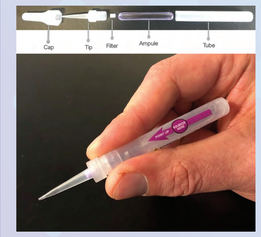
# Pooled Results of Two Phase 3 Multicenter, Randomized, Vehicle-Controlled Trials Using a Proprietary Drug-Device Combination Product Containing 0.7% (w/v) Cantharidin (VP-102) for the Topical Treatment of Molluscum Contagiosum (CAMP-1 and -2)

**Lawrence F Eichenfield MD**[1], Wendy McFalda[2], Bradford Brabec[3], Pearl Kwong[4], Elaine Siegfried[5], Pieter d'Arnaud[6], Jayson Rieger[7], Matthew Davidson[7], Cynthia Willson[7], Patrick Burnett[7]

[1]UC San Diego and Rady Children's Hospital, San Diego, CA, [2]Clarkston Skin Research, Clarkston, MI, [3]Midwest Children's Health Research Inst., Lincoln, NE, [4]Solutions Through Advanced Research, Jacksonville, FL, [5]St. Louis Univ., St. Louis, MO, [6]Instat Consulting, Inc., Chatham, NJ, [7]Verrica Pharmaceuticals Inc., West Chester, PA

VP-102




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

## INTRODUCTION

- Molluscum contagiosum (MC) is a highly contagious pediatric skin infection caused by the molluscum contagiosum virus, a DNA pox virus.[1]
- There are no FDA-approved treatments for MC. If untreated, lesions persist an average of 13 months, with some cases remaining unresolved for more than 2 years.[2,3]
- The active ingredient, cantharidin, is a naturally occurring vesicant that causes degradation of desmosomal plaques.[4]
- VP-102 is a proprietary drug-device combination containing 0.7% (w/v) cantharidin, delivered via a single-use precision applicator.

## DEMOGRAPHICS AND HISTORY

### Baseline Demographics

| | VP-102 (N=311) | Vehicle (N=216) |
|---|---|---|
| **Age (years)** | | |
| Mean (SD) | 7.5 (6.7) | 6.8 (5.8) |
| Median | 6.0 | 6.0 |
| Range | 2 – 60 | 2 – 54 |
| **Age Group – no. (%)** | | |
| ≥2 to 5 yr | 138 (44.4) | 105 (48.6) |
| ≥6 to 11 yr | 139 (44.7) | 89 (41.2) |
| ≥12-18 yr | 23 (7.4) | 17 (7.9) |
| ≥19 yr | 11 (3.5) | 5 (2.3) |
| **Gender – no. (%)** | | |
| Female | 155 (49.8) | 105 (48.6) |
| Male | 156 (50.2) | 111 (51.4) |
| **Race or Ethnic Group – no. (%)** | | |
| White | 277 (89.1) | 201 (93.1) |
| Black or African American | 14 (4.5) | 7 (3.2) |
| Asian | 6 (1.9) | 1 (0.5) |
| American Indian/Alaskan Native | 0 | 1 (0.5) |
| Other | 14 (4.5) | 6 (2.8) |

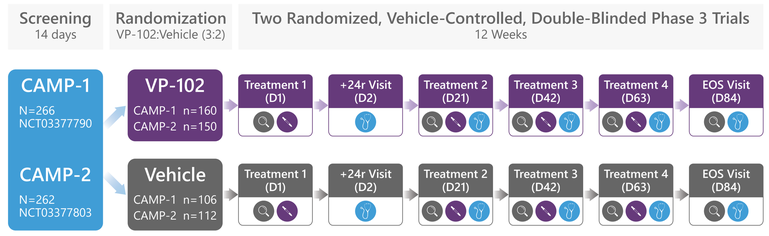
### Medical History

| | VP-102 (N=311) | Vehicle (N=216) |
|---|---|---|
| **Baseline Lesion Count** | | |
| Mean (SD) | 20.5 (23.1) | 22.5 (22.3) |
| Median | 12.0 | 15.5 |
| Range | 1 – 184 | 1 – 110 |
| **Time Since Clinical Diagnosis (days)** | | |
| Mean (SD) | 123.3 (200.7) | 126.2 (199.3) |
| Median | 26.0 | 31.5 |
| Range | 1 – 1247 | 1 – 1302 |
| **Age at Diagnosis (years)** | | |
| Mean (SD) | 7.1 (6.7) | 6.5 (5.9) |
| Median | 6.0 | 5.0 |
| Range | 1 – 60 | 1 – 54 |
| **Previous Treatment for Molluscum – no. (%)** | | |
| Yes | 90 (28.9) | 71 (32.9) |
| **Atopic Dermatitis (AD) – no. (%)** | | |
| History or Active AD | 50 (16.1) | 35 (16.2) |
| Active AD* | 23 (7.4) | 20 (9.2) |

* Active atopic dermatitis was determined by concomitant medication usage of the following medications during the study: topical corticosteroids, topical calcineurin inhibitors, and/or PDE-4 inhibitors.

