**Clinical Development Program of Novel Topical Nitric Oxide Releasing Medication Berdazimer Gel 10.3% for the Once-Daily Treatment of Molluscum Contagiosum**

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**Synopsis**

- **Nitric oxide (NO)**, an endogenous small molecule, provides localized immunity against foreign organisms by catalyzing the production of inorganic nitrite and nitrate radicals as a direct broad-spectrum antimicrobial agent.
- Until recently, the development of topical NO treatments was limited by the inability to store and safely deliver NO in a form that could be safely applied topically. Berdazimer gel 10.3% (Approved to Berdazimer sodium 12%) is an investigational product that consists of two components: a gel containing berdazimer sodium coadministered with a hydrogel to maintain NO delivery.

**Objectives**

- To review the clinical development program for berdazimer gel 10.3% as a potential therapy for MC.

**Results**

- **PK Analysis**: The study enrolled patients with >20 MC lesions, with >35 patients randomized in each cohort (Cohort 1: ≤20 MC lesions, Cohort 2: >20, ≤35 MC lesions, Cohort 3: >35 MC lesions). The PK period of once-daily berdazimer gel was 12 weeks, including an extension period.

**Conclusions**

- **Phase 2 Dose Finding**: Berdazimer gel 10.3% applied once daily was selected as the lead regimen for phase 3 development, balancing lesion clearance and tolerability.

**Safety Analyses**

- **Safety and tolerability**: Berdazimer gel 10.3% was generally well tolerated with no serious adverse events reported. Common adverse events included moderate erythema and redness at the application site, which resolved without discontinuation. No patients demonstrated clinically relevant neurologic, hemeopathologic, or other safety abnormalities.

**Efficacy**

- **Efficacy: Primary Endpoint Analyses**: In the Phase 2 placebo and 2:1 Berdazimer gel 10.3% comparison, complete lesion clearance was achieved in >50% of vehicle patients at week 12.

**References**