Responder Characteristics in Molluscum Contagiosum (MC) Subjects Treated with VP-102 Achieving Complete Clearance:

Pooled Results of Two Phase 3 Multicenter, Randomized, Vehicle-Controlled Trials for the Topical Treatment of MC

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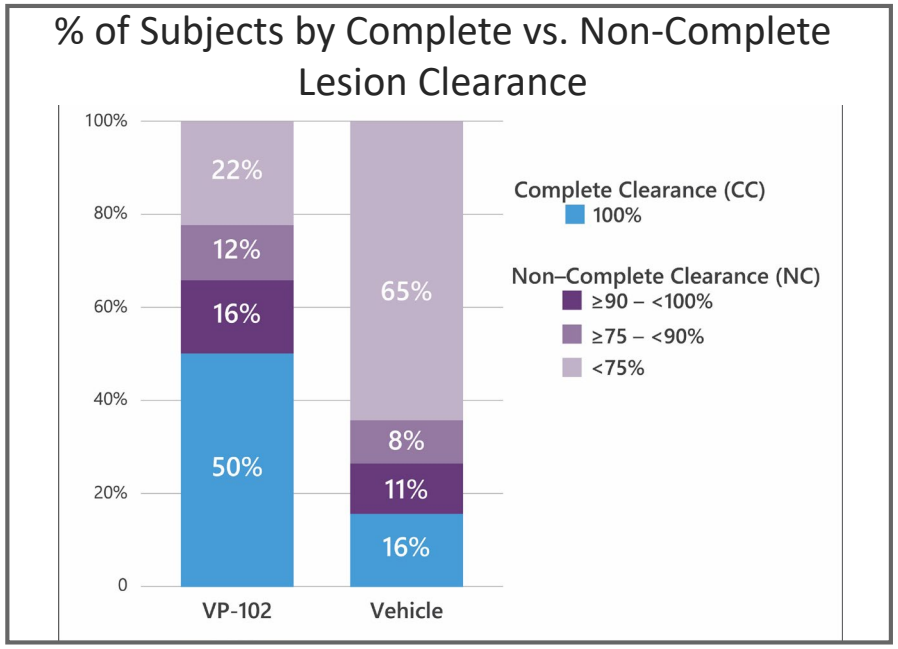
Disclosures: The studies were sponsored by Verrica Pharmaceuticals Inc. Editorial support was provided by Versant Learning Solutions and funded by Verrica Pharmaceuticals Inc. **L. Eichenfield:** Honoraria from Wiley-Blackwell, Valeant, Galderma, Pfizer, Dr. Reddy, DS Labs, Cutanea Life Sciences, Medimetriks, Leo, Novan, Sanofi/Regeneron, Anacor, Asana, Glenmark, Dermavant, MatriSys, Verrica, Lilly, Dermira, Forte, and Almirall; fees from Galderma, Leo, Sanofi/Regeneron, Valeant; stock from TopMD, Verrica; grants from Pfizer, Verrica, Almirall. **S. Cohen:** No relationships to report. **J. Pelletier:** Honoraria from Verrica. **P. d'Arnaud:** Contractor for Verrica. **M. Olivadoti:** Employee for Verrica. **P. Burnett:** Employee for Verrica; stock from Verrica.

Background and Methods

- VP-102 is a proprietary drug-delivery device combination containing a topical formulation of cantharidin (0.7% w/v) under investigation for the treatment of molluscum contagiosum (MC).
- In this *post-hoc* analysis, VP-102-treated subjects were separated into 2 categories at the end of study (EOS) visit (Day 84): those who achieved complete lesion clearance (**CC**) of all baseline and new lesions versus those who did not (non-complete clearance, **NC**).
- The objective was to compare demographics and outcomes between the CC and NC groups to identify characteristics potentially predictive of response to treatment with VP-102.



