CAMP-1 and CAMP-2: Phase 3, Randomized, Double-Blind, Vehicle-Controlled, Pivotal Studies Investigating VP-102, a Novel Drug-Device Combination Containing a Topical Formulation of Cantharidin for the Treatment of Molluscum Contagiosum

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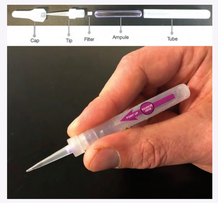
INTRODUCTION

Molluscum contagiosum (MC) virus is a highly contagious pediatric skin infection caused by MCV, a DNA poxvirus.

There are no FDA-approved treatments for MC. If untreated, lesions persist an average of 13 months, with some cases remaining unresolved for ≥ 2yrs.



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

VP-102 is a proprietary drug-device combination of 0.7% w/v cantharidin delivered via a single-use precision applicator. The active ingredient, cantharidin, is a naturally occurring vesicant that causes degradation of desmosomal plaques.

DEMOGRAPHICS AND 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%)

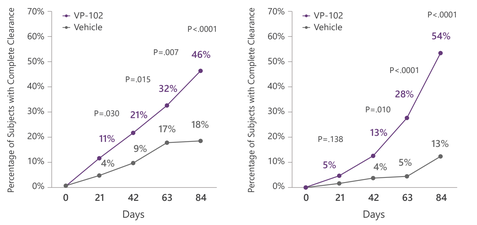
Molluscum Medical History

	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

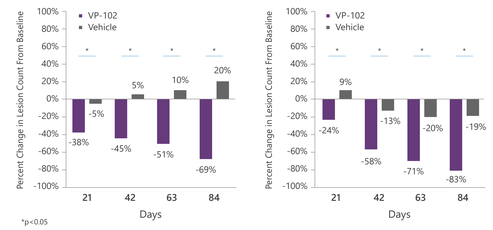
RESULTS

Endpoints were the percent of subjects with complete clearance at Day 84 (primary), percent of subjects with complete clearance at Days 21, 42, and 63, and safety and tolerability.

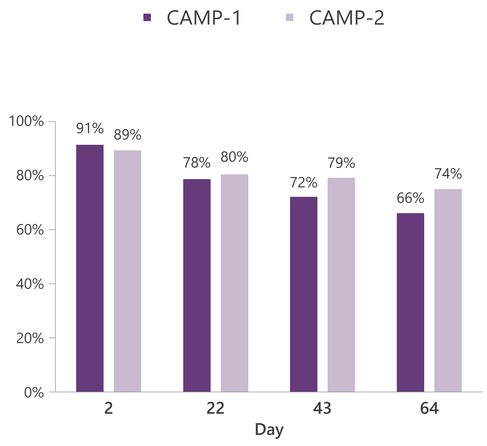
Complete Clearance: ITT Population



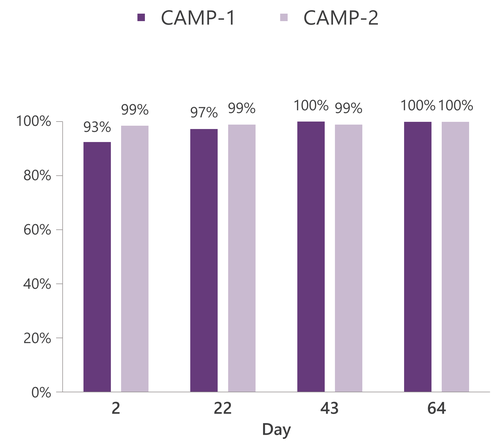
Mean Lesion Count from Baseline



Blistering Incidence 24 hours After Each Treatment



Blisters Smaller Than a Dime



STUDY DESIGN

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

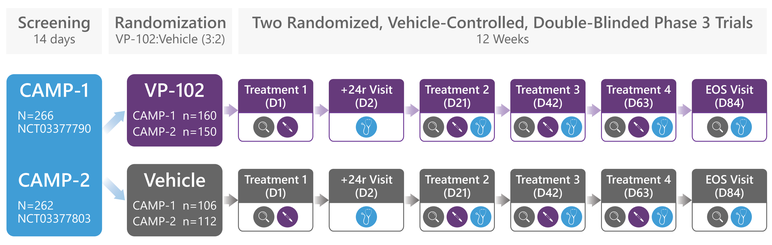
Assessments of expected local skin reactions (LSRs), including incidence/size of blisters, erythema, pain, pruritus, and edema were measured at each visit through patient/caregiver report, as well as at 24 hours, 7 day, and 14 days after each treatment.

Dermatology Exam

Treatment Application

Evaluation of Response to Treatment (ERT)

EOS End of Study



SAFETY & TOLERABILITY

Treatment Emergent Adverse Events (TEAEs)

	CAMP-1		CAMP-2	
Subjects with at least one...	VP-102 (n=160) n (%)	Vehicle (n=106) n (%)	VP-102 (n=150) n (%)	Vehicle (n=112) n (%)
Treatment Emergent Adverse Event (TEAE)	159 (99)	76 (73)	143 (95)	74 (66)
Mild	157 (98)	66 (64)	141 (94)	74 (66)
Moderate	105 (65)	41 (39)	60 (40)	18 (16)
Severe	19 (12)	1 (1)	4 (3)	0 (0)
TEAE related to drug	158 (98)	60 (58)	143 (95)	67 (60)
Serious TEAE	0 (0)	1 (1)	0 (0)	0 (0)
TEAE leading to discontinuation	5 (3)	0 (0)	1 (1)	1 (1)
Local Skin Reaction TEAE	158 (98)	60 (58)	143 (95)	67 (60)

TEAEs Occurring in >5% of Subjects in Any Group

	CAMP-1		CAMP-2	
Application Site	VP-102 (n=160) n (%)	Vehicle (n=106) n (%)	VP-102 (n=150) n (%)	Vehicle (n=112) n (%)
Vesicles	157(97.5)	29 (27.9)	141 (94)	34 (30.4)
Pain	110 (68.3)	19 (18.3)	85 (55.3)	14 (12.5)
Pruritus	103 (64)	36 (34.6)	64 (42.7)	34 (30.4)
Erythema	67 (41.6)	29 (27.9)	70 (46.7)	27 (24.1)
Scab	62 (38.5)	23 (22.1)	85 (56.7)	21 (18.8)
Discoloration	53 (33.5)	18 (17.3)	46 (30.7)	9 (8)
Dryness	24 (14.9)	11 (10.6)	39 (26)	20 (17.9)
Edema	21 (13)	6 (5.8)	8 (5.3)	2 (2.7)
Erosion	10(6.2)	2 (1.9)	11 (7.3)	0 (0)

SUMMARY

- VP-102 patients achieved a higher rate of complete clearance at D84 (primary endpoint) compared to vehicle in both trials (P<0.0001), as well as significant decreases in lesion counts at each time point
- TEAEs were primarily mild to moderate, with the most common being related to the drug's mechanism of action (including application site vesicles, erosion, scab, and erythema)
- TEAE discontinuation rates for VP-102 and Vehicle groups were 5 (3%) and 0 for CAMP-1, and 1 (1%) for both groups for CAMP-2
- Blistering was an expected local skin reaction due to the the pharmacodynamic action of cantharidin; incidence and size of blisters did not increase over time

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Disclosures

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