Safety and Efficacy of VP-102 in Molluscum Contagiosum by Age Group: Pooled Results of Two Phase 3 Multicenter, Randomized, Vehicle-Controlled Clinical Trials

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BACKGROUND

- Molluscum contagiosum (molluscum) is a common viral skin infection that predominately affects children.
- VP-102 is a proprietary drug-device combination product containing cantharidin (0.7%, w/v) under investigation for the treatment of molluscum in participants 2 years of age or older.
- These exploratory analyses examined the pooled safety and efficacy data from two Phase 3 clinical trials of VP-102 for treatment of molluscum, stratified by participant baseline age.

METHODS

- Participants \geq 2 years of age with molluscum were enrolled in two identical Phase 3 trials and randomized in a 3:2 ratio to receive either topical VP-102 or vehicle.
- Study drug was applied topically to all baseline and new lesions once every 21 days until complete clearance of lesions, or up to a maximum of 4 applications.
- Efficacy and safety assessed in pre-specified analyses by age group (2–5y, 6–11y, 12–18y, ≥19y) including:
- Percentage of participants with complete clearance of all baseline and new lesions by day 84 (end of study visit).
- Percent change in lesion count from baseline to each visit (days 21, 42, 63, and 84).
- Incidence of treatment-related treatment emergent adverse events (TR-TEAEs) with a specific focus on related local skin reactions.

RESULTS

Baseline Demographics and Molluscum Medical Histories by Age Group

	VP-102				Vehicle			
	2–5 years (n=137)	6–11 years (n=140)	12–18 years (n=22)	≥19 years (n=11)	2–5 years (n=106)	6–11 years (n=89)	12–18 years (n=18)	≥19 years (n=5)
)								
D)	3.7 (1.04)	8.0 (1.64)	13.2 (1.85)	35.4 (14.4)	3.6 (1.08)	7.7 (1.44)	13.2 (1.66)	37.2 (10.6)
o. (%)								
	64 (46.7)	70 (50.0)	11 (50.0)	9 (81.8)	54 (50.9)	40 (44.9)	10 (55.6)	3 (60.0)
	73 (53.3)	70 (50.0)	11 (50.0)	2 (18.2)	52 (49.1)	49 (55.1)	8 (44.4)	2 (40.0)
No. (%)								
z/Latino	26 (19.0)	25 (17.9)	4 (18.2)	3 (27.3)	10 (9.4)	14 (15.7)	5 (27.8)	2 (40.0)
panic/Latino	111 (81.0)	115 (82.1)	18 (81.8)	8 (72.7)	95 (89.6)	75 (84.3)	13 (72.2)	2 (40.0)
orted	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	1 (20.0)
(%)								
n Indian/Alaskan Native	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (0.9)	0 (0.0)	0 (0.0)	0 (0.0)
	2 (1.5)	2 (1.4)	1 (4.5)	1 (9.1)	0 (0.0)	0 (0.0)	1 (5.6)	0 (0.0)
African American	5 (3.6)	6 (4.3)	2 (9.1)	0 (0.0)	3 (2.8)	4 (4.5)	1 (5.6)	0 (0.0)
	125 (91.2)	125 (89.3)	17 (77.3)	10 (90.9)	100 (94.3)	82 (92.1)	15 (83.3)	5 (100.0)
	5 (3.6)	7 (5.0)	2 (9.1)	0 (0.0)	2 (1.9)	3 (3.4)	1 (5.6)	0 (0.0)
ion Count*								
0)	24.0 (24.5)	17.6 (17.0)	13.4 (18.5)	26.8 (55.7)	25.5 (24.4)	21.7 (21.2)	13.7 (10.1)	3.2 (2.2)
Range)	15.0 (1–107)	11.0 (1–103)	8.0 (1–75)	5.0 (1–184)	17.5 (1–110)	15.0 (1–95)	13.0 (1–36)	2.0 (1–6)
Clinical Diagnosis (Days)								
0)	108.9 (159.5)	133.7 (219.9)	195.5 (307.5)	14 (35.7)	97.8 (139.7)	148.8 (239.9)	206 (260.4)	36 (55.1)
Range)	45.0 (1–1,010)	26.0 (1–1,104)	51.0 (1–1,247)	1.0 (1–120)	22.0 (1–715)	46.0 (1–1,302)	107.5 (1–957)	1.0 (1–127)
s Treatment for Molluscum								
	38 (27.7)	39 (27.9)	9 (40.9)	3 (27.3)	31 (29.2)	33 (37.1)	6 (33.3)	2 (40.0)
natitis (AD) - No. (%)								
or Active AD	30 (21.9)	15 (10.7)	5 (22.7)	0 (0.0)	23 (21.7)	10 (11.2)	2 (11.1)	0 (0.0)
)+	12 (8.8)	8 (5.7)	3 (13.6)	0 (0.0)	13 (12.3)	6 (6.7)	1 (5.6)	0 (0.0)
tion.								

