

# **Company Overview**

September 2019



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### **INVESTMENT HIGHLIGHTS**

#### Two of the Largest Unmet Needs in Dermatology

- Prevalence of ~6 million in molluscum contagiosum<sup>(1)</sup> and ~22 million in common warts in the U.S.<sup>(2)</sup>
- No FDA approved drugs to treat molluscum or warts

#### ★ New Drug Application (NDA) Submitted for VP-102 for the Treatment of Molluscum Contagiosum

#### **★** Positive Phase 3 Results in Molluscum Contagiosum

- Achieved statistical significance for primary endpoints in our Phase 3 CAMP-1 and CAMP-2 pivotal trials for VP-102
- P-value < 0.0001 for primary endpoint in both pivotal trials

#### **★** Positive Topline Phase 2 Results in Common Warts

 VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable warts at Week 12 (Day 84) and the secondary endpoint of the percentage reduction of warts

#### **★** Innovative Product Candidate

• Drug-device combination of a proprietary formulation and a novel single-use applicator

#### **Physician Acceptance**

• 95% of pediatric dermatologists have used API<sup>(3)</sup>

#### **\*** Barriers to Competition

- New chemical entity regulatory exclusivity upon approval
- IP pending on product candidate, including on novel formulation, applicator and methods of use
- Drug-device combination makes a 'true generic' unlikely

#### Proven Team

 Industry-leading, experienced management team with extensive clinical development and product launch experience



<sup>(1)</sup> Prevalence in the US of 5.1% to 11.5% in children aged 0-16 years. (Fam Pract. 2014 Apr;31(2):130-6). US Census estimates ~69.4MM children aged 0 to 16 years in 2016.

<sup>(2)</sup> IMS National Disease and Therapeutic Index (NDTI) Rolling 5 Years Ending June 2016. Nguyen et al, Laser Treatment of Nongenital Verrucae A Systemic Review. JAMA Dermatology. 2016; 152(9): 1025-1033

<sup>(3)</sup> Based on a survey of 115 dermatologists the results of which have been extrapolated to pediatric dermatologists.

## **OUR PRODUCT PORTFOLIO**

	PRECLINICAL	PHASE 1	PHASE 2	PHASE 3	NDA SUBMISSION	NEXT EXPECTED MILESTONE
Molluscum Contagiosum					$\longrightarrow$	FDA acceptance of NDA
<b>Common Warts</b>			<del></del>			Initiate pivotal trials in 1Q 2020
<b>External Genital Warts</b>			$\rightarrow$			Topline Phase 2 results in 2H 2020
Plantar Warts <sup>(1)</sup>	•	•				IND submission in 4Q 2019

We retain exclusive, royalty-free rights to our product candidates across all indications globally

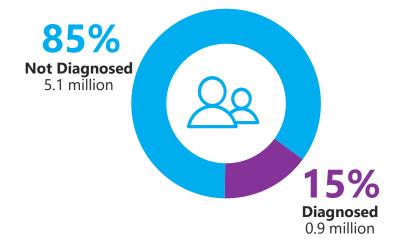
(1) Phase 2 ready assuming leverage of data from VP-102.



## TWO OF THE LARGEST UNMET NEEDS IN DERMATOLOGY

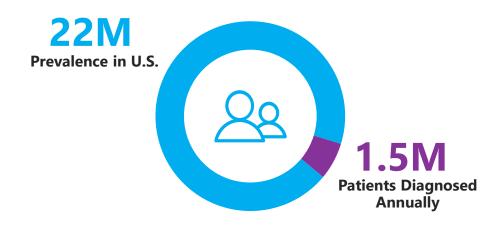
#### **Molluscum**

US Prevalence of ~6 million<sup>(1)</sup> with ~1 million diagnosed annually<sup>(2)</sup>



#### **Common Warts**

US Prevalence of ~22 million<sup>(3)</sup> with ~1.5 million diagnosed annually<sup>(4)</sup>



- (1) Prevalence in the US of 5.1% to 11.5% in children aged 0-16 years. (Fam Pract. 2014 Apr;31(2):130-6). US Census estimates ~69.4MM children aged 0 to 16 years in 2016.
- (2) IQVIA projected dataset for 12 months ending October 2017
- (3) IMS National Disease and Therapeutic Index (NDTI) Rolling 5 Years Ending June 2016. Nguyen et al, Laser Treatment of Nongenital Verrucae A Systemic Review. JAMA Dermatology. 2016; 152(9): 1025-1033
- (4) IQVIA Anonymous Longitudinal Patient Level Data (APLD) for 12 months ending September 2018





## THE PROBLEM

## Molluscum Contagiosum



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## MOLLUSCUM BACKGROUND

#### **OVERVIEW**

Caused by a pox virus

Primarily infects children, with the highest incidence occurring in children <14 years old

Highly contagious

If untreated, lesions persist an average of 13 months, with some cases remaining unresolved for 2+ years

Often leads to anxiety and social challenges for the patients and parents and negatively impacts quality of life

#### **ETIOLOGY AND CLINICAL PRESENTATION**

#### **Transmission**

- Skin to skin contact
- Sharing of contaminated objects (e.g., clothing, towels, swimming pool toys)

