VP-102 Tolerability Evaluated by Concomitant Analgesic Medication Usage in Two Phase 3 Trials for Molluscum Contagiosum

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INTRODUCTION

- Drug tolerability is the degree to which a patient can tolerate a drug's adverse effects.
- VP-102, a drug-device combination product containing cantharidin (0.7%), a vesicant, is approved for treatment of molluscum contagiosum (molluscum) in patients aged 2 and older.
- Local skin reactions (LSRs) are expected, including pain.
- In Phase 3 trials, 97% of LSRs were mild to moderate.
- The discontinuation rate due to an adverse reaction was 2.3%:0.5% (drug:vehicle) in treated subjects, respectively.
- This post-hoc analysis evaluated VP-102 tolerability based on analgesic usage over the study course.

METHODS

- VP-102 or vehicle was applied to all baseline and new lesions once every 21 days until complete clearance, or up to a maximum of 4 applications.
- Acetaminophen or ibuprofen were permitted for application site pain and/or other Adverse Reactions.

DEMOGRAPHICS & MEDICAL HISTORY

	VP-102 (n=311)	Vehicle (n=216)
Age (years)		
Mean (SD)	7.5 (6.7)	6.8 (5.8)
Median (Range)	6.0 (2–60)	6.0 (2–54)
Gender—no. (%)		
Male	156 (51)	111 (51.4)
Race or Ethnic Group—no. (%)		
White	277 (91)	201 (93.1)
Black or African American	14 (4.5)	7 (3.2)
Asian	6 (1.9)	1 (0.5)
American Indian/Alaskan Native	0	1 (0.5)
Other	14 (4.5)	6 (2.8)
Baseline Lesion Count		
Mean (SD)	20.4 (23.0)	22.6 (22.3)
Median (Range)	12.0 (1–184)	16.0 (1–110)
Atopic Dermatitis (AD)—no. (%)		
History or Active AD	50 (16.1)	35 (16.2)
Active AD*	23 (7.4)	20 (9.3)

* Active AD was determined by concomitant use of the following medications during the study: topical corticosteroids, topical calcineurin inhibitors, and/or PDE-4 inhibitors.

RESULTS: SAFETY

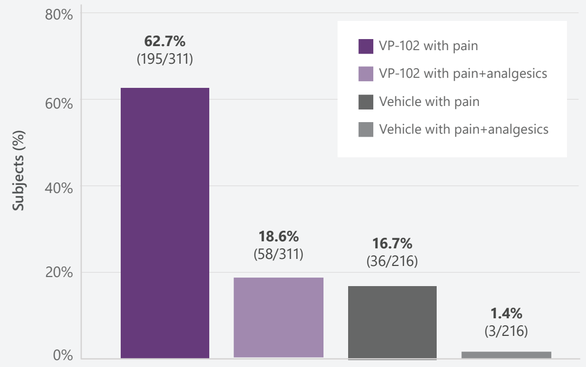
Percentage With Selected Adverse Reactions (Incidence ≥1%) by Severity

	VP-102 (n=311)			Vehicle (n=216)		
Preferred Term Name	**Mild**	**Moderate**	**Severe**	**Mild**	**Moderate**	**Severe**
Application site vesicles	60%	32%	4%	27%	2%	0%
Application site pain and pain	41%	20%	2%	16%	1%	0%
Application site pruritus and pruritis	47%	8%	1%	30%	7%	0%
Application site scab and scab	39%	9%	0%	20%	1%	0%
Application site erythema and erythema	24%	21%	<1%	20%	7%	0%
Application site discoloration	28%	4%	<1%	12%	1%	0%
Application site dryness	19%	2%	0%	14%	1%	0%
Application site edema	7%	3%	0%	3%	1%	0%
Application site erosion	6%	1%	0%	1%	0%	0%
Contact dermatitis	0%	1%	0%	0%	0%	0%

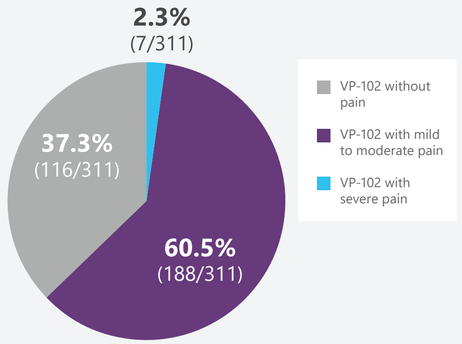
- Analgesic usage for AEs other than LSR pain included 6% (19/311) for application site vesicles.
- There were no treatment-related SAEs reported.

RESULTS: EFFICACY

Incidence of Analgesic Usage in Subjects with Pain



Incidence of Pain in VP-102 Subjects by Severity



- Median analgesic use for LSR pain (range) was 2 (1–14) days for the entire study, and 2 (1–9) days after the first application.
- 29% of participants who reported analgesic usage took medication ≤1 day.

CONCLUSIONS

- In this largely pediatric population, VP-102 was well-tolerated, with a short duration of elective analgesic use.

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