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Atopic Derm

Age (years) Mean (SD

Gender - N

Male

Ethnicity

Race - No. (

Black or

Other

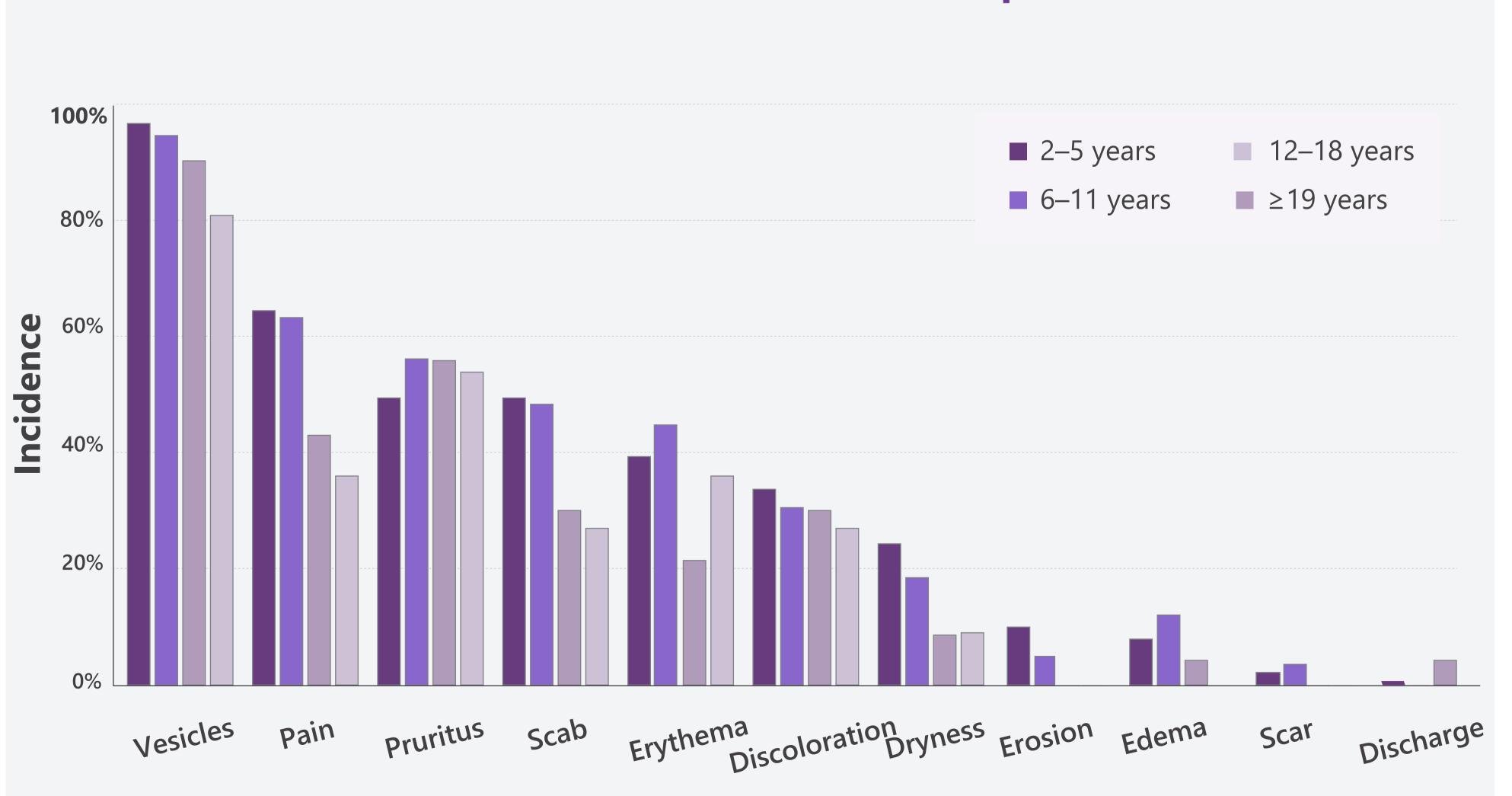
aseline Les

Mean (SD

Median (I

* The *n* for the baseline lesion count in subjects 6 –11 years was 139 (not 140).