## Diagnosis & Symptoms

- Typically 10 to 30 lesions
- 100+ lesions can be observed
- Lesions may be the only sign of infection and are often painless
- Can be diagnosed with skin biopsy to differentiate from other lesions



#### **Complications**

- Skin irritation, inflammation, and re-infection
- · Follicular or papillary conjunctivitis if lesions on eyelids
- Cellulitis



## CURRENT TREATMENTS FOR MOLLUSCUM ARE NOT FDA APPROVED AND HAVE MANY LIMITATIONS

Broad use limited by unproven efficacy, scarring, lack of availability, safety concerns & pain

Significantly undertreated patient population

	DESCRIPTION	LIMITATIONS
Cryotherapy	Freezing the lesions with liquid nitrogen	<ul><li>Pain and scarring</li><li>Unsuitable for use in children</li></ul>
Curettage	Using a curette or a surgical instrument with a scoop at the tip to scrape the lesions	<ul><li>Pain and scarring</li><li>Unsuitable for use in children</li></ul>
Laser Surgery	Applying a laser to target and destroy the lesions	<ul><li>Pain, cost and lack of availability</li><li>Unsuitable for use in children</li></ul>
Topical Products	Applying various acids (e.g. salicylic acid), creams or blistering solutions to destroy the lesions	Unproven efficacy
Off-Label Drugs	Retinoids, antiviral medicines, or immune modulating therapies	<ul><li>Limited efficacy</li><li>Side-effects</li></ul>
Natural Remedies	Applying natural oils (e.g. tea tree oil) with antimicrobial properties	<ul><li>Unproven efficacy</li><li>Pain, irritation and allergic reactions</li></ul>
		<b>V</b> EDDICA



## THE SOLUTION

**VP-102** 



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# VP-102 IS A PROPRIETARY DRUG-DEVICE COMBINATION OF CANTHARIDIN ADMINISTERED THROUGH OUR SINGLE-USE PRECISION APPLICATOR

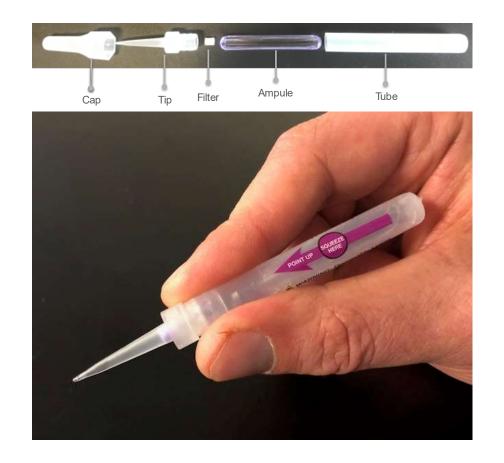
## **GMP-controlled formulation** of cantharidin with:

- API that is greater than 99% pure
- Defined pharmaceutical batch process

Long-term, room temperature stability

**Visualization agent** to see which lesions have been treated

**Bittering agent** to mitigate oral ingestion by children









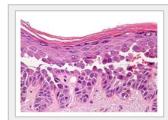
## **CANTHARIDIN ELICITS A DUAL RESPONSE IN THE SKIN**



### Superficial blistering of lesional skin

Cantharidin is a vesicant, causing the pharmacodynamic response of blistering in the skin.

Once applied, cantharidin activates neutral serine proteases that cause degeneration of the desmosomal plaque and intraepidermal blistering.<sup>(1)</sup>



Desmosome Cleavage and Blister Formation



### **Elicits Inflammation & Immune Response**

Cantharidin stimulates leukocyte infiltration (e.g., neutrophils, macrophages, B and T cells and eosinophils) and the release of chemokines and cytokines including TNF-a, IL-8 and CXCL-5.<sup>(2)</sup>



<sup>(1)</sup> J Invest Dermatol. 1962 Jul;39:39-45.

<sup>(2)</sup> J Immunol Methods. 2001 Nov 1;257(1-2):213-20.2

## **SIGNIFICANT CLINICAL PROGRESS OF VP-102** FOR THE TREATMENT OF MOLLUSCUM

	TRIAL AND STATUS	FORMULATION / APPLICATION METHOD	TRIAL DESIGN	TRIAL OBJECTIVES
HASE 3	Pivotal Trial CAMP-1 Complete	VP-102	<ul> <li>N=266</li> <li>Conducted under SPA</li> <li>Randomized, double blind, multi-center, placebo controlled</li> </ul>	<ul> <li>To evaluate the efficacy of dermal application of VP-102 relative to placebo for complete clearance at day 84</li> <li>To assess the safety and tolerability of VP-102</li> </ul>
à	Pivotal Trial CAMP-2 Complete	VP-102	<ul> <li>N=262</li> <li>Randomized, double blind, multi-center, placebo controlled</li> </ul>	<ul> <li>To evaluate the efficacy of dermal application of VP-102 relative to placebo for complete clearance at day 84</li> <li>To assess the safety and tolerability of VP-102</li> </ul>
E 2	<b>Innovate Trial</b> Complete	VP-102	<ul><li>Open-label, single-center</li><li>N=33</li></ul>	<ul> <li>To determine possible systemic exposure from a single 24-hour application of VP-102</li> <li>To confirm safety and efficacy with applicator</li> </ul>
PHAS	<b>Pilot Trial</b> Complete	Our proprietary formula of cantharidin used in VP-102, applied with the wooden stick part of a cotton-tipped swab	<ul><li>Open-label, single-center</li><li>N=30</li></ul>	To evaluate safety and efficacy and determine optimal treatment duration

