PAEDIATRIC DERMATOLOGY

RESULTS OF PHASE 2 STUDY EVALUATING THE EFFICACY AND SAFETY OF SB206, TOPICAL BERDAZIMER SODIUM GEL, IN SUBJECTS WITH MOLLUSCUM CONTAGIOSUM

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There is no approved topical prescription medicine to treat molluscum contagiosum (MC). SB206 is an investigational topical product that consists of 2 components; a gel containing berdazimer sodium that releases nitric oxide (NO) when co-administered with a hydrogel. NO, an endogenous small molecule, is known to be a immune modulator as well as a antimicrobial agent.

A Phase 2, 12-week, randomized, vehicle-controlled ascending dose trial was conducted in patients with MC to evaluate the efficacy and safety of SB206 compared to vehicle (VH).

Patients ≥2 years of age were randomized 3:1 (active: vehicle) to ascending, sequential dose groups of SB206. After 30 patients randomized in a dose group completed 2 weeks of treatment, the Data Safety Monitoring Board reviewed unblinded safety and tolerability data and recommended to open the higher dose group. Consequently, 256 patients were randomized into the following dose groups: 47 (4% BID), 48 (8% BID), 47 (12% BID), 48 (12% QD) and 66 (VH). The primary endpoint was the proportion of patients demonstrating complete clearance of MC at Week 12 in the modified intent-to-treat (mITT) population.

The following proportion of patients achieved complete clearance at Week 12: 13.2% and 10.6% (4% BID), 41.0% and 33.3% (8% BID), 35.1% and 27.7% (12% BID), 41.9% and 37.5 % (12% QD) and 20.0% and 18.2% (VH) in the mITT and ITT population, respectively. The efficacy signals appeared as early as 2 weeks. There were no SAEs or deaths. The number (%) of patients who discontinued treatment due to AEs were 0 in vehicle group and 7 (4%) in the combined SB206 groups. Most AEs were application site reactions. No quantifiable systemic exposure of SB206 was observed.

Overall, SB206 was well tolerated and efficacious in treating MC in this study and further studies are warranted.