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Pooled Results of Two Randomized Phase 3 Trials Evaluating VP-102, a Drug-Device Combination Product Containing Cantharidin 0.7% (w/v) for the Treatment of Molluscum Contagiosum

Molluscum contagiosum is a common skin infection caused by a poxvirus that primarily affects children. Currently there is no FDA-approved treatment for molluscum. Phase 3 clinical trials suggest that VP-102, a combination drug-device product, could be safe and effective for use in molluscum participants aged 2 or older.

VP-102 is a shelf-stable, proprietary drug-device combination product containing a topical solution of the active ingredient cantharidin (a vesicant), along with acetone, gentian violet (a surgical dye), and denatonium benzoate (a bittering agent). Once the solution is applied to molluscum lesions, it dries to form a thin flexible film. VP-102 should be removed by washing with soap and water approximately 24 hours after treatment.

Two randomized, double-blind, vehicle-controlled phase 3 trials named CAMP -1 and CAMP-2 were conducted to evaluate VP-102 in treating molluscum in participants 2 years or older.

Study participants were 2 years of age and older and had received a clinical diagnosis of molluscum. There were no limits to lesion counts, only that participants' lesions could be treated with the solution from a maximum of 2 applicators per visit.

Study participants were randomized at baseline to receive either VP-102 or vehicle, applied to any baseline and new lesions present on days 1, 21, 42, and 63, with an end of study visit at day 84. Participants came in for a safety visit on Day 2 and were also contacted by phone to ask about their response to treatment within 24 hours, 7 days, and 14 days after each treatment visit.

The primary efficacy endpoint was the proportion of VP-102-treated participants achieving complete clearance of all treatable baseline and new molluscum lesions at the end of the study visit. The secondary efficacy endpoint included the proportion of VP-102-treated participants achieving complete clearance of all treatable baseline and new molluscum lesions at each visit. The percentage change in lesion count from baseline to each visit was also measured as an exploratory endpoint.

310 participants were treated with VP-102 and 218 were treated with vehicle. Fifty percent of participants receiving VP-102 achieved complete clearance of

all lesions at the end of the study period, while only 15.6% of participants receiving vehicle achieved complete clearance.

Additionally, statistically significantly higher percentages of participants receiving VP-102 achieved complete lesion clearance beginning after a single treatment at treatment visit 2 versus participants receiving vehicle and continued
throughout the study. By the end of the study, mean molluscum lesion counts had decreased by 76% for participants treated with VP-102 versus 0.3% for participants treated with vehicle.

For example, a subject in the VP-102 group could have had 100 lesions at baseline, with a decrease to approximately 24 lesions at the end of the study, or a subject with 25 lesions at baseline with a decrease to approximately 6 lesions at the end of the study. The vehicle group showed essentially no change in percentage of lesions across the study.

The most common adverse events in the VP-102 group were application site blistering, itch, pain, and erythema which were generally mild or moderate in severity and expected due to the pharmacodynamic action of the active ingredient cantharidin. There were no serious adverse events reported that were considered related to treatment with VP-102.

The pooled results of the CAMP studies offer robust efficacy and safety data that support the use of VP-102 for the treatment of molluscum in patients 2 years of age or older if approved by the FDA. The findings could help healthcare professionals and caregivers deliver effective care for molluscum and may manage expectations regarding treatment outcomes.