Proportion of Subjects Achieving a Molluscum Lesion Count of 0 or 1 at the Day 84 End of Study Visit in Phase 3 Clinical Trials with VP-102 CAMP-1 and CAMP-2

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INTRODUCTION

- VP-102, a proprietary drug-device combination product containing cantharidin (0.7% w/v), is under investigation for treatment of molluscum contagiosum (MC).
- In two phase 3 trials (Cantharidin Application in Molluscum Patients [CAMP-1 and CAMP-2]), 528 subjects ≥ 2 years of age with MC, were randomized (3:2) to receive topical application of VP-102 or vehicle.
- The primary efficacy endpoint was the percentage of subjects obtaining complete clearance (CC) of all baseline and new treatable molluscum lesions at Day 84.
- This *post hoc* analysis evaluates the proportion of subjects with 0 or 1 MC lesions present at the End of Study Visit (EOS) Day 84 in the pooled CAMP-1 and -2 trials subjects.

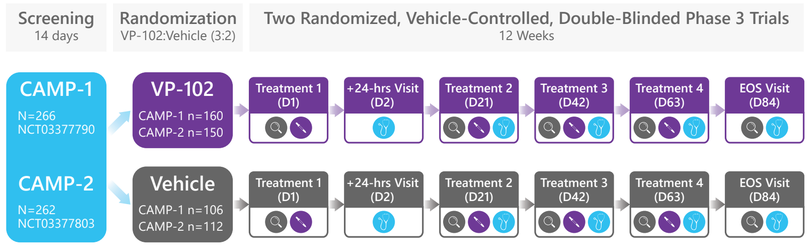
METHODS

- Subjects in the CAMP-1 and CAMP-2 received VP-102 or vehicle applied topically to all baseline and new MC lesions once every 21 days until complete clearance of MC lesions, up to a maximum of 4 applications.
- MC lesion counts were conducted at Treatment Visit Days 21, 42, 63 and EOS Day 84.

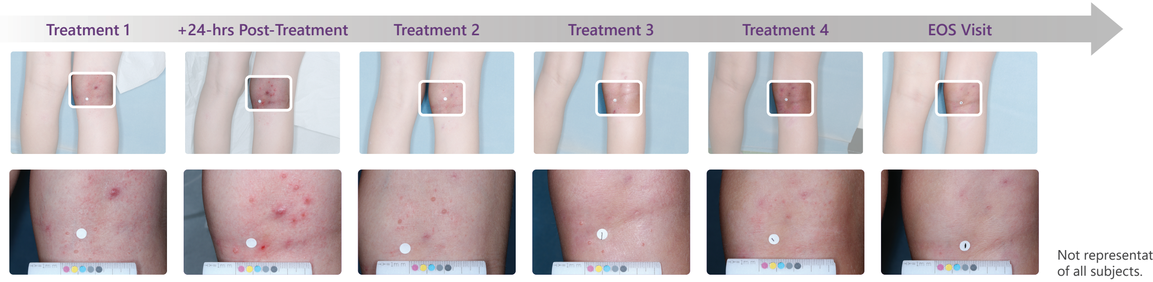
STUDY DESIGN

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

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

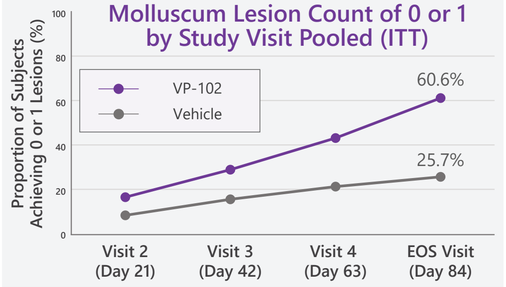


VP-102-TREATED SUBJECT



Not representative of all subjects.

RESULTS



- VP-102 treatment resulted in significantly higher percentage of subjects achieving complete clearance of MC at EOS Day 84; VP-102 vs vehicle (50% vs.15.6%) ($p<0.0001$).
- Mean molluscum lesion counts decreased 76% for VP-102 and 0.3% for vehicle at day 84 ($p<0.0001$).
- Subjects with a MC lesion count of 0 or 1 at Day 84 was statistically significantly higher in the VP-102 group than the vehicle group (60.6% VP-102; 25.7% vehicle, $p<0.0001$).
- 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.[1]

DEMOGRAPHICS & MEDICAL HISTORY

Baseline Demographics

	CAMP-1		CAMP-2	
	VP-102	Vehicle	VP-102	Vehicle
Randomized (n)	160	106	150	112
Completed (n)	150 (94%)	100 (94%)	139 (93%)	108 (96%)
Age (years)				
Mean	7.5	6.3	7.4	7.3
Median	6.0	5.0	6.0	6.0
Min, Max	2, 41	2, 40	2, 60	2, 54
Gender				
Female	85 (53%)	61 (58%)	69 (46%)	46 (41%)
Male	75 (47%)	45 (42%)	81 (54%)	66 (59%)

Molluscum Medical History

	CAMP-1		CAMP-2	
	VP-102 (n=160)	Vehicle (n=106)	VP-102 (n=150)	Vehicle (n=112)
Time Since Clinical Diagnosis (days)				
Mean	127	129	118	124
Median	25	32	28	31
Min, Max	1, 1247	1, 1302	1, 977	1, 957
Age at Diagnosis (years)				
Mean	7.1	6.1	7.1	7.0
Any Previous Treatment for Molluscum?				
Yes	41 (26%)	30 (28%)	48 (32%)	42 (38%)
Active Atopic Dermatitis?				
Yes	12 (8%)	13 (12%)	11 (7%)	7 (6%)
Baseline Lesion Count				
Mean	22	25	19	20
Min, Max	1, 107	1, 110	1, 184	1, 86

CONCLUSIONS

- Treatment with VP-102 resulted in a higher proportion of subjects with 0 or 1 MC lesion remaining at Day 84 compared to vehicle.
- For those subjects who did not achieve complete clearance, reduction of MC lesions may help lead to a reduced viral burden, decrease auto-inoculation, and limit transmission to others.

References

1. 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.
2. Eichenfield LF et. al. *Safety and Efficacy of VP-102, a Proprietary, Drug-Device Combination Product Containing Cantharidin, 0.7% (w/v), in Children and Adults With Molluscum Contagiosum: Two Phase 3 Randomized Clinical Trials.* JAMA Dermatol. 2020 Dec;156(12):1315–1323.

Disclosures

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