John C. Browning, MD, 1 Carolyn Enloe, MPH, 2 Martina Cartwright, PhD, 2 Adelaide Hebert, MD, 3 Tomoko Maeda-Chubachi, MD, PhD, MBA 2

1Texas Dermatology & Laser Specialists, San Antonio, TX; 2Novan Inc, Durham, NC; 3UTHealth McGovern Medical School, Houston, TX

Efficacy and Safety of Topical Nitric Oxide–Releasing Berdazimer Gel in Patients With Molluscum Contagiosum: Results from B-SIMPLE4, A Phase 3 Randomized Clinical Trial

Objective

Berdazimer Gel, 10.3% is not FDA approved. The safety and effectiveness of Berdazimer gel, 10.3% is unknown.

Methods

Secondary Endpoints

For the Safety and Tolerability analysis, patients reported any AE that occurred during the 12 weeks of treatment regardless of relationship to study drug.

Results

Safety and Tolerability

Table 2: TEAEs at Application Site Affecting 25% of Patients in Either Group, By Severity

Table 4: Summary of LSRs by Composite Score and Other Local AEs

Conclusion

Once-daily application of berdazimer gel, 10.3%, a novel topical NO–releasing medication, appears to demonstrate efficacy and favorable safety in patients 6 months and older with molluscum contagiosum.