonly reported adverse events in patients treated with Jublia® were application site dermatitis and application site vesicles.

### **About Onychomycosis<sup>1</sup>**

Onychomycosis is a common nail infection caused predominantly by dermatophyte fungi that typically occurs under the toenail, though fingernails may also be affected. Approximately 35 million Americans suffer from onychomycosis.<sup>2</sup> The fungi that cause onychomycosis live in warm, moist environments, including swimming pools and showers, and may invade the skin through tiny cuts or small separations between the nail and nail bed.

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.

### **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.

- It is not known whether JUBLIA is effective in children.
- 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.

You are encouraged to report negative side effects of prescription drugs to the FDA.

Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch) or call 1-800-FDA-1088.

Click [here](#) for full prescribing information.

### 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).

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<sup>1</sup> Mayo Clinic. (2018). Nail Fungus. Retrieved from <https://www.mayoclinic.org/diseases-conditions/nail-fungus/symptoms-causes/syc-20353294>. Accessed June 2018.

<sup>2</sup> Capriotti, Joseph, and Kara Capriotti. "Onychomycosis Treated with a Dilute Povidone-Iodine/Dimethyl Sulfoxide Preparation." *International Medical Case Reports Journal*, 8 Oct. 2015, pp. 231–233., doi:10.2147/imcrj.s90775.