**Safety, Pharmacokinetics, and Efficacy of Efinaconazole 10% Topical Solution for the Treatment of Onychomycosis in Pediatric Patients**

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**SYNOPSIS**
- Onychomycosis—a chronic fungal infection—can occur in children, ranging in prevalence from 0.35%–5.5% worldwide.1
- Onychomycosis has been reported to be responsible for approximately 15% of all nail involvement in children.2
- Treatment of onychomycosis is challenging, and can require systemic antifungals for prolonged periods of time; however, parents and healthcare practitioners are hesitant to use long-term systemic treatments in children.3
- Efinaconazole 10% topical solution (JUBLIA® Ortho Dermatologics, Bridgewater, NJ) is a novel agent indicated for the topical treatment of onychomycosis of the toenails due to T. rubrum and T. mentagrophytes

**OBJECTIVE**
To evaluate efinaconazole 10% topical solution in pediatric patients with onychomycosis

**METHODS**
This phase 2, multicenter, parallel-group, evaluator-blinded, randomized safety, pharmacokinetics (PK), and efficacy of efinaconazole 10% topical solution in pediatric patients with onychomycosis was conducted.

**RESULTS**

**Study Population**
A total of 62 patients were enrolled in the study, 12 (19.3%) patients did not complete the study (withdrawn by parental request), 4 (6.5%) lost to follow-up, 5 (8.1%) participant request, n=52

**Efficacy**
- **Primary Efficacy Outcome**
  - Mycologic cure: negative potassium hydroxide (KOH) and negative fungal culture.

**Efficacy Assessments**
- Mycologic cure
- Complete cure
- Clinical involvement

**Figure 1. Mean Efinaconazole and H3 Metabolite Plasma Concentration-Time Profiles After Topical Administration of Efinaconazole Solution on Day 28 (PK Analysis Population)**

**Figure 2. Clinical Efficacy (Safety Population, LOCF)**

**Figure 3. Complete Cure (Safety Population, LOCF)**

**Figure 4. Mycologic Cure (Safety Population, LOCF)**

**CONCLUSIONS**
- Efinaconazole 10% topical solution administered once daily for a year was well tolerated in the pediatric population.
- The systemic exposure to efinaconazole in the pediatric population was comparable to that previously reported in adults (C_max, 0.87 ng/mL; AUC_0-24, 12.15 ng·h/mL).

**AUTHOR DISCLOSURES**
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**REFERENCES**
4. Prescribing Information. JUBLIA® (efinaconazole) topical solution, 10%. Ortho Dermatologics. AG has served as consultant, speaker, and investigator for Ortho Dermatologics. RP is an employee of Bausch Health US, LLC and may hold stock and/or stock options in its parent company. LE has served as investigator and consultant for Ortho Dermatologics. BE has provided clinical research support (research funding to University) for Abbvie, Anaptys-Bio, Boehringer Ingelheim, Bristol Myers Squibb, Celgene, Ely Lilly, Leo, Menlo, Merck, Novartis, Pfizer, Sun, Ortho Dermatologics, Vanda; and as consultant (received honorarium) from Boehringer Ingelheim, Celgene, Ely Lilly, Leo, Menlo, Merck, Novartis, Pfizer, Sun, Ortho Dermatologics, Vanda. JS is a consultant for Ortho Dermatologics. AG has served as consultant, speaker, and investigator for Ortho Dermatologics. RP is an employee of Bausch Health US, LLC and may hold stock and/or stock options in its parent company.