COVE-1: A Phase 2, Open-Label Study To Evaluate Efficacy, Safety, and Tolerability of a Proprietary Drug-Device Combination Product Containing 0.7% w/v Cantharidin (VP-102) for Topical Treatment of Common Warts

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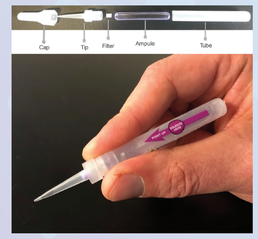
VP-102



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

INTRODUCTION

- Cutaneous viral warts (verrucae vulgaris) are a common condition, with an estimated lifetime incidence of 79%.[1]
- There are numerous treatments, but most are of limited efficacy.
- Compounded cantharidin has been used for the treatment of warts since the 1950s but lacks large scale trials and a standardized formulation.[2]
- This Phase II study evaluated the safety and efficacy of VP-102, a drug-device combination with cantharidin (0.7% w/v) for the treatment of common warts.

METHODS

- Eligible patients were 2 years or older and had 1-6 warts measuring ≤10mm in diameter and ≤3mm in height.

Dermatology and LSR Exams

Wart Counts, Measurements, and Locations

Drug Application and Occlusion with 3M™ Blenderm™ Surgical Tape**

24-hr and 7-day ERT Phone Call

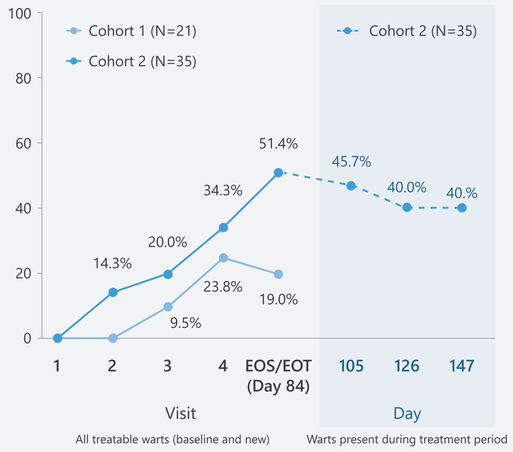
Wart Paring†

Screening Period Up to 14 days prior to first treatment	Cohort 1	Cohort 2
Treatment Visit 1	Day 1*	Day 1
Treatment Visit 2	Day 14*	Day 21
Treatment Visit 3	Day 28*	Day 42
Treatment Visit 4	Day 42*	Day 63
Follow-Up Visits	Day 84 (EOS)	Day 84 (EOT) Days 105, 126, and 147

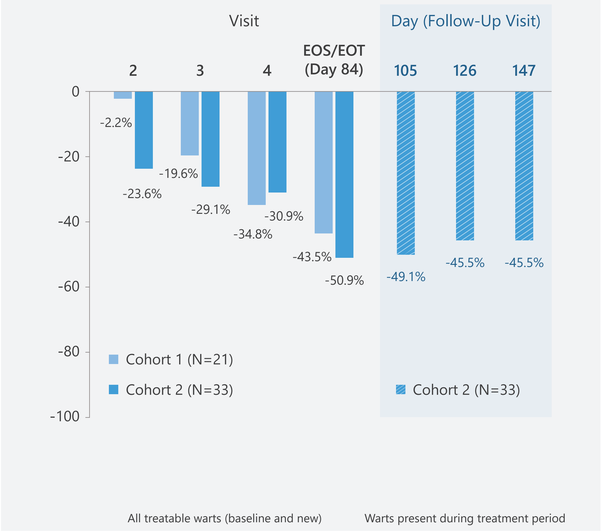
* Minimum interval between treatments was 14 days, but could be longer depending on clinical response. ** Drug and tape removed 24-hrs post-treatment.
† Wart paring performed at any Treatment Visit when adherent thick scale was present and the investigator considered it safe to apply.
LSR=Lesion Site Reaction; ERT=Evaluation of Response to Treatment; EOS=End of Study; EOT=End of Treatment.

EFFICACY

Percentage of VP-102-Treated Patients With Complete Clearance of Common Warts



Percentage Change in Number of Common Warts from Baseline in VP-102-Treated Patients



SAFETY & TOLERABILITY

Incidence of TEAEs ≥5%*

	Cohort 1 N=21 (To Day 84)	Cohort 2 N=34 (To Day 147)
Incidence: N (%)		
Application Site Vesicles	20 (95.2)	27 (79.4)
Application Site Pain	15 (71.4)	26 (76.5)
Application Site Erythema	13 (61.9)	19 (55.9)
Application Site Pruritus	9 (42.9)	16 (47.1)
Application Site Scab	8 (38.1)	20 (58.8)
Application Site Dryness	6 (28.6)	13 (38.2)
Application Site Edema	4 (19.0)	6 (17.6)
Application Site Discoloration	1 (4.8)	8 (23.5)
Application Site Exfoliation	0	4 (11.8)
Application Site Erosion	0	3 (8.8)
Papilloma Viral Infection**	0	3 (8.8)

* Local skin reactions were expected due to the pharmacodynamic action of cantharidin. ** Warts reported with verbatim term of 'ring wart' and coded to MeDRA.

Incidence of TEAEs ≥5%: Severity

	Cohort 1 N=21 (To Day 84)			Cohort 2 N=34 (To Day 147)		
Incidence: N (%)	Mild	Moderate	Severe	Mild	Moderate	Severe
Application Site Vesicles	18 (85.7)	1 (4.8)	1 (4.8)	16 (47.1)	10 (29.4)	1 (2.9)
Application Site Pain	11 (52.4)	3 (14.3)	1 (4.8)	17 (50)	6 (17.6)	3 (8.8)
Application Site Pruritus	9 (42.9)	0	0	16 (47.1)	0	0
Application Site Erythema	7 (33.3)	5 (23.8)	1 (4.8)	14 (41.2)	5 (14.7)	0
Application Site Scab	6 (28.6)	1 (4.8)	1 (4.8)	18 (52.9)	2 (5.9)	0
Application Site Dryness	6 (28.6)	0	0	12 (35.3)	1 (2.9)	0
Application Site Edema	2 (9.5)	2 (9.5)	0	5 (14.7)	0	1 (2.9)
Application Site Discoloration	1 (4.8)	0	0	6 (17.6)	1 (2.9)	1 (2.9)
Application Site Erosion	0	0	0	0	2 (5.9)	1 (2.9)
Application Site Exfoliation	0	0	0	3 (8.8)	1 (2.9)	0
Papilloma Viral Infection	0	0	0	1 (2.9)	2 (5.9)	0

CONCLUSIONS

- VP-102 demonstrated efficacy in the reduction of the percentage of common warts from baseline to D84 as well as the rates of complete clearance of warts.
- VP-102 showed a favorable tolerability and safety profile. The most common treatment-emergent AEs were mild to moderate and included application site blistering, pain, pruritus, erythema, and scabbing. These were considered related to the pharmacodynamic action of cantharidin.
- Due to the higher complete clearance rate observed in Cohort 2 (51% complete clearance at D84), the treatment regimen of Cohort 2 will be utilized in future Phase 3 studies.

Disclosures

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References

1. Clemons et al., *J Drugs and Dermatol*, 2003. 2. Epstein, Kligman, *Arch Dermatol*, 1958.