

# Safety and Efficacy of VP-102 (cantharidin, 0.7% w/v) in Molluscum Contagiosum by Lesion Body Region by Day in Pooled Phase 3 Trials

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## BACKGROUND

- VP-102 is a proprietary drug-device combination product containing a controlled formulation of cantharidin (0.7% w/v) that has been investigated in two Phase 3 trials for the treatment of molluscum contagiosum.
- Anatomical and epidermal differences across distinct areas of the body could lead to variations in efficacy and safety by body region.
- The objective of this exploratory analysis was to determine the safety and efficacy of VP-102 by analyzing pooled data segmented by regions of the body by visit/day.

## METHODS

- Segmentation of lesions by body region at baseline included the following areas:
  - Head/Neck
  - Chest/Abdomen
  - Back/Buttocks
  - Groin
  - Upper Extremities
  - Lower Extremities
- Lesion counts by body region were obtained at each visit (Days 1, 21, 42, 63, and 84). Efficacy was measured by complete clearance of baseline and new lesions in the identified region.
- Subjects could present with multiple body regions at baseline. Lesions occurring in new regions after baseline were not tracked in these analyses.
- Safety analyses were conducted for subjects with lesions treated in the identified body region during or after treatment Visit 1 and before treatment Visit 2.
- The delineations of body areas and determination of treatability of lesions located within 10 mm of mucosal openings were made by the investigators.

## MOLLUSCUM BASELINE CHARACTERISTICS

### Body Regions With Lesions at Baseline (ITT Population) \*

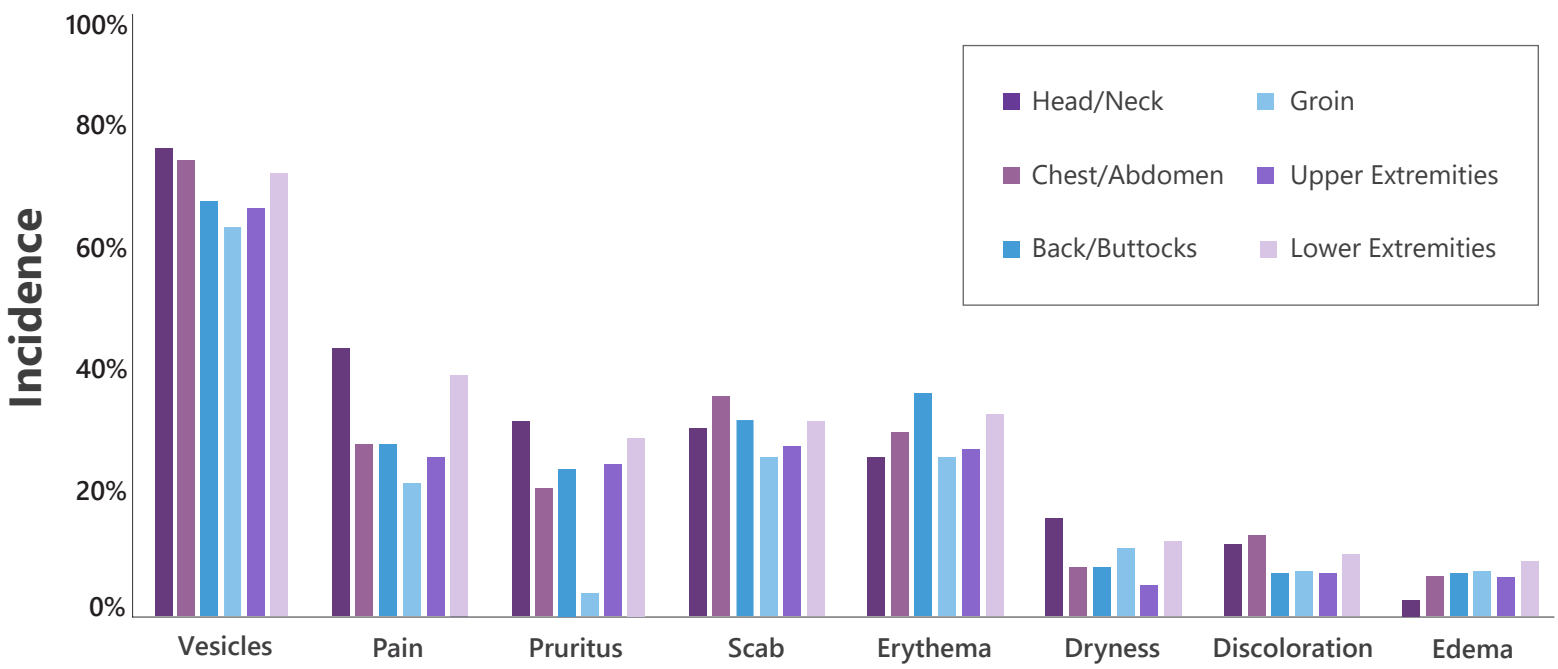
	VP-102 (n=310)	Vehicle (n=218)
Total Number of Body Regions with Lesions at Baseline*	729	557
Total Number of Body Regions with Lesions at Baseline by Subject* n	309	217
Mean	2.36	2.57
SD	1.197	1.304
Median	2.00	2.00
Min-Max	1.0–6.0	1.0–6.0
Number of Subjects with Lesions at Baseline - No(%)		
Head/Neck	77 (24.8)	53 (24.3)
Chest/Abdomen	142 (45.8)	118 (54.1)
Back/Buttocks	117 (37.7)	91 (41.7)
Groin	28 (9.0)	25 (11.5)
Upper Extremities	179 (57.7)	131 (60.1)
Lower Extremities	186 (60.0)	141 (64.7)

There were no significant differences in mean number of lesions or total number of body regions at baseline between the VP-102 and vehicle groups (all p>0.05).