## WE HAVE SUCCESSFULLY COMPLETED TWO PIVOTAL PHASE 3 TRIALS (CAMP-1 & CAMP-2) IN MOLLUSCUM



**Trial Design** 

Two identically designed, randomized, double-blinded, multicenter, placebo controlled trials

CAMP-1 conducted under FDA Special Protocol Assessment (SPA)

12-week study period



**Endpoints** 



Percent of subjects with complete clearance of molluscum at Day 84

#### **Secondary:**

Percent of subjects with complete clearance at week 3, 6, and 9 Safety & tolerability



**Population** 

Subjects 2+ years of age with MC lesions who have not received any type of treatment within the past 14 days Enrollment complete with 266 subjects for CAMP-1 and 262 subjects for CAMP-2



**Application** 

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

VP-102 or placebo will be left on for 24 hours before removal with soap and warm water



## **DEMOGRAPHICS IN PHASE 3 MOLLUSCUM TRIALS**

	CAN	/IP-1	CAIVIP-2		
	VP-102 (N=160)	Placebo (N=106)	VP-102 (N=150)	Placebo (N=112)	
Randomized	160	106	150	112	
Completed	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%)	

CAMP-2

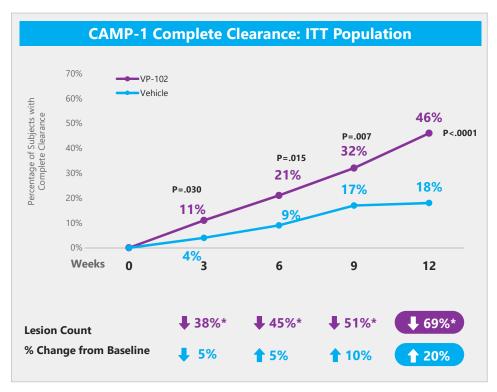
## **MOLLUSCUM HISTORY FOR SUBJECTS IN PHASE 3 TRIALS**

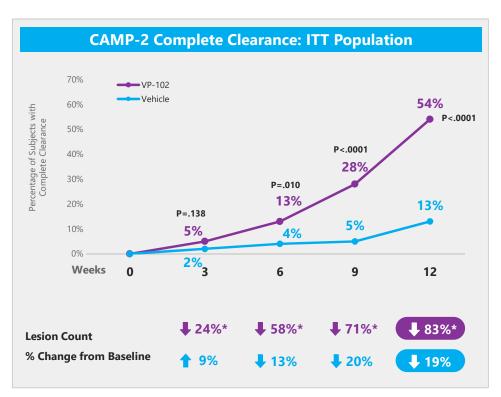
CAMP-1	<b>VP-102</b> (N=160)	
Time Since Clinical Diagnosis (days)		
Mean	127	129
Median	25	32
Min, Max	1, 1247	1, 1302
Age at Diagnosis		
Mean	7.1	6.1
Any Previous Treatment for Molluscum	1?	
Yes	41 (26%)	30 (28%)
Active Atopic Dermatitis		
Yes	12 (8%)	13 (12%)
<b>Baseline Lesion Count</b>		
Mean	22	25
Min, Max	1, 107	1, 110

CAMP-2	<b>VP-102</b> (N=150)	Placebo (N=112)
Time Since Clinical Diagnosis (days)	118	124
Mean		124
Median Min, Max	28 1, 977	31 1, 957
<b>Age at Diagnosis</b> Mean	7.1	7.0
Any Previous Treatment for Molluscur Yes	<b>n?</b> 48 (32%)	42 (38%)
<b>Active Atopic Dermatitis</b> Yes	11 (7%)	7 (6%)
<b>Baseline Lesion Count</b> Mean Min, Max	19 1, 184	20 1, 86
TVIIII, IVIGX	1, 104	<b>VERRICA</b> PHARMACEUTICALS

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## PHASE 3 STUDIES IN MOLLUSCUM DEMONSTRATE STATISTICALLY SIGNIFICANT EFFICACY ON PRIMARY ENDPOINT OF COMPLETE CLEARANCE





\* Lesion count p<0.05 (pre-specified exploratory endpoint)

Note: Data reported reflects lesion count % change from baseline information for CAMP-1 resulting from continued analysis of complete data set for CAMP-1 and CAMP-2 post release of topline Phase 3 results on 3 Jan 2019.



## **SAFETY SUMMARY FOR MOLLUSCUM PHASE 3 TRIALS**

#### CAMP-1

Subjects with at least one	<b>VP-102</b> (N=161) n (%)	<b>Placebo</b> (N=104) n (%)
TEAE (Treatment Emergent AE)	159 (99)	76 (73)
Mild TEAE	157 (98)	66 (64)
Moderate TEAE	105 (65)	41 (39)
Severe TEAE	19 (12)	1 (1)
TEAE related to drug	158 (98)	60 (58)
Serious TEAE	0 (0)	1 (1)
<b>TEAE</b> leading to discontinuation	5 (3)	0 (0)
Local Skin Reaction TEAE	158 (98)	60 (58)

**AE= Adverse Event** 

Note: Data reported reflects AE information for CAMP-1 resulting from continued analysis of complete data set for CAMP-1 and CAMP-2 post release of topline Phase 3 results on 3 Jan 2019.

