# Pooled Results of VP-102 Safety and Efficacy in Phase 3 Trials for Molluscum Contagiosum by Fitzpatrick Skin Type (FST)

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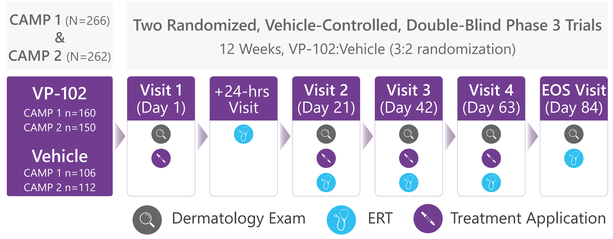
## INTRODUCTION

- VP-102, a single-use proprietary drug-device combination product (cantharidin 0.7%), is under investigation for treatment of molluscum contagiosum (MC). In 2 phase 3 trials, 528 subjects ≥ 2 years with MC, were randomized (3:2) to receive topical application of VP-102 or vehicle.
- While most subjects were Caucasian VP-102:vehicle (N=277:202 [89.4%:92.7%]), there was representation across all FSTs. FST is a tool which assesses skin burn propensity during phototherapy but can be misused to imply constitutive skin color/ethnicity.[1]
- Skin of Color patients with molluscum often experience pigmentary changes with or without treatment. However, FST has not been captured in molluscum treatment trials.
- This *post hoc* analysis was designed to assess VP-102 efficacy (subjects achieving complete clearance (CC) (%)) and safety by FST group, compared to the overall study population.

## METHODS




EOS=end; ERT=evaluation of response to treatment.

- VP-102 or vehicle was applied to all baseline and new lesions once every 21 days until CC, or up to 4 applications.
- Subjects were evaluated at Days 21, 42, 63, 84.
- Treatment emergent adverse events (TEAEs) were assessed throughout the study.

## DEMOGRAPHICS & MEDICAL HISTORIES

### Baseline Characteristics

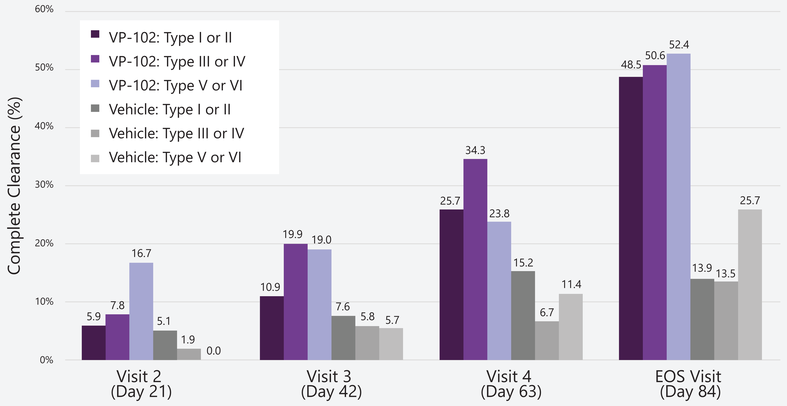
| | VP-102 (n=311) | Vehicle (n=216) |
|---|---|---|
| **Age (years)** | | |
| Mean (SD) | 7.5 (6.7) | 6.8 (5.8) |
| Median (Range) | 6.0 (2–60) | 6.0 (2–54) |
| **Gender - no. (%)** | | |
| Male | 156 (50.2) | 111 (51.4) |
| **Race or Ethnic Group - no. (%)** | | |
| White | 277 (89.1) | 201 (93.1) |
| 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) |

### Molluscum Medical Histories

| | VP-102 (n=311) | Vehicle (n=216) |
|---|---|---|
| **Baseline Lesion Count** | | |
| Mean (SD) | 20.4 (23.0) | 22.6 (22.3) |
| Median (Range) | 12.0 (1–184) | 16.0 (1–110) |
| **Atopic Dermatitis (AD) - no. (%)** | | |
| History or Active AD | 50 (16.1) | 35 (16.2) |
| Active AD* | 23 (7.4) | 20 (9.3) |
| **Fitzpatrick Skin Type - No. (%)** | | |
| I | 20 (6.5) | 8 (3.7) |
| II | 81 (26.1) | 71 (32.6) |
| III | 97 (31.3) | 70 (32.1) |
| IV | 69 (22.3) | 34 (15.6) |
| V | 33 (10.6) | 32 (14.7) |
| VI | 9 (2.9) | 3 (1.4) |

## RESULTS

### Complete Lesion Clearance by Fitzpatrick Skin Type (Pooled IIT Population)




EOS=end of study.

- A significantly higher percentage of subjects achieved CC in the VP-102 group than with vehicle at Day 84; VP-102 vs. vehicle (50% vs. 15.6%) ($p<0.0001$).
- Mean percent change from baseline in MC lesion counts decreased 76% for VP-102 and 0.3% for vehicle at Day 84 ($p<0.0001$).
- The most common TEAEs in the VP-102 group were application site blistering, pruritus, pain, and erythema, which were generally mild or moderate in severity.[2]
- Study included 180 subjects with FST I or II (n=101 VP-102; n=79 vehicle), 270 with FST III or IV (n=166 VP-102; n=104 vehicle), and 77 with FST V or VI (n=42 VP-102; n=35 vehicle).
- CC of MC lesions across FST groups was 48.5%, 50.6%, 52.4% for types I/II, III/IV, and V/VI when treated with VP-102 and 13.9%, 13.5%, and 25.7% in vehicle group, respectively ($p<0.0001$ for types I/II and III/IV, and $p=0.0008$ for type V/VI).
- The incidence of TEAEs by FST subgroup was similar to the overall study population.

## CONCLUSION

- VP-102 was safe and effective across all Fitzpatrick Skin Type groups, consistent with results from the overall study population.

### References

1. Ware O et.al. *Racial Limitations of Fitzpatrick Skin Type.* Cutis. 2020;105: 77-80.

2. Eichenfield L et.al. *Pooled Results of Two Randomized Phase III Trials Evaluating VP-102, a Drug-Device Combination Product Containing Cantharidin 0.7% (w/v) for the Treatment of Molluscum Contagiosum.* Am J Clin Dermatol. 2021. Mar;22(2): 257-265.

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H=honoraria; C=clinical funds; S=stocks; E=employee.