\* Only those subjects who were assessed for lesions in all six body regions at baseline were considered.

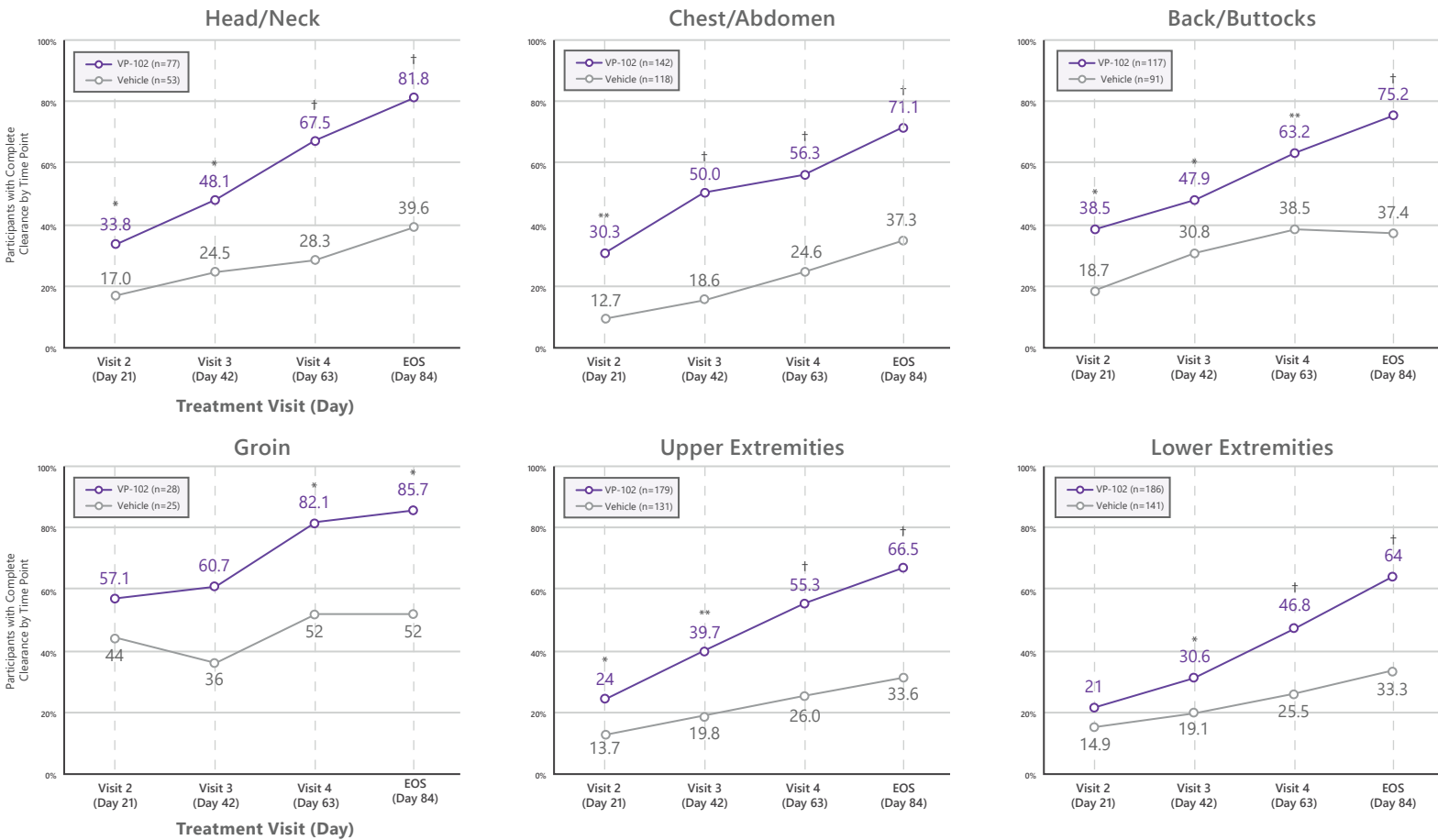
## SAFETY

### Incidence of Application Site TEAEs by Body Location in VP-102-Treated Subjects (Safety Population)



## EFFICACY

### Subjects with Complete Lesion Clearance by Body Region by Visit/Day (ITT Population)



\* p ≤ 0.05, \*\* p ≤ 0.001, † p ≤ 0.0001  
EOS=end of study.

## CONCLUSIONS

- In all body regions, treatment with VP-102 resulted in a statistically significantly greater percentage of subjects with clearance of baseline and new molluscum lesions compared to vehicle.
- Different body regions may require different numbers of treatments.
- The incidence of adverse events was similar in the six body regions and visits.
- Further studies are needed to make strong conclusions about use in the groin and face/neck region due to lower number of subjects in these groups.

### Disclosures

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