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CAMP-2	VP-102	Placebo
Subjects with at least one	(N=150) n (%)	(N=112) n (%)
TEAE (Treatment Emergent AE)	143 (95)	74 (66)
Mild TEAE	141 (94)	74 (66)
Moderate TEAE	60 (40)	18 (16)
Severe TEAE	4 (3)	0 (0)
TEAE related to drug	143 (95)	67 (60)
Serious TEAE	0 (0)	0 (0)
TEAE leading to discontinuation	1 (1)	1 (1)
Local Skin Reaction TEAE	143 (95)	67 (60)
		19 <b>VERRICA</b>

## CAMP-1 ADVERSE EVENTS (1)

		VP-102 (N=161)			Placebo (N=104)	
		n (%)			n (%)	
PREFERRED TERM NAME	MILD	MOD	SEV	MILD	MOD	SEV
Application site vesicles	79 (49.1)	70 (43.5)	8 (5.0)	25 (24.0)	4 (3.8)	0 (0.0)
Application site pruritus	85 (52.8)	18 (11.2)	1 (0.6)	33 (31.7)	5 (4.8)	0 (0.0)
Application site pain	58 (36.0)	45 (28.0)	7 (4.3)	18 (17.3)	2 (1.9)	0 (0.0)
Application site erythema	32 (19.9)	37 (23.0)	0 (0.0)	21 (20.2)	9 (8.7)	0 (0.0)
Application site scab	46 (28.6)	16 (9.9)	0 (0.0)	24 (23.1)	1 (1.0)	0 (0.0)
Application site discoloration	48 (29.8)	5 (3.1)	1 (0.6)	16 (15.4)	2 (1.9)	0 (0.0)
Application site dryness	23 (14.3)	1 (0.6)	0 (0.0)	11 (10.6)	0 (0.0)	0 (0.0)
Application site edema	15 (9.3)	6 (3.7)	0 (0.0)	4 (3.8)	2 (1.9)	0 (0.0)

<sup>(1)</sup> AEs occurring in > 10% of subjects in any arm

Note: Data reported reflects AE information for CAMP-1 resulting from continued analysis of complete data set for CAMP-1 and CAMP-2 post release of topline Phase 3 results on 3 Jan 2019.



## CAMP-2 ADVERSE EVENTS (1)

		VP-102 (N=150)			Placebo (N=112)	
		n (%)			n (%)	
PREFERRED TERM NAME	MILD	MOD	SEV	MILD	MOD	SEV
Application site vesicles	108 (72.0)	30 (20.0)	3 (2.0)	34 (30.4)	0 (0.0)	0 (0.0)
Application site scab	74 (49.3)	11 (7.3)	0 (0.0)	20 (17.9)	2 (1.8)	0 (0.0)
Application site pruritus	60 (40.0)	5 (3.3)	0 (0.0)	29 (25.9)	8 (7.1)	0 (0.0)
Application site pain	69 (46.0)	14 (9.3)	0 (0.0)	16 (14.3)	0 (0.0)	0 (0.0)
Application site erythema	41 (27.3)	28 (18.7)	1 (0.7)	22 (19.6)	6 (5.4)	0 (0.0)
Application site dryness	35 (23.3)	4 (2.7)	0 (0.0)	19 (17.0)	1 (0.9)	0 (0.0)
Application site discoloration	39 (26.0)	7 (4.7)	0 (0.0)	9 (8.0)	0 (0.0)	0 (0.0)

<sup>(1)</sup> AEs occurring in >10% of subjects in any arm



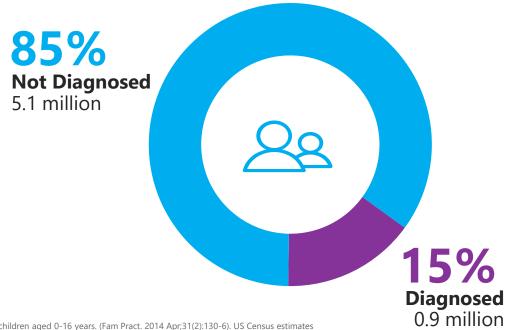






### **REALIZING THE MOLLUSCUM OPPORTUNITY**

US Prevalence of ~6 million in molluscum<sup>(1)</sup> with ~1 million diagnosed annually<sup>(2)</sup>



<sup>(1)</sup> Prevalence in the US of 5.1% to 11.5% in children aged 0-16 years. (Fam Pract. 2014 Apr;31(2):130-6). US Census estimates ~69.4MM children aged 0 to 16 years in 2016.

