20. INNOVATE: A Phase 2, Open-Label Study to Evaluate the Safety, Efficacy, and Systemic Exposure of VP-102 Topical Film-Forming Solution [0.7% (w/v) cantharidin] in Subjects (2 years and older) with Molluscum Contagiosum

Sahra Niazi MD[1], Bradford Brabec MD[1], Luke Anschutz MD[1], Cindy Willson RN, BSN[2], Matthew Davidson PhD[2], Patrick Burnett MD, PhD[2]

[1]Midwest Children's Health Research Institute, LLC, 1336 West A, Lincoln, NE 68522, [2]Verrica Pharmaceuticals, Inc., 10 N High St Suite 200, West Chester, PA 19380

INTRODUCTION

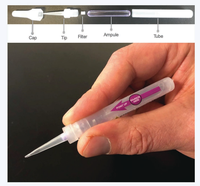
Molluscum contagiosum (MC) is a common, highly contagious pediatric skin infection caused by a DNA poxvirus. The prevalence of MC in the US is ~6 million patients, with 90% under the age of 18 years.

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

OBJECTIVES

To determine systemic exposure (primary), safety, and efficacy, as well as impact on Quality of Life (QoL) from the dermal application of VP-102 to MC lesions.

VP-102 is a proprietary drug-device combination of 0.7% w/v cantharidin delivered via a single-use precision applicator.



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

Cantharidin is a naturally occurring vesicant that causes degradation of the desmosomal plaques.

METHODOLOGY

Thirty-three subjects were enrolled for open-label treatment with VP-102. Treatments occurred every 21 days until clear, for a maximum of 4 treatments.

A subset of subjects with ≥21 lesions (n=17, Exposure group) were included in blood collection assessments to measure systemic exposure after a single application over a 24-hour period.

Key efficacy end points were the percent of subjects exhibiting complete clearance of MC lesions at the end of Study (EOS) visit (D84) and the percent reduction of MC lesions from Baseline at Day 84.

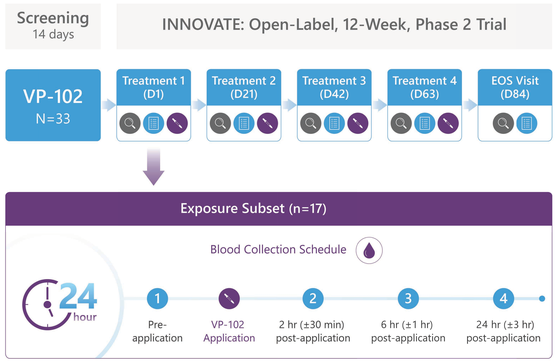
Exploratory end points included rates of complete lesion clearance at Days 21, 42, and 63.

Dermatology Exam

Children's Dermatology Life Quality Index (CDLQI)

Treatment Application

EOS End of Study



DEMOGRAPHICS

32 of 33 subjects completed the Phase 2, OL study.

One subject in the Exposure subset was lost to follow up after the first treatment visit. That subject provided 2 samples (Baseline and 2-hr).

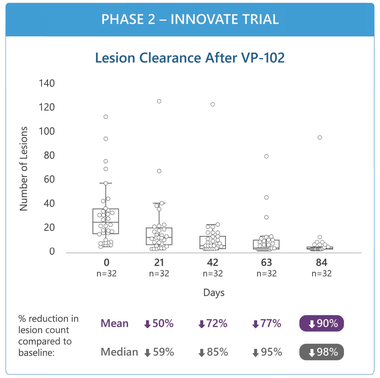
The remainder of the subset (16 subjects) provided all 4 samples for a total of 66 samples.

	VP-102 N=33
Completed (n)	32 (97%)
Age (years)	6.7
Min, Max	2, 15
Gender	
Female	15 (45.5%)
Male	18 (54.5%)
Time Since Diagnosis	
Mean	92 days
Median	36 days
Range	0,423

EFFICACY OUTCOMES

Treatment with VP-102 resulted in a 50% rate of complete clearance (16 of 32 completing subjects) at Day 84 and a 90% mean reduction in lesion count.

Treatment also resulted in an improvement in quality of life as assessed by the CDLQI.



- Complete clearance rates prior to Day 84 were: 9% (Day 21), 28% (Day 42) and 41% (Day 63)
- Median lesion count was reduced from 23 (range 3-113) at Baseline to 1 (range 0-95) at Day 84
- The mean±SD CDLQI score was improved from 2.6±3.4 at Baseline to 0.4±0.9 at Day 84

SAFETY OUTCOMES

29 of 33 subjects (87.9%) reported at least one TEAE.

TEAEs considered as related to treatment included:

- Pain (n=18, 54.5%)
- Administration site pain (n=1)
- Application site vesicles (n=1)
- Burning sensation (n=1)
- Cellulitis (n=1)
- Impetigo (n=1)
- Subcutaneous abscess (n=1)
- Tinea infection (n=1)

All TEAEs were mild or moderate with no reported serious TEAEs or TEAEs leading to discontinuation.

EXPOSURE OUTCOMES

Plasma drug levels were below the lower limit of quantitation (LLOQ) in 65 of 66 samples.

In one subject, the level was above the LLOQ at 2 hrs after VP-102 application (3.4ng/mL), but not detectable at 6 and 24 hrs.

SUMMARY

Treatment with VP-102 (0.7% cantharidin) resulted in:

- 50% rate of complete clearance of MC lesions (16 of 32 subjects) at Day 84
- 90% mean reduction in lesion count
- Improvement in quality of life as assessed by the CDLQI

Treatment with VP-102 was well-tolerated in subjects with MC. No subjects discontinued due to an TEAE and all TEAEs were mild or moderate.

Systemic exposure to cantharidin was negligible with 65/66 samples below the LLOQ.

Contact Information

Sahra Niazi MD
Midwest Children's Health Research Institute, LLC,
1336 West A, Lincoln, NE 68522
sahra.niazi@cch-neb.com

Disclosures

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