Active atopic dermatitis was determined by concomitant medication usage of the following medications during the study: topical corticosteroids, topical calcineurin inhibitors, and phosphodiesterase-4 inhibitors.

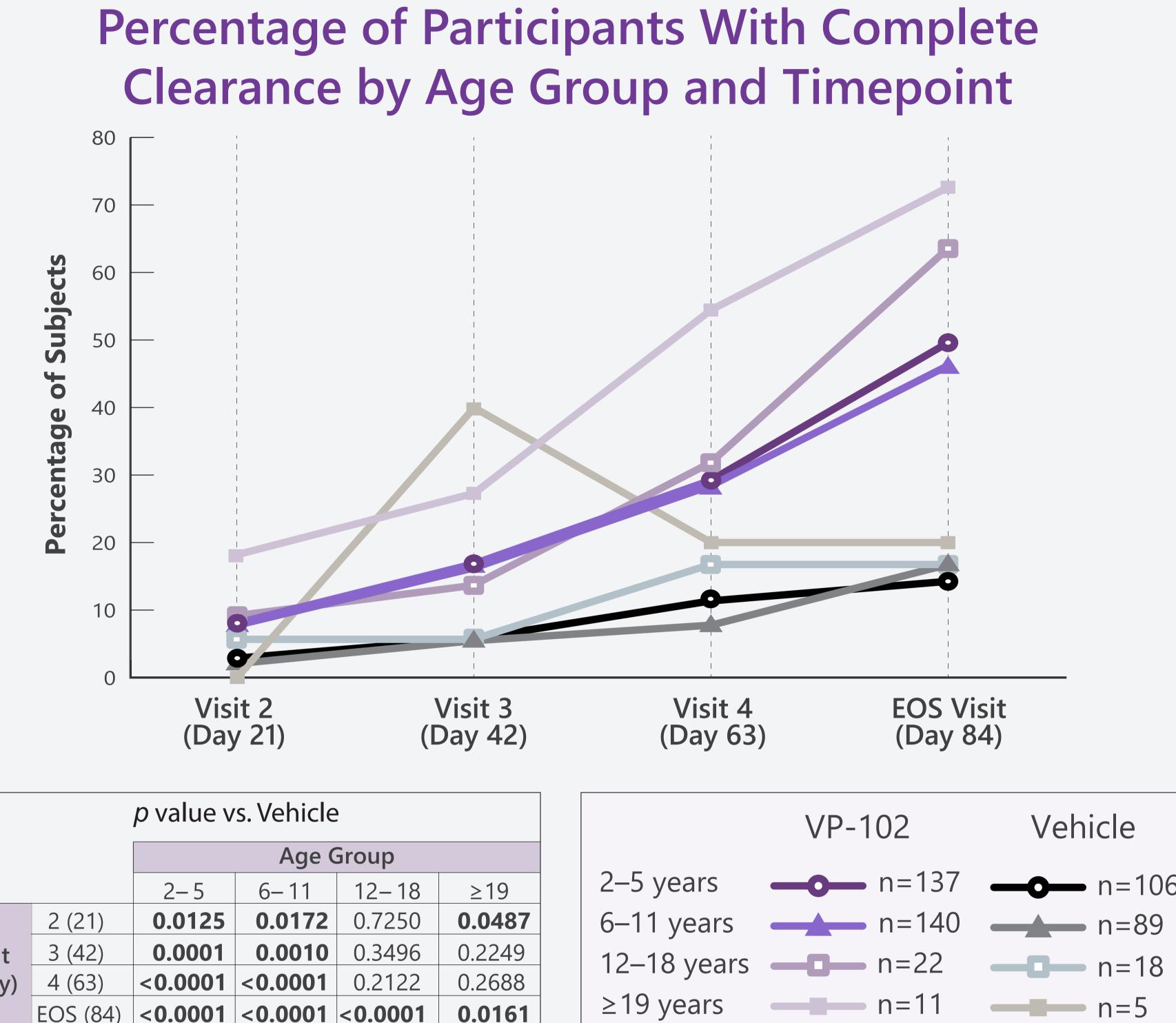


