Safety and Efficacy of VP-102 in Molluscum Contagiosum (MC) Subjects by Lesion Count Quartile:

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

Lawrence F. Eichenfield[1], Pearl Kwong[2], Mercedes E. Gonzalez[3], Anthony J. Mancini[4], Pieter d'Arnaud[5], Melissa Olivadoti[6], Patrick Burnett[6]

[1]UC San Diego and Rady Children's Hospital, San Diego, CA; [2]Solutions Through Advanced Research, Jacksonville, FL; [3]Skin Research Institute, Coral Gables, FL; [4]Ann & Robert H. Lurie Children's Hospital of Chicago/Northwestern University, Chicago, IL; [5]Instat Consulting, Inc., Chatham, NJ; [6]Verrica Pharmaceuticals Inc., West Chester, PA.

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. **P. Kwong:** Honoraria from Aclaris, Almirall, Biofrontera, Cutanea, Galderma, Dermira, La Roche-Posay, L'Oreal, Pfizer, Dermavant, Verrica; grants from Eli Lilly, Celgene, Novartis, Pfizer, Menlo, Aclaris, Verrica. **M. Gonzalez:** Honoraria from Pierre Fabre, Dove/Unilever, Encore Dermatology, Galderma, Verrica; fees from Gersan Lehrman. **A. Mancini:** Honoraria from Dermavant, Cassiopeia, Pfizer, Verrica. **P. d'Arnaud:** Contractor for Verrica. **M. Olivadoti:** Employee for Verrica. **P. Burnett:** Employee for Verrica; stock from Verrica.

Background

- Two Phase 3 clinical trials with identical protocols were completed using VP-102, a proprietary drug-delivery device combination containing cantharidin (0.7% w/v) for the topical treatment of molluscum contagiosum (MC).
- This pre-specified exploratory analysis of pooled data aimed to determine whether lesion count at baseline affected safety and efficacy outcomes in VP-102 vs vehicle-treated subjects.
- Subjects were separated into four quartiles by baseline lesion count (see figure, right.)

Categorization of Study Subjects by Baseline Lesion Count Quartile

Quartile 1	Quartile 2	Quartile 3	Quartile 4
1–7 lesions	8–14 lesions	15–28 lesions	≥29 lesions

Methods

- Subjects 2 years or older were randomized 3:2 to topical administration of VP-102 or vehicle applied to all baseline and new lesions once every 21 days until clear, or a maximum of 4 applications.
- Lesion counts were recorded by assessors blinded to the subject's treatment group assignment at Days 21, 42, 63, and at the end-of-study visit (EOS) at Day 84.
- Adverse events (AEs) were documented throughout the study with a specific focus on local skin reactions (LSRs), which were expected due to the pharmacodynamic action of cantharidin as a vesicant.

Baseline Demographics and Medical Histories Were Similar Across Quartiles

- VP-102-treated subjects with higher lesion counts had a younger mean age, a shorter time since diagnosis, and a more frequent history of, or currently active, atopic dermatitis.

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

	VP-102			
	Quartile 1 (n=94)	Quartile 2 (n=82)	Quartile 3 (n=67)	Quartile 4 (n=68)
Age (years)				
Mean (SD)	9.0 (9.27)	7.5 (5.83)	6.0 (2.73)	6.7 (5.86)
Median (Range)	7.0 (2.0–60.0)	6.0 (2.0–42.0)	5.0 (2.0–13.0)	5.0 (2.0–43.0)
Gender - No. (%)				
Female	44 (46.8)	48 (58.5)	30 (44.8)	33 (48.5)
Male	50 (53.2)	34 (41.5)	37 (55.2)	35 (51.5)
Ethnicity - No. (%)				
Hispanic/Latino	27 (28.7)	17 (20.7)	11 (16.4)	4 (5.9)
Not Hispanic/Latino	67 (71.3)	65 (79.3)	56 (83.6)	64 (94.1)
Race - No. (%)				
Asian	0 (0.0)	3 (3.7)	0 (0.0)	3 (4.4)
Black or African American	5 (5.3)	1 (1.2)	4 (6.0)	4 (5.9)
White	86 (91.5)	72 (87.8)	62 (92.5)	57 (83.8)
Other	3 (3.2)	6 (7.3)	1 (1.5)	4 (5.9)