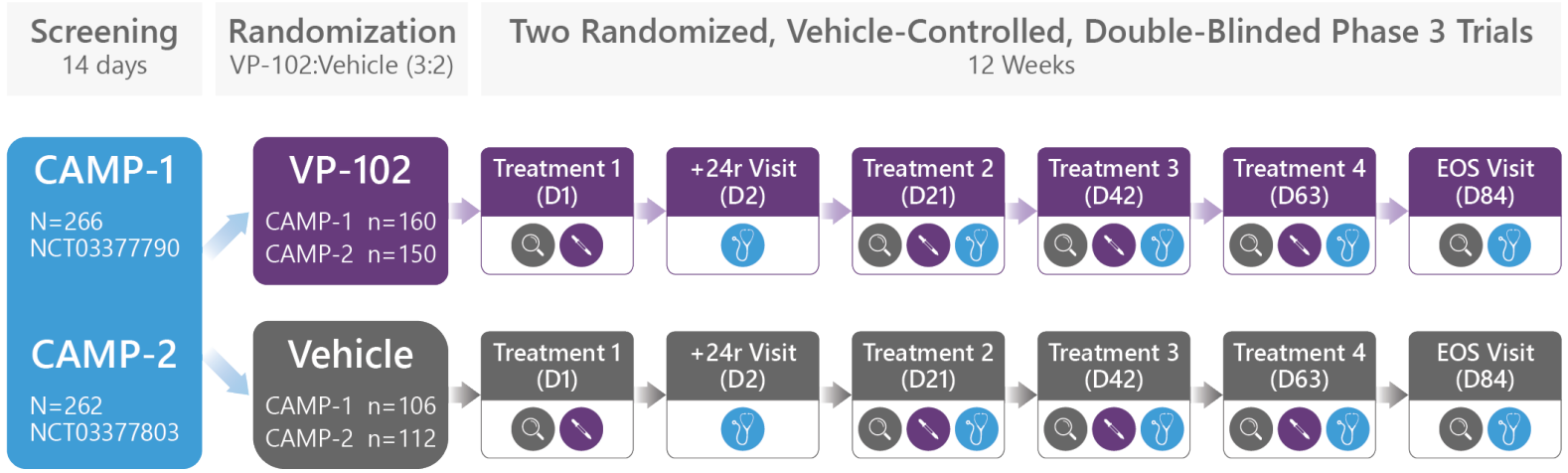
Study drug (VP-102 or vehicle) was administered topically to all treatable lesions every 21 days until clearance or a maximum of 4 applications.

Dermatology Exam

Evaluation of Response to Treatment (ERT)

Treatment Application

EOS End of Study



Baseline Demographics and Medical Histories Were Similar Between Groups

Baseline Demographics for VP-102-Treated Subjects (ITT Population)

	VP-102	
	Complete Clearance (n=155)	Non-Complete Clearance (n=155)
Age (years)		
Mean (SD)	8 (7.45)	6.9 (5.85)
Median (Range)	6 (2.0–60.0)	6 (2.0–57.0)
Gender - No. (%)		
Female	77 (49.7)	77 (49.7)
Male	78 (50.3)	78 (50.3)
Ethnicity - No. (%)		
Hispanic/Latino	35 (22.6)	23 (14.8)
Not Hispanic/Latino	120 (77.4)	132 (85.2)
Race - No. (%)		
Asian	3 (1.9)	3 (1.9)
Black/African American	6 (3.9)	7 (4.5)
White	141 (91.0)	136 (87.7)
Other	5 (3.2)	9 (5.8)

* A subject was allocated to the Complete Clearance group if they achieved 100% clearance of MC lesions at the Day 84/EOS visit.

Baseline Molluscum Medical Histories for VP-102-Treated Subjects (ITT Population)

	VP-102	
	Complete Clearance (n=155)	Non-Complete Clearance (n=155)
Baseline Lesion Count †		
Mean (SD)	17.9 (20.26)	23.1 (25.35)
Median (Range)	10 (1–106)	14 (1–184)
Time Since Clinical Diagnosis (days)		
Mean (SD)	129.4 (211.41)	116.3 (190.23)
Median (Range)	34 (1–1,247)	22 (1–1,010)
Any Previous Treatment for Molluscum - No. (%)		
Yes	38 (24.5)	51 (32.9)
No	117 (75.5)	104 (67.1)
History of Atopic Disease - No. (%)		
Yes	46 (29.7)	54 (34.8)
No	109 (70.3)	101 (65.2)

* A subject was allocated to the Complete Clearance group if they achieved 100% clearance of MC lesions at the Day 84/EOS visit.

† p=0.045

Safety Outcomes Were Similar Between VP-102 Groups

- Application site treatment-emergent adverse events (TEAEs) were expected due to the pharmacodynamic action of cantharidin, a topical vesicant.
- The overall rates of TEAEs due to treatment were similar between the CC and NC groups.
  - There were two statistically significant differences in local site reactions between the CC and NC groups: the NC group had higher rates of application site pain and pruritis.

Selected Application Site TEAEs by Complete vs Non-Complete Clearance in VP-102-Treated Subjects (Safety Population, Incidence ≥5%)

	VP-102	
	Complete Clearance (n=155)	Non-Complete Clearance (n=155)
Vesicles	150 (96.8)	148 (94.9)
Pain†	82 (52.9)	111 (71.2)
Pruritus**	74 (47.7)	95 (60.9)
Scab	70 (45.2)	77 (49.4)
Erythema	68 (43.9)	71 (45.5)
Discoloration	48 (31.0)	52 (33.3)
Dryness	37 (23.9)	26 (16.7)
Erosion	12 (7.7)	10 (6.4)

This figure does not include all TEAEs reported in the studies, but rather a pre-specified subset of application site reactions.

† p=0.0009

** p=0.0199

Conclusions

- In this study of subjects with MC treated with VP-102, baseline demographics and MC histories were similar between those who achieved complete clearance of all baseline and new lesions (CC) at the EOS visit compared to those who did not (NC).

- Safety outcomes were similar in both groups, except for application site pain and pruritus. Both were higher for the NC group.

- **These data suggest that any subject within the requirements of the study protocol could be a candidate for complete clearance of all baseline and new MC lesions after up to four treatments with VP-102.**