PSORIASIS

SAFETY AND EFFICACY OF APREMILAST IN PEDIATRIC PATIENTS WITH MODERATE TO SEVERE PLAQUE PSORIASIS: RESULTS FROM A PHASE 2 OPEN-LABEL STUDY

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Introduction: Psoriasis is a chronic inflammatory skin disorder that often begins in childhood.

Objective: We evaluated safety and efficacy of apremilast (APR) in pediatric patients.

Materials and Methods: Phase 2, randomized, open-label study with 2-week PK analysis and 48-week extension period in pediatric patients with moderate/severe plaque psoriasis (PASI ≥12, psoriasis-affected BSA ≥10%, sPGA ≥3). Adolescents (Group 1) aged 12 to 17 years weighing ≥35 kg to <70 kg received APR 20 mg BID (APR20); those ≥70 kg received APR 30 mg BID (APR30). Children (Group 2) aged 6 to 11 years (≥15 kg) received APR20. Titration was not implemented. An exploratory efficacy analysis of percent change in PASI score from baseline was performed. Safety/efficacy up to Week 50 is reported.

Results: As of May 31, 2018, 42 patients were enrolled and had evaluable safety and efficacy data (Group 1 APR20: n=13; Group 1 APR30: n=8; Group 2 APR20: n=21). Most patients (95.2%) experienced an AE, but 95.0% were mild/moderate. One patient (Group 2 APR20: 4.8%) had a serious AE (syncope). Two patients discontinued because of AEs (Group 1 APR20 and APR30: 0.0%; Group 2 APR20: n=2/21 [9.5%]). Common AEs included nausea (52.4%), headache (45.2%), abdominal pain (42.9%), viral URTI (40.5%), diarrhea (35.7%), vomiting (31.0%), and gastroenteritis (19.0%). Two patients had AEs of transient moderate weight loss that resolved at follow-up. Mean (95% CI) percent change from baseline in PASI score at end of treatment (up to 50 weeks) was –47.5% (–66.0, –29.0) (Group 1 APR20), –32.4% (–77.0, 12.2) (Group 1 APR30), and –71.3% (–85.9,

–56.7) (Group 2 APR20).

Conclusions: In adolescents and children with moderate/severe psoriasis, APR demonstrated a safety and tolerability profile similar to adults. Exploratory efficacy reported at Week 16 was generally maintained in patients who remained on APR for up to 50 weeks.