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

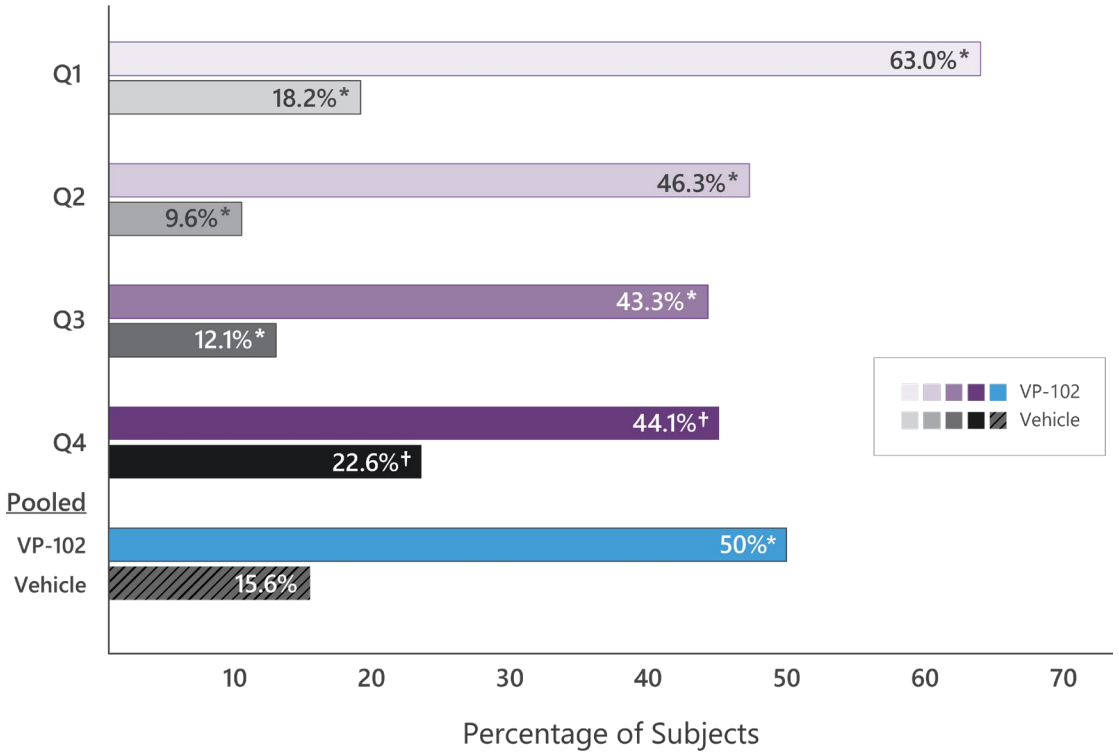
	VP-102			
	Quartile 1 (n=94)	Quartile 2 (n=82)	Quartile 3 (n=67)	Quartile 4 (n=68)
Baseline Lesion Count				
Mean (SD)	3.7 (2.05)	10.5 (1.87)	20.7 (4.04)	55.0 (26.49)
Median (Range)	4.0 (1–7)	10.0 (8–14)	21.0 (15–28)	48.5 (29–184)
Time Since Clinical Diagnosis (days)				
Mean (SD)	134.3 (228.78)	116.8 (176.86)	121.0 (218.89)	118.2 (168.46)
Median (Range)	20.0 (1–1247)	30.5 (1–977)	23.0 (1–1104)	57.5 (1–925)
Age at Clinical Diagnosis				
Mean (SD)	8.7 (9.32)	7.2 (5.81)	5.7 (2.79)	6.3 (5.94)
Median (Range)	6.0 (1–60)	6.0 (1–42)	5.0 (1–13)	5.0 (1–43)
Any Previous Treatment for Molluscum - No. (%)				
Yes	29 (30.9)	23 (28.0)	17 (25.4)	21 (30.9)
No	65 (69.1)	59 (72.0)	50 (74.6)	47 (69.1)
Atopic Dermatitis (AD) - No. (%)				
History or Active AD	8 (8.5)	7 (8.5)	16 (23.9)	19 (27.9)
Active AD*	3 (3.2)	2 (2.4)	7 (10.4)	11 (16.2)

* 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.

