Safety and Efficacy of Ycanth™ (VP-102) (0.7% w/v Cantharidin) in Molluscum Contagiosum by Lesion Location: Pooled Results of Two Phase 3 Multicenter, Randomized, Vehicle-Controlled Trials

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Proprietary drug-device combination not yet approved by FDA. Photo is for representative purposes only.

INTRODUCTION

- Ycanth™ (VP-102) is a proprietary drug-delivery device combination 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 (MC).
- 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 the location of the lesions on the body.

METHODS

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 Patients 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)	47 (33.3)

* Only those subjects who were assessed for lesions at all 6 body regions at baseline are considered. There were no significant differences between the VP-102 and Vehicle groups ($p<0.05$).

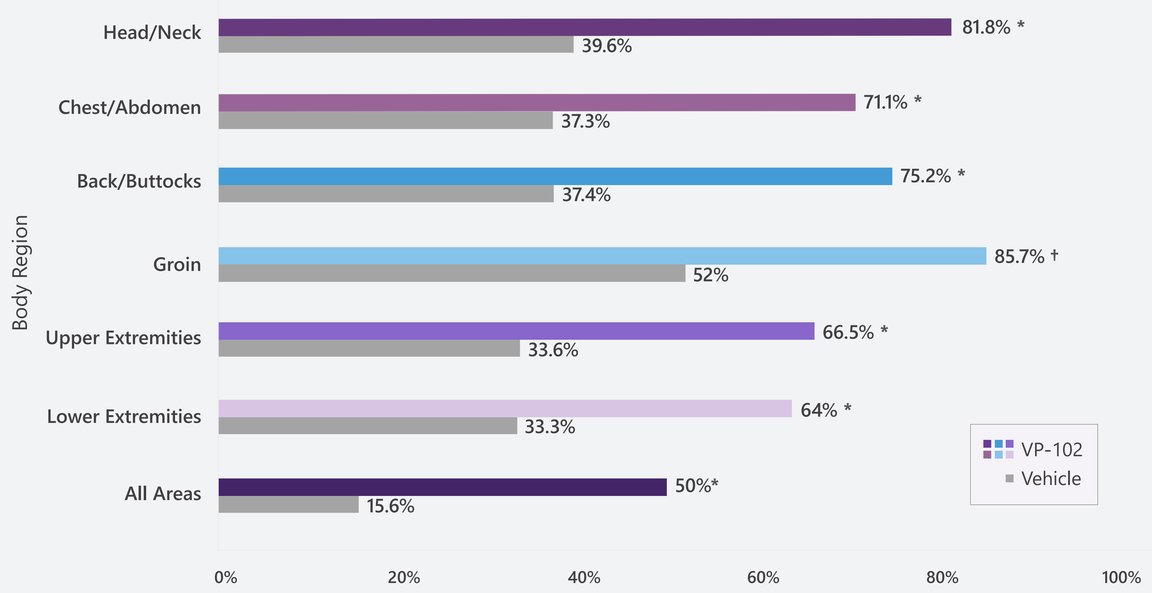
- Segmentation of lesions by body region at baseline included the following areas:
  - Head/Neck
  - Chest/Abdomen
  - Groin
  - Upper Extremities
  - Lower Extremities
- Lesion counts by body region were obtained at each visit (Days 1, 21, 42, 63, and 84). Efficacy was measured by complete clearance of baseline and new lesions in the identified region.
- Subjects could present with multiple body regions. Lesion locations occurring at baseline were tracked throughout the study. Lesions occurring in new regions after baseline were not tracked in this analysis.
- A safety analysis was conducted for patients who had lesions treated in the identified region at a particular visit.
  - This analysis included pre-specified application site TEAEs reported during or after Visit 1 and before Visit 2 (see figure in Safety section), in which all subjects had MC lesions treated in the coordinated areas.

CONCLUSIONS

- Ycanth™ (VP-102) treatment resulted in a statistically significantly greater percentage of subjects with clearance of all baseline and new MC lesions in all body regions compared to vehicle treatment.
- Rates and types of adverse events were similar in the six body regions. The most common TEAEs included application site vesicles, pruritus, scab, erythema, dryness, discoloration, pain, and edema.

EFFICACY

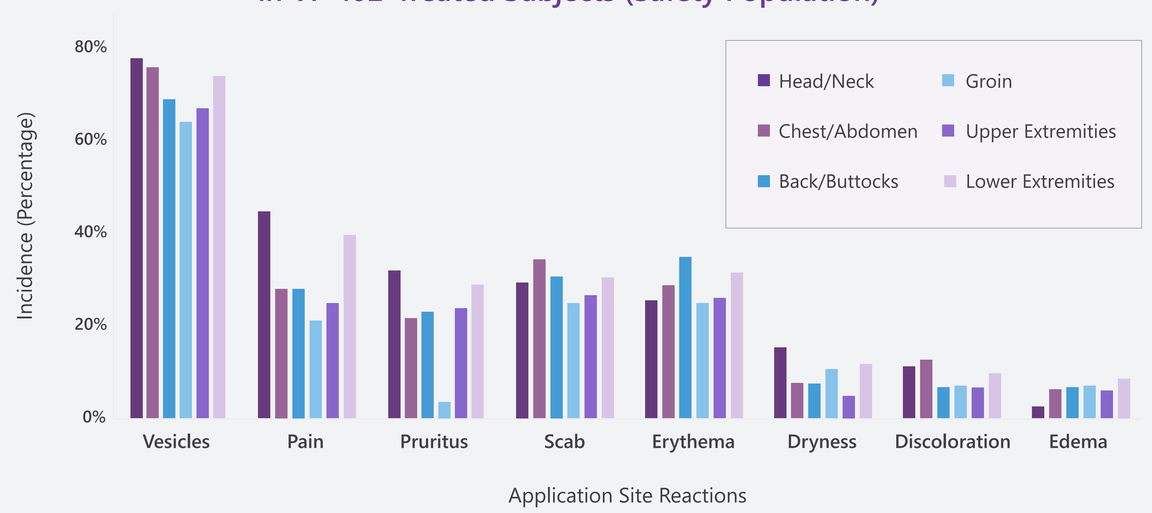
Percentage of Subjects with Complete Clearance of MC Lesions at Day 84 by Body Region (ITT Population)



* P<0.0001
† P=0.0076

SAFETY

Incidence ≥5% of Application Site TEAEs by Body Location in VP-102-Treated Subjects (Safety Population)*



* This figure does not include all TEAEs reported in the studies, but rather the pre-specified subset of application site reactions reported during or after Treatment Visit 1 and before Visit 2.

Disclosures
This study was sponsored by Verrica Pharmaceuticals Inc. Editorial support was provided by Versant Learning Solutions, and funded by Verrica Pharmaceuticals Inc.

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