23 VERRICATE PHARMACEUTICALS

<sup>(2)</sup> IQVIA projected dataset for 12 months ending October 2017

## DERMATOLOGISTS ARE FAMILIAR WITH VP-102'S API & WOULD USE IF AVAILABLE



Physicians who do not use the API of VP-102 stated inaccessibility as a primary reason why they are not using<sup>(1)</sup>

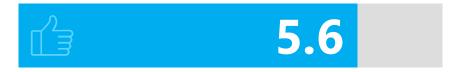


Physicians reported they would use VP-102 if the cost of the drug was covered<sup>(2)</sup>

<sup>(1)</sup> Pompei DT et al. Cantharidin Therapy: Practice patterns and attitudes of health care providers. Journal of the American Academy of Dermatology. 2013; 68(6). Survey of 400 healthcare providers, 87.7% of responders were US based dermatologists. (2) Company survey of 40 physicians.

## PHYSICIANS ARE HIGHLY FAVORABLE TO VP-102 PROFILE

### **Derms and Ped Derms** (1)



#### **KEY REASONS TO USE IF APPROVED**

Efficacy Precise and pain free application

FDA approval Convenience of administration

### **Pediatricians** (1)



Scale of 1 (unlikely to use at all) to 7 (highly likely to use)

#### **KEY REASONS TO USE IF APPROVED**

Efficacy Fits into their current office model

Frustrated with not treating and having no viable options

(1) Physician Qualitative research- one-hour individual interviews [n=30 Pediatricians, 13 Dermatologist, 5 Pediatric Dermatologists]

## INITIAL PAYER RESEARCH SUGGESTS FAVORABLE REIMBURSEMENT LANDSCAPE FOR VP-102

	COHORT SIZE	AVERAGE LIVES COVERED
Medical Directors	7	9.8M
Pharmacy Directors	6	4.2M
IDN Stakeholders	2	6.5M



The 15 Payer Organizations and Plans Represented in the Interviews Cover a Total of 105 Million Commercial & Medicaid Lives

Source: Third party study commissioned by the Company.

## INITIAL PAYER RESEARCH SUGGESTS FAVORABLE REIMBURSEMENT LANDSCAPE FOR VP-102

## **Key Takeaways**

- Payers interviewed **recognize a significant unmet need** for molluscum contagiosum and lack of an effective treatment
- Some of the **key concerns** mentioned about the undertreatment of the condition include the **risk of infection, scarring, or spread of the disease**
- Payers **perceived VP-102 to be highly favorable** based on the majority of patients experiencing clearance within 12 weeks
- Given the unmet need and favorable clinical outcomes in Phase 2 trials, payers anticipate the majority of patients would have access to VP-102 with minimal to no restrictions



## INTEGRATED COMMERCIAL APPROACH WITH MULTIPLE STRATEGIC LEVERS

## **Commercial Strategy**



### KOL Engagement

Strong established relationships and support

### Buy and Bill or Specialty Pharmacy

Distribution with supportive HUB services

Dedicated field reimbursement Team

## **Specialized Sales Team**

Targeting office based dermatologists and select pediatricians

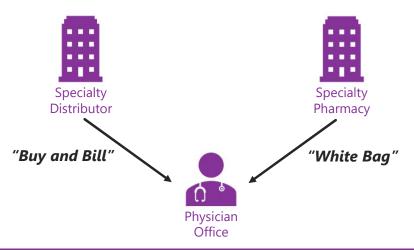
#### Dedicated Institutional Team

Specialists to promote to pediatric dermatologists in academic settings and group practices

#### Disease Awareness

Increase treatment seekers through costefficient consumer advertising

## VP-102 DESIGNED TO BE CLINICIAN ADMINISTERED AND INTEND TO DISTRIBUTE THROUGH SPECIALTY PRODUCT CHANNELS, IF APPROVED



Potential Physician Reimbursement Opportunities						
"Buy and Bill"	"White Bag"					
Office visit	Office visit					
Procedure for lesion destruction	Procedure for lesion destruction					
VP-102 (ASP + X%)						



Distribution model will be supported by a patient and HCP services platform (HUB)

- Benefits investigation/verification to determine coverage
- Full reimbursement support for miscellaneous J-code under medical benefit (1)
- Prior authorization support
- Co-pay/co-insurance assistance



Dedicated field reimbursement team to support physician offices

(1) Verrica intends to file for a product-specific J-code for VP-102



## PRE-COMMERCIALIZATION ACTIVITIES ONGOING

#### **ENGAGEMENT AT KEY CONFERENCES**



WINTER CLINICAL DERMATOLOGY

FALL CLINICAL DERMATOLOGY CONFERENCE®

Poster Presentation



American Academy of Pediatrics



National and Regional Meetings



National and Regional Meetings







#### **DISEASE AWARENESS**

Caregiver MC education through digital and social tools

HCP MC education through congresses, speaker programs, and professional journal space

#### **OTHER**

Trade distribution channel development

Customer segment insights

Brand strategy, customer segmentation, and targeting

Commercial systems infrastructure



## VERRICA HAS SEVERAL POTENTIAL WAYS TO MAINTAIN EXCLUSIVITY



## Regulatory **Exclusivity**

5.5 years of exclusivity for cantharidin as API potentially available upon approval (inclusive of potential for 6 months for pediatric indication)



## Compounding Pharmacies

If VP-102 is approved, traditional compounding pharmacies will NOT be able to continue compounding cantharidin regularly or in inordinate amounts, except under patient specific circumstances as prescribed by a physician.