Total Incidence of TR-TEAES by Age Group in VP-102-Treated Participants

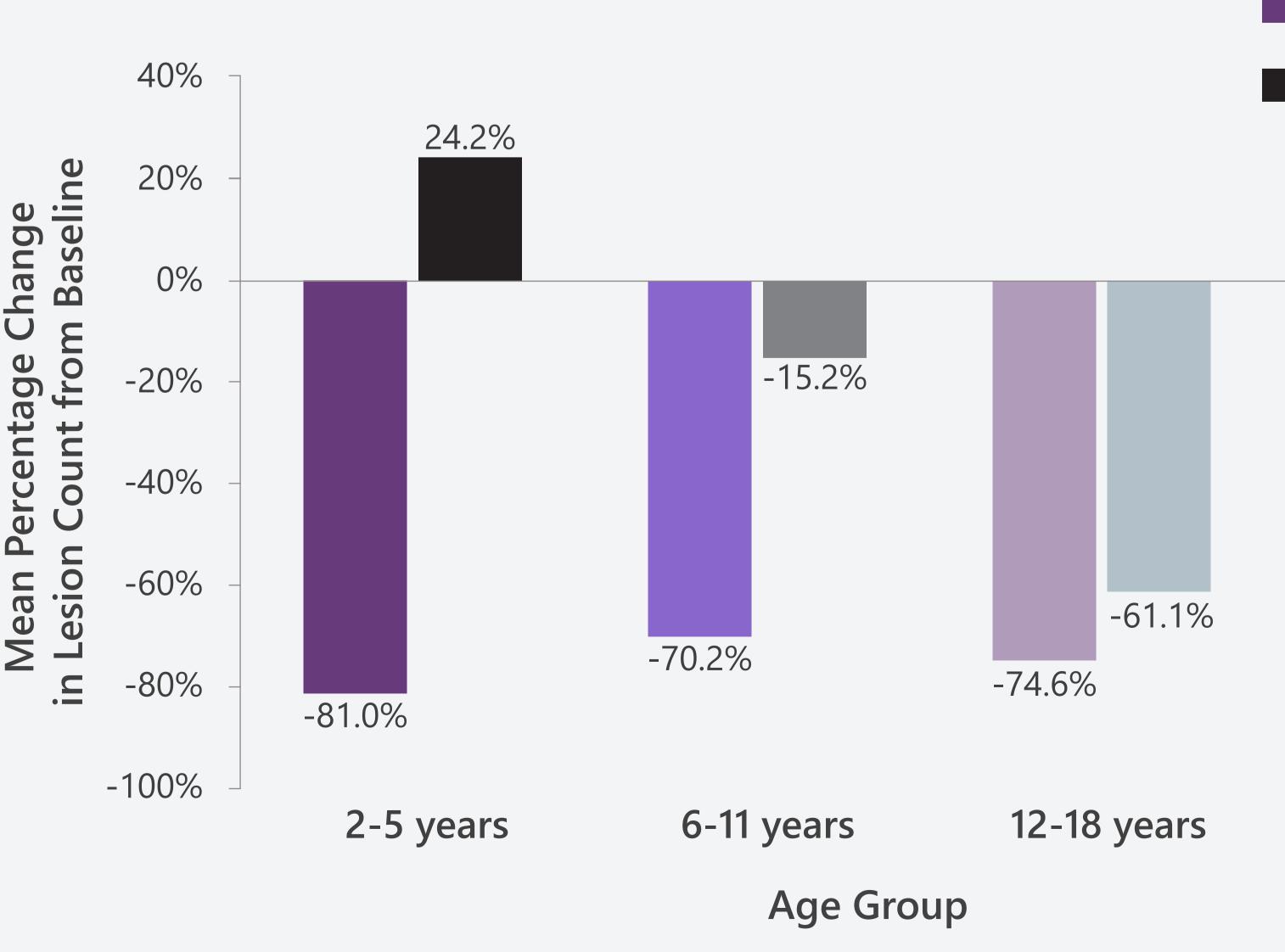
Application Site Reactions*

Safety population

* TR-TEAE reported at an incidence of 2% or greater.