## STUDY DESIGN

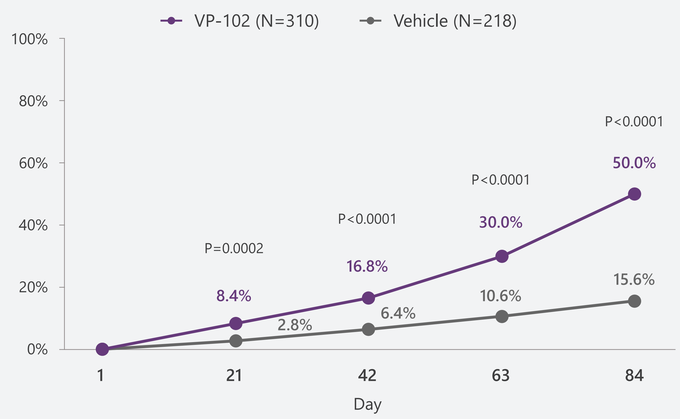
Dermatology Exam | Treatment Application | Evaluation of Response to Treatment (ERT) | EOS End of Study



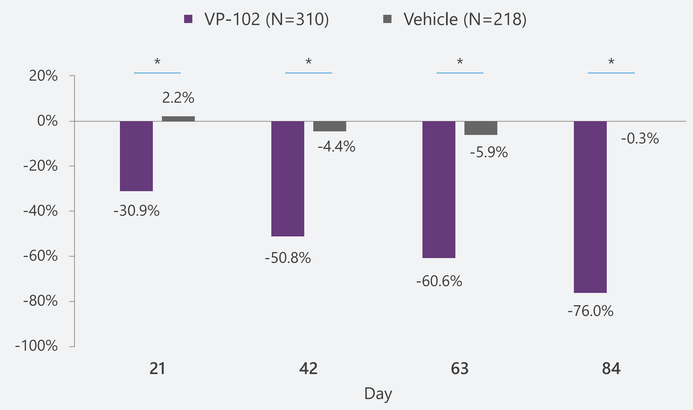

Patients were treated every 3 weeks until clear, or up to a maximum of 4 treatments.

## EFFICACY

### Percentage of Patients With Complete Clearance of Molluscum Lesions at Day 84 (ITT Population)




### Percentage Mean Change in Lesion Count from Baseline to Day 84 (ITT Population)




* P<0.0001

## SAFETY & TOLERABILITY BY SEVERITY

### Treatment Emergent Adverse Events (TEAEs) ≥5% by Severity

| | VP-102 (N=311) | | | Vehicle (N=216) | | |
|---|---|---|---|---|---|---|
| At Least One Incidence: N (%) | Mild | Moderate | Severe | Mild | Moderate | Severe |
| Application Site Vesicles | 187 (60.1) | 100 (32.2) | 11 (3.5) | 59 (27.3) | 4 (1.9) | 0 |
| Application Site Pruritus | 145 (46.6) | 23 (7.4) | 1 (0.3) | 62 (28.7) | 13 (6.0) | 0 |
| Application Site Pain | 127 (40.8) | 59 (19.0) | 7 (2.3) | 34 (15.7) | 2 (0.9) | 0 |
| Application Site Scab | 120 (38.6) | 27 (8.7) | 0 | 44 (20.4) | 3 (1.4) | 0 |
| Application Site Discoloration | 87 (28.0) | 12 (3.9) | 1 (0.3) | 25 (11.6) | 2 (0.9) | 0 |
| Application Site Erythema | 73 (23.5) | 65 (20.9) | 1 (0.3) | 43 (19.9) | 15 (6.9) | 0 |
| Application Site Dryness | 58 (18.6) | 5 (1.6) | 0 | 30 (13.9) | 1 (0.5) | 0 |
| Application Site Edema | 21 (6.8) | 8 (2.6) | 0 | 7 (3.2) | 3 (1.4) | 0 |
| Application Site Erosion | 20 (6.4) | 2 (0.6) | 0 | 2 (0.9) | 0 | 0 |

## CONCLUSIONS

- Pooled data showed that VP-102 treatment resulted in a statistically significantly higher rate of complete lesion clearance at Day 84 (primary endpoint) and a statistically significant decrease in lesion counts at each time point compared to vehicle.
- TEAEs were primarily mild to moderate, with the most common (e.g., application site vesicles, pruritus, pain, and scab) being related to the pharmacodynamic action of cantharidin.
- TEAE discontinuation rates were 1.9% for VP-102 and 0.5% for vehicle.

### Disclosures

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

VERRICA™ PHARMACEUTICALS Reinventing Skin Science

**References**

1. Bugert, *Poxviruses*. 2007; 2. Hanna, *Pharmacology and Therapeutics*. 2006; 3. Olsen, *Lancet*. 2015; 4. Forbat, *Pediatric Dermatology*. 2017.