The FDA has the authority to regulate compounders. Improper compounding can result in monetary fines plus felony convictions in case of repeat offenses and intent to fraud/mislead.



#### Manufacturing

VP-102 has the potential to address stability issues with standard packaging and container/closure systems

Limited commercial CMOs with facilities for handling highly potent and highly flammable liquid products Entered into a supply agreement for naturally-sourced cantharidin; subject to specified minimum annual purchase orders and forecasts, supplier agreed that it will not supply cantharidin, any beetles or other raw material from which cantharidin is derived to any other customer in North America



## True Generic Unlikely

Unlikely to receive approval under an ANDA due to uniqueness from patent pending protection and significant differences likely between VP-102 and potential competitors

Cannot do traditional PK/bioequivalence study (no blood level profile for VP-102)

May require new clinical studies with new formulation and new delivery approach that shows equivalence without violating any of Verrica's IP

## **OVERVIEW OF INTELLECTUAL PROPERTY PORTFOLIO**

KEY CLAIMS AND PATENT APPLICATIONS	VALUE TO VERRICA	
Our specific formulation (VP-102), key safety additions and novel cantharidin formulations (PCT/US2014/052184)	May prevent generics from copying our ether-free formulation or from making similar formulations	
Single use applicator containing cantharidin formulations (PCT/US2014/052184)	May prevent generics from utilizing a single-use applicator for cantharidin that contains both a glass ampule to maintain product stability and a filter placed prior to dispensing tip, which helps increase administration accuracy and prevents direct contact with skin	
Specific design of our commercial applicator (PCT/US2018/036353)	May prevent generics from utilizing a similar applicator	
Methods of use for cantharidin in the treatment of molluscum (PCT/US2018/037808 and PCT/US2018/036353)	May prevent generics from a similar treatment regimen and label	
Methods for purifying cantharidin and analyzing cantharidin or cantharidin solutions (PCT/US2016/14139)	May force generics to find alternative methodologies to produce GMP cantharidin or determine if their API or drug product is GMP compliant	
Methods for complete cantharidin synthesis (PCT/US2015/066487)	Synthetic version would reduce risks of outside contaminants and environmental factors affecting the naturally-sourced API. May prevent generics competing with a synthetic version of cantharidin	

Any patents issued from our applications are projected to expire between 2034 and 2039, excluding any patent term adjustment and patent term extensions







## **VERRUCA VULGARIS (COMMON WARTS)**

#### **OVERVIEW**

Caused by human papilloma virus (HPV)

Infects patients of all ages

Persistent infection, highly refractory

Typically 2-5 lesions

No FDA approved drug for the treatment of common warts

#### **ETIOLOGY AND CLINICAL PRESENTATION**

#### **Transmission**

- Skin to skin contact
- Touching of contaminated objects

## Diagnosis & Symptoms

- Dome shaped flesh-colored lesions commonly on the hands, fingers, knees or elbows
- · Lesions may occur in groups or in a linear pattern
- Lesions can cause considerable pain and discomfort, may spread with skin trauma, and can be itchy



#### **Complications**

- Scarring may occur
- · Dyspigmentation of affected areas
- · Bacterial superinfection of lesions
- · Irritation, pain, and redness of surrounding skin



## WE HAVE SUCCESSFULLY COMPLETED A PHASE 2 STUDY (COVE-1) IN COMMON WARTS



**Study Design** 

Efficacy, safety & tolerability

Open label study with two cohorts

Cohort 1: one center Cohort 2: four centers



**Endpoints** 

#### **Primary**

Percent of subjects with complete clearance of all treatable warts (baseline and new) at Day 84

#### Secondary

Percent of subjects achieving complete clearance of all treatable warts at Visits 2, 3, and 4 Change from baseline in number (%) of treatable warts at Day 84



**Patients** 

Cohort 1: 21 subjects 2+ years of age with common warts, who have not received any type of treatment within the past 14 days

Cohort 2: 35 subjects 12+ years of age with common warts, who have not received any type of treatment within the past 14 days



**Application** 

Study drug (VP-102) is administered topically to each treatable wart to a maximum of 4 applications

Cohort 1 is treated until clear, Cohort 2 receives one additional treatment at the first visit clearance was observed up to a maximum of 4 total applications

Frequency of administration is at least 14 days (Cohort 1) or 21 days (Cohort 2)

Paring was allowed in Cohort 2

VP-102 will be left on for 24 hours before removal with soap and warm water



## **DEMOGRAPHICS IN COVE-1 STUDY**

	<b>COHORT 1 VP-102</b> (N=21)	<b>COHORT 2 VP-102</b> (N=35)
Randomized	21	35
Age (years)		
Mean	38	38
Median	37	42
Min, Max	7, 83	12, 67
Gender		
Female	11 (52.4%)	22 (62.9%)
Male	10 (47.6%)	13 (37.1%)
Discontinued	4 (19.0%)	2 (5.7%)
Lost to follow-up	2 (9.5%)	1 (2.9%)
Withdrawal by subject	2 (9.5%)	0
Protocol violation	0	1 (2.9%)

**ERRICA**PHARMACEUTICALS

## WART HISTORY FOR SUBJECTS IN COVE-1 STUDY

Co	hort	1
----	------	---

**VP-102** (N=21)

**Time Since Clinical Diagnosis (months)** 

Mean 70.3

**Age at Diagnosis** 

Mean 32.1

**Any Previous Treatment for Common Warts?** 

Yes 3 (14.3%)