Efficacy Outcomes Were Similar Across Quartiles

- All VP-102 quartiles had statistically significantly higher clearance rates of all baseline and new lesions vs vehicle ($p<0.05$). **Complete clearance rates were similar across all VP-102 quartiles.**

Percentage of Subjects with Complete Lesion Clearance at EOS/Day 84



* P<0.0001

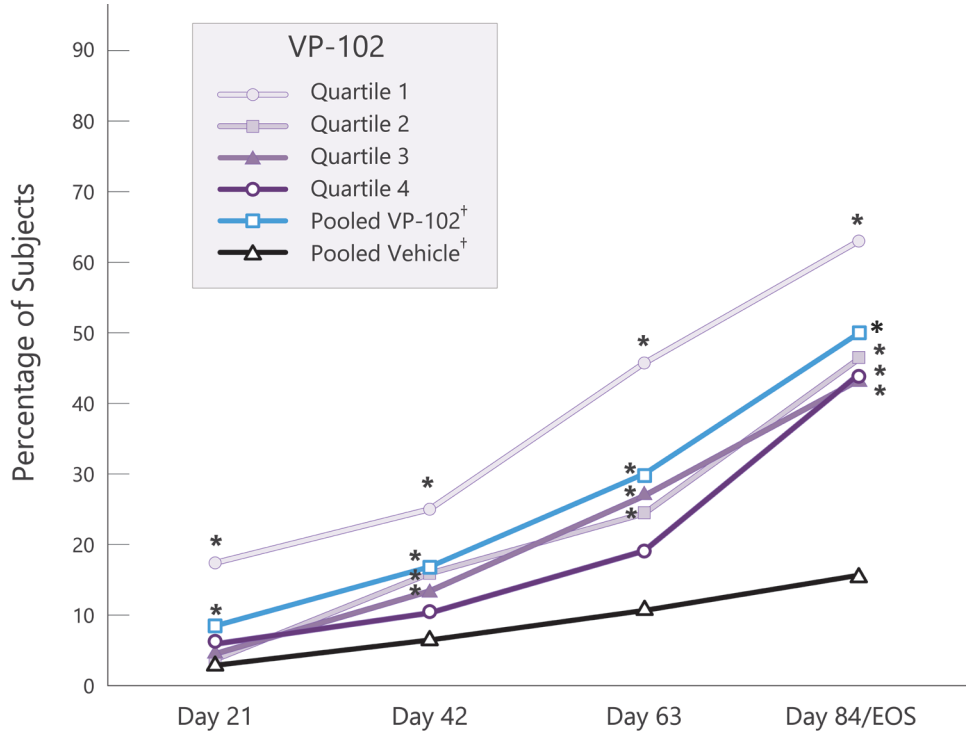
† P=0.0005

** Pooled data includes patients of all quartiles for reference.

EOS = end of study

- There was an association between VP-102 quartile and separation from vehicle – the VP-102 quartiles with the fewest lesions separated from vehicle earlier ($p<0.05$).

Percentage of Subjects with Complete Lesion Clearance By Time Point



* VP-102 group reported statistically significantly higher percentages of complete lesion clearance versus vehicle group ($P<0.05$).

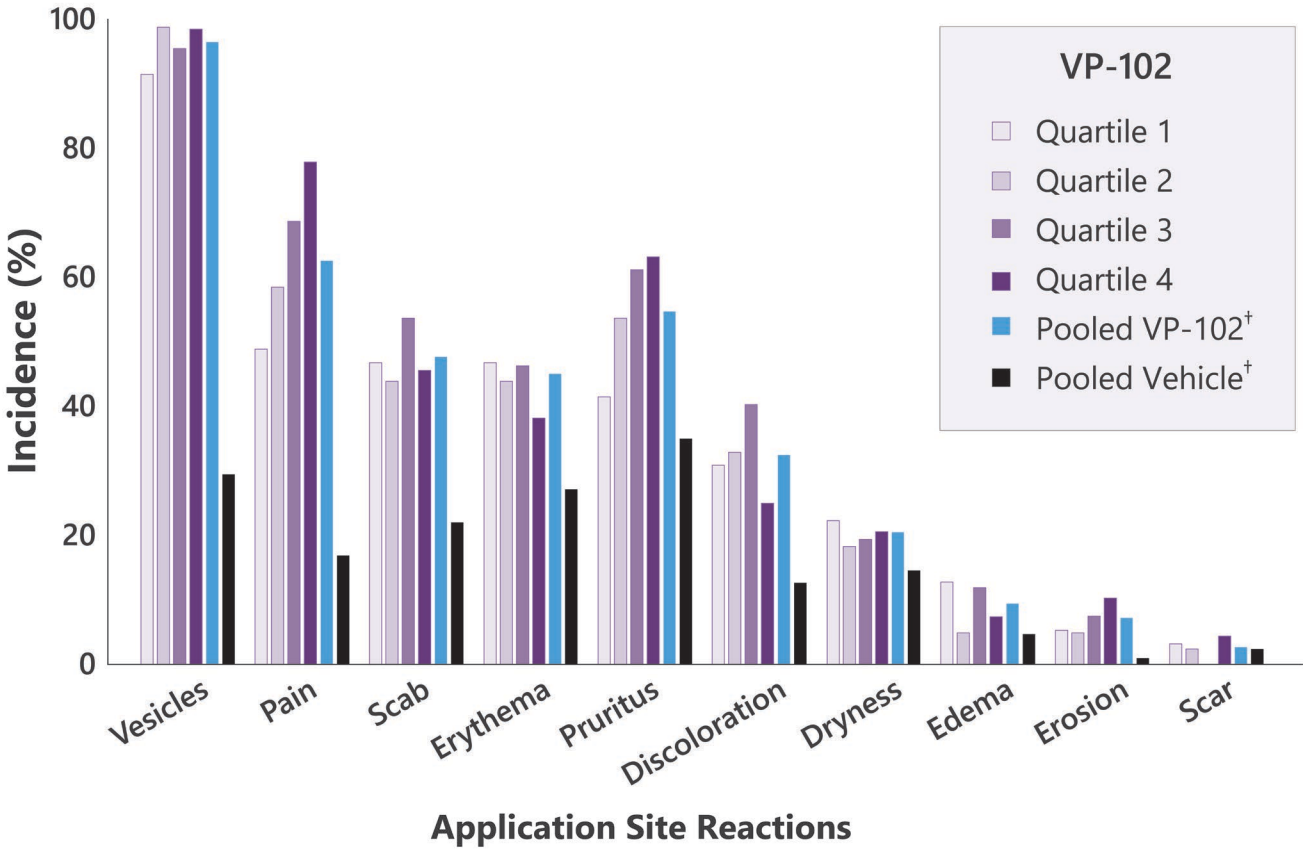
† Pooled data includes patients of all quartiles for reference.

EOS=end of study.

Safety Outcomes

- Selected treatment emergent adverse events (TEAEs) at the application site were similar across quartiles with VP-102 treatment.

Selected Application Site TEAEs*



* Not all TEAEs reported. Pre-specified subset of application site reactions included.

† Pooled data includes patients of all quartiles for reference.

TEAE=treatment-emergent adverse events.

Conclusions

- VP-102-treated subjects were similar in baseline characteristics and MC medical histories across quartiles.
- VP-102 groups showed a statistically significantly higher percentage of subjects with complete clearance in all quartiles compared to vehicle groups.
- Pooled discontinuation of study drug due to AEs was 1.9% for VP-102 and 0.5% for vehicle groups.
- Efficacy and safety outcomes were similar in VP-102 subjects regardless of quartile.
- **These data suggest that the number of MC lesions at baseline does not strongly impact efficacy and safety outcomes with VP-102 treatment.**