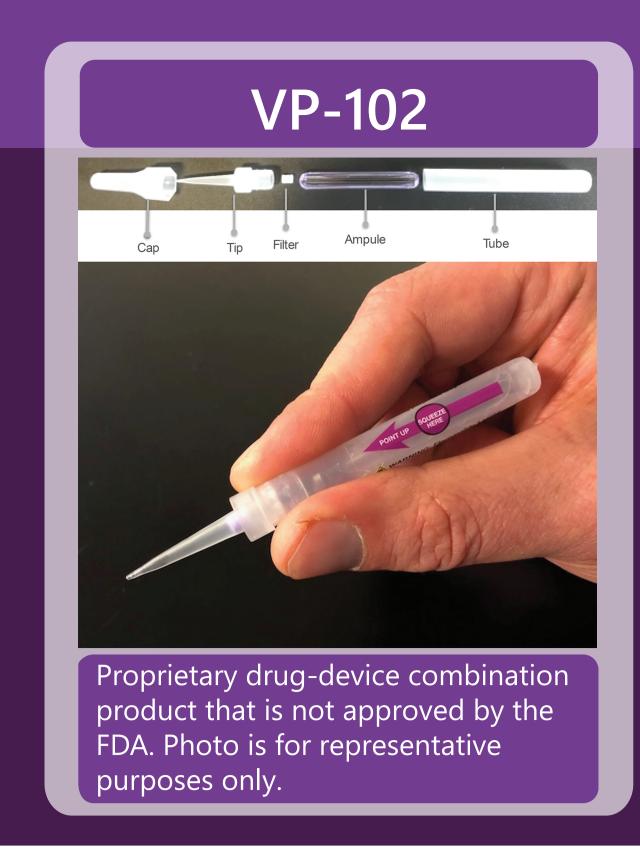


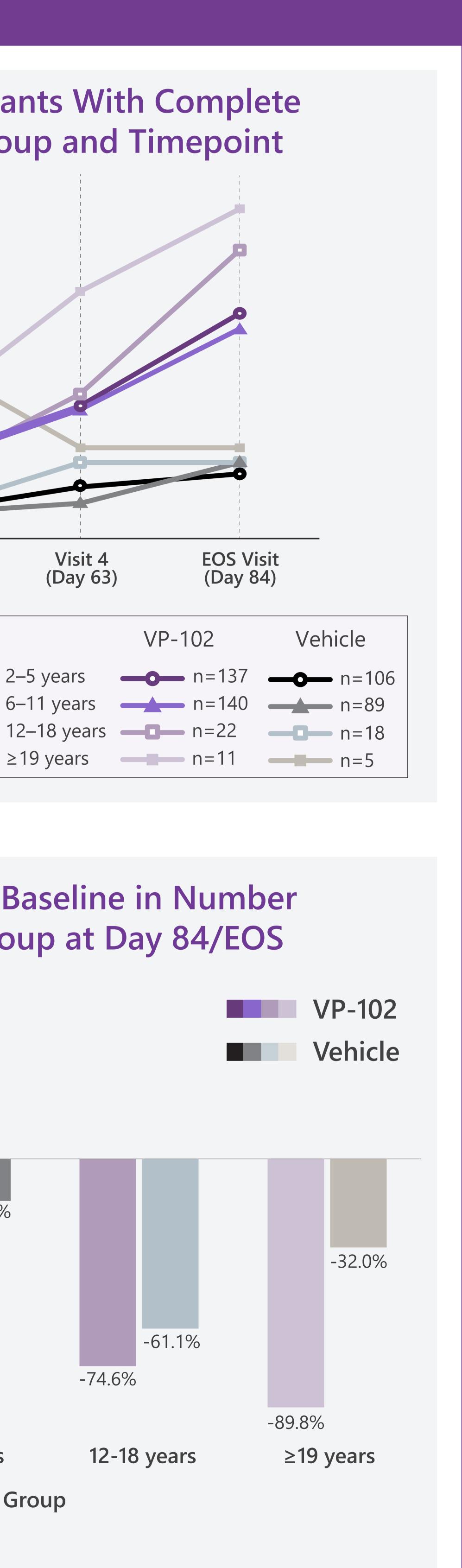
Percent Change from Baseline in Number of Lesions by Age Group at Day 84/EOS



T population; EOS=end of study.

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CONCLUSIONS

- Baseline lesion count was highest in younger children (ages 2-5), while older children (ages 12-18) and adults were more likely to have received previous treatment.
- Treatment of molluscum with VP-102 showed statistically significantly higher percentage of participants with complete clearance across all age groups compared to vehicle at day 84/EOS, and differences in percent change from baseline in lesion counts.
- TR-TEAEs were mostly mild to moderate in the VP-102 group and incidence was similar across all age groups.
- VP-102 has the potential to be used in all age groups. Due to a limited number of adult participants, further studies are needed to make conclusions in this population.

Disclosures

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