**Wart number at Baseline** 

Mean 2.19

Cohort 2

VP-102
(N=35)

Time Since Clinical Diagnosis (months)

Mean 15.9

Age at Diagnosis

Mean 36.4

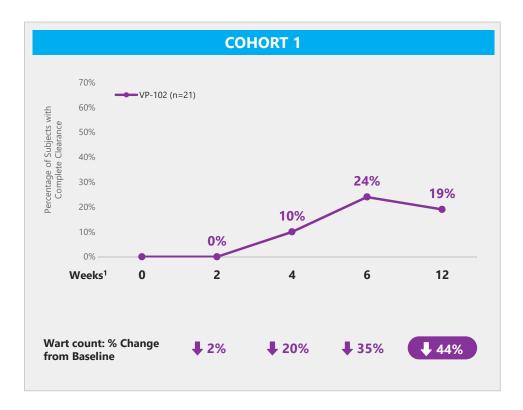
Any Previous Treatment for Common Warts?

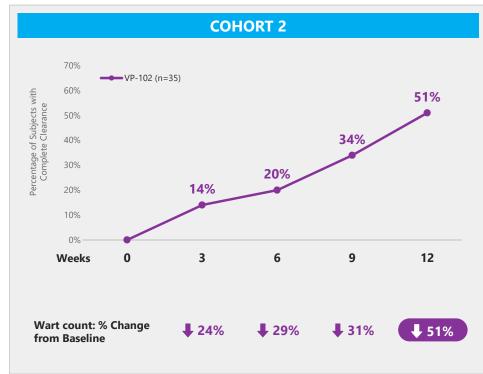
Yes 24 (68.6%)

Wart number at Baseline

Mean 1.65

# VP-102 DEMONSTRATED CLINICALLY MEANINGFUL EFFICACY ON PRIMARY ENDPOINT OF COMPLETE CLEARANCE IN COVE-1 STUDY





(1) Cohort 1 was amended to allow varying treatment intervals beyond every 14 days depending on a specific subject's clinical response



# **SAFETY SUMMARY FOR COVE-1 STUDY**

CO	L		D٦	T 1
LU	П	U	ΚI	

Subjects with at least one	<b>VP-102</b> (N=21) n (%)
TEAE (Treatment Emergent AE)	20 (95.2)
Mild TEAE	20 (95.2)
Moderate TEAE	9 (42.9)
Severe TEAE	2 (9.5)
TEAE related to drug	20 (95.2)
Serious TEAE	0 (0)
TEAE leading to discontinuation	0 (0)
Local Skin Reaction TEAE	20 (95.2)
TEAE of Papilloma Viral Infection	0 (0)

AE= Adverse Event

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COHORT 2	<b>VP-102</b> (N=34)
Subjects with at least one	n (%)
TEAE (Treatment Emergent AE)	32 (94.1)
Mild TEAE	32 (94.1)
Moderate TEAE	19 (55.9)
Severe TEAE	4 (11.8)
TEAE related to drug	32 (94.1)
Serious TEAE	0 (0)
TEAE leading to discontinuation	0 (0)
Local Skin Reaction TEAE	32 (94.1)
TEAE of Papilloma Viral Infection	3 (8.8)
	39 <b>VERRICA</b> PHARMACEUTICALS

# **ADVERSE EVENTS IN COVE-1 STUDY**

	Cohort 1 (N= 21)	<b>Cohort 2 (N=34)</b>
	n (%)	n (%)
PREFERRED TERM NAME		
Application site vesicles	20 (95.2)	27 (79.4)
Application site pain	20 (95.2)	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)	19 (55.9)
Application site discoloration	1 (4.8)	8 (23.5)
Application site dryness	6 (28.6)	14 (41.2)

AEs occurring in >20% of subjects in any arm

## **REALIZING THE COMMON WARTS OPPORTUNITY**

US Prevalence of ~22 million in common warts<sup>(1)</sup> with ~1.5 million diagnosed annually<sup>(2)</sup>



<sup>(1)</sup> IMS National Disease and Therapeutic Index (NDTI) Rolling 5 Years Ending June 2016. Nguyen et al, Laser Treatment of Nongenital Verrucae A Systemic Review. JAMA Dermatology. 2016; 152(9): 1025-1033



<sup>(2)</sup> IQVIA Anonymous Longitudinal Patient Level Data (APLD) for 12 months ending September 2018







# **CONDYLOMA ACUMINATUM (GENITAL WARTS)**

#### **OVERVIEW**

Caused by human papilloma virus (HPV)

Lesions on the surface of the skin in the genital and perianal regions

Highly contagious and recurrences are common

Treatment options have limitations

#### **ETIOLOGY AND CLINICAL PRESENTATION**

#### **Transmission**

- Skin to skin contact
- Spread through sexual contact

# Diagnosis & Symptoms

- Can be flat, dome-shaped, keratotic, pedunculated and cauliflower-shaped
- Lesions may occur singularly, in clusters, or as plaques
- Lesions can be itchy, and can cause pain and discomfort

### Complications

- Irritation, pain, and redness of surrounding skin
- · Dyspigmentation of affected areas
- Scarring may occur
- Bacterial superinfection of lesions



# PHASE 2 STUDY (CARE) IN EXTERNAL GENITAL WARTS (EGW)



#### **Study Design**

Multi-center, double-blind, placebo-controlled

Dose regimen, efficacy, safety & tolerability

Study comprised of two parts (A and B)
Primary objective of Part A is to identify the two
best dosing regimens for evaluation in Part B



#### **Endpoints**

#### **Primary**

Percent of subjects with complete clearance of all treatable warts at Day 84

#### **Secondary**

Percent of subjects achieving complete clearance of all treatable warts at Visits 2, 3, and 4



#### **Patients**

Part A: ~18 subjects 18+ years of age with 2-30 external genital and/or perianal warts for ≥ 4 weeks at baseline visit

Part B:  $\sim$ 90 subjects 18+ years of age with 2-30 external genital and/or perianal warts for  $\geq$  4 weeks at baseline visit



#### **Application**

Study drug (VP-102) is administered topically to each treatable wart to a maximum of 4 applications or until complete clearance

Part A: To include 3 treatment groups with a 2-hour, 6-hour and 24-hour duration of skin exposure before removal with soap and warm water

Part B: Two selected treatment dosing regimens (duration of skin exposure) based on Part A with follow up period through Day 147 Frequency of administration is every 21 days



# SIGNIFICANT RECENT AND EXPECTED MILESTONES

DATE	EVENT
<b>✓</b> 1Q 2019	Positive topline results from two pivotal Phase 3 trials in molluscum
<b>✓</b> 2Q 2019	Positive topline results from Phase 2 trial in common warts
<b>⋖</b> 2Q 2019	Initiate Phase 2 trial in external genital warts
<b>⋖</b> 3Q 2019	VP-102 NDA submission in molluscum
<b>4Q 2019</b>	FDA acceptance of VP-102 NDA submission in molluscum
<b>4Q 2019</b>	VP-103 IND submission in plantar warts
<b>1Q 2020</b>	Initiate pivotal trials in common warts
∠ 2H 2020	Topline results from Phase 2 trial in external genital warts

## **INVESTMENT HIGHLIGHTS**

#### Two of the Largest Unmet Needs in Dermatology

- Prevalence of ~6 million in molluscum contagiosum<sup>(1)</sup> and ~22 million in common warts in the U.S.<sup>(2)</sup>
- No FDA approved drugs to treat molluscum or warts

#### New Drug Application (NDA) Submitted for VP-102 for the Treatment of Molluscum Contagiosum

#### **★** Positive Phase 3 Results in Molluscum Contagiosum

- Achieved statistical significance for primary endpoints in our Phase 3 CAMP-1 and CAMP-2 pivotal trials for VP-102
- P-value < 0.0001 for primary endpoint in both pivotal trials

#### **★** Positive Topline Phase 2 Results in Common Warts

 VP-102 achieved positive results on both the primary endpoint of complete clearance of all treatable warts at Week 12 (Day 84) and the secondary endpoint of the percentage reduction of warts

#### **★** Innovative Product Candidate

• Drug-device combination of a proprietary formulation and a novel single-use applicator

#### **Physician Acceptance**

• 95% of pediatric dermatologists have used API<sup>(3)</sup>

#### **\*** Barriers to Competition

- New chemical entity regulatory exclusivity upon approval
- IP pending on product candidate, including on novel formulation, applicator and methods of use
- Drug-device combination makes a 'true generic' unlikely

#### Proven Team

 Industry-leading, experienced management team with extensive clinical development and product launch experience



<sup>(1)</sup> Prevalence in the US of 5.1% to 11.5% in children aged 0-16 years. (Fam Pract. 2014 Apr;31(2):130-6). US Census estimates ~69.4MM children aged 0 to 16 years in 2016.

<sup>(2)</sup> IMS National Disease and Therapeutic Index (NDTI) Rolling 5 Years Ending June 2016. Nguyen et al, Laser Treatment of Nongenital Verrucae A Systemic Review. JAMA Dermatology. 2016; 152(9): 1025-1033

<sup>(3)</sup> Based on a survey of 115 dermatologists the results of which have been extrapolated to pediatric dermatologists.



# **Appendix**



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# HISTORICAL COMPOUNDED CANTHARIDIN PRESENTS A NUMBER OF LIMITATIONS

# 1 Varying concentration

- Evaporation of volatile solvents leads to concentration increases
- Patients can receive more drug than clinically necessary resulting in excessive blistering

# Inconsistent purity and lack of controlled product manufacturing

 Risk of impurities present such as residual solvents and pesticides

# 3 Lack of reimbursement

 Not FDA approved and therefore not eligible for drug reimbursement



# 4 Inconvenient and variable administration

- Application with the wooden stick part of a cotton-tipped swab can lead to patients receiving more drug than necessary
- Inability for physicians to identify where the drug has been applied

## **5** Limited availability

- Illegal to import formulated cantharidin
- Generally not available in hospitals and academic settings, which require FDA approved product
- Only an estimated 7% of 503B compounders produce formulations containing cantharidin<sup>(1)</sup>



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**Selected** Launched **Products** 















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