UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the
Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 13, 2016**

ACLARIS THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37581	**46-0571712**
(Commission File No.)	(IRS Employer Identification No.)

101 Lindenwood Drive, Suite 400

Malvern, PA 19355

(Address of principal executive offices and zip code)

Registrant's telephone number, including area code: **(484) 324-7933**

(Former name or former address, if changed since last report.)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 8.01 Other Events.

On September 13 and 14, 2016, members of management of Aclaris Therapeutics, Inc., or the Company, will hold meetings to review, among other things, the Company's product candidate pipeline and clinical development. In addition, on September 14, 2016, Neal Walker, the President and Chief Executive Officer of the Company, will present at the Morgan Stanley 2016 Global Healthcare Conference on, among other things, the Company's product candidate pipeline and clinical development. A copy of the presentation that will accompany the meetings and which is being presented at the Morgan Stanley conference is available on the Company's website at www.aclaristx.com, and is filed as Exhibit 99.1 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference. A second presentation regarding the Company's wart disease program is also available on the Company's website at www.aclaristx.com, and is filed as Exhibit 99.2 to this Current Report on Form 8-K, the contents of which are incorporated herein by reference. The information contained in this Current Report on Form 8-K speaks only as the date hereof. While the Company may elect to update the information in this Current Report on Form 8-K in the future, the Company disclaims any obligation to do so except to the extent required by applicable law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Aclaris Therapeutics Corporate Overview Presentation.
99.2	Aclaris Therapeutics Wart Disease Presentation.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Aclaris Therapeutics, Inc.

Date: September 13, 2016

By: /s/ Frank Ruffo
Frank Ruffo
Chief Financial Officer

Company Overview

Dr. Neal Walker
President and CEO

September 2016

Disclaimer

This presentation contains forward-looking statements, including statements regarding the treatment and market opportunity for SK, common warts, alopecia areata, androgenetic alopecia, vitiligo, and the future operations of Aclaris. These statements involve substantial known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. The forward-looking statements in this presentation represent our views as of the date of this presentation. For further information regarding these risks, uncertainties and other factors you should read Aclaris' Annual Report on Form 10-K for the year ended December 31, 2015, Aclaris' Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 and Aclaris' other filings it makes with the Securities and Exchange Commission from time to time. We anticipate that subsequent events and developments will cause our views to change. However, while we may elect to update these forward-looking statements at some point in the future, we have no current intention of doing so except to the extent required by applicable law. You should, therefore, not rely on these forward-looking statements as representing our views as of any date subsequent to the date of this presentation.

This presentation also contains estimates and other statistical data made by independent parties and by us relating to market size and other data about our industry. This data involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and the future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.

ACLARIS THERAPEUTICS

The Aclaris Opportunity

MANAGEMENT TEAM EXPERTISE IN DERMATOLOGY

- Founded and sold several companies
- Directly relevant experience in Dermatology
- Board-certified dermatologists as CEO and CSO
- Developed and commercialized multiple products

DRUG DEVELOPMENT PIPELINE

A-101: Proprietary formulation of high concentration H_2O_2

- Seborrheic Keratosis
  - Phase 3 Data 4Q 2016
- Common Warts
  - Phase 2 Data 3Q 2016

ATI-50001/ATI-50002/ATI-50003: JAK 3 and 1/3 Inhibitors

- Alopecia Areata
- Vitiligo
- Androgenetic Alopecia (AGA)

ATTRACTIVE DERMATOLOGY MARKETS

- Time and capital efficient
- Highly concentrated prescriber base
- Large unmet market segments with no FDA-approved drugs
- Growing market for cash pay aesthetic and medical dermatology products

Build a Fully Integrated Dermatology Company

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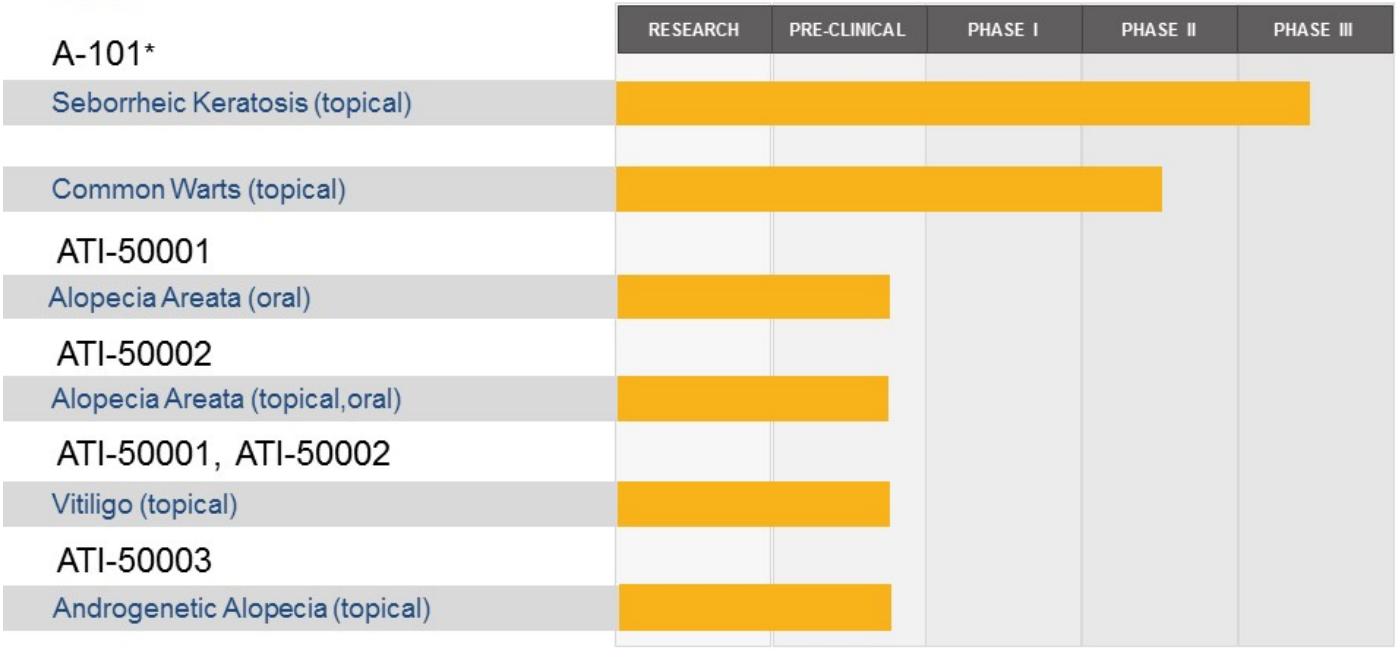
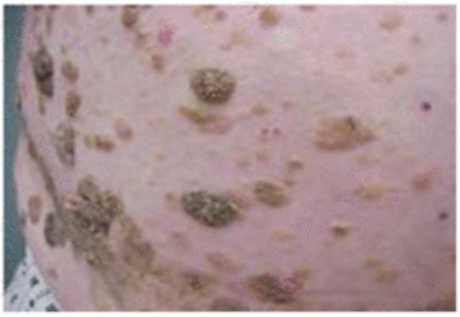
Our Drug Candidates

Exclusive, Worldwide Right to Commercialize A-101, A-102, ATI-50001, ATI-50002, and ATI-50003.

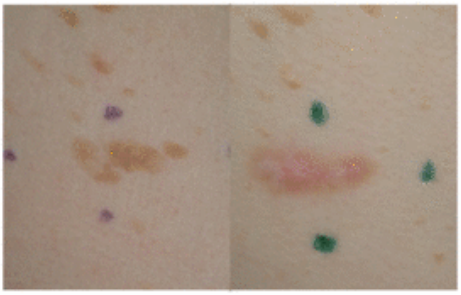


* Also developing A-102 topical gel as a lifecycle management opportunity for A-101

Seborrheic Keratosis (SK) Background



Untreated SK



Before Treatment **3 Months Post Cryosurgery**

- SK is one of most common diagnoses made by dermatologists
  - >83 million people with the disease in the U.S.
  - 18.5 million patient visits to dermatologists
  - 8.3 million procedures to remove SKs annually
  - $1.2 billion - historic costs of treatments for SK
- Patients seek diagnosis and treatment
  - Fear of skin cancer
  - Concern about appearance
  - Discomfort from itching and inflammation
- Current options for SK removal: cryosurgery, curettage, electrodessication or excision

  Limitations of current removal options:
  - Dyspigmentation (hypo or hyper)
  - Scarring
  - Pain
  - Surgical - invasive
  - Treatment of numerous SK is impractical

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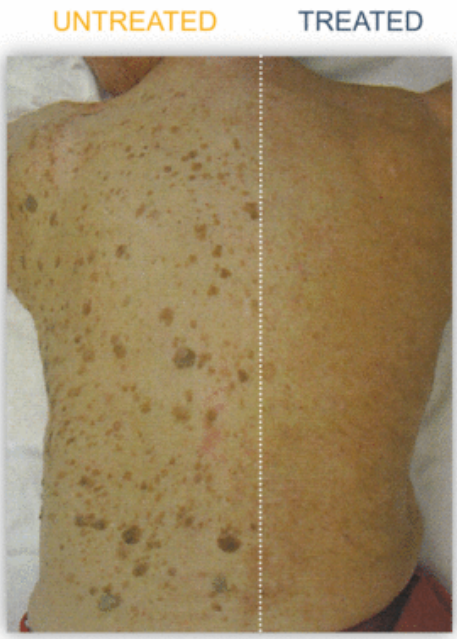
Potential to Be First FDA-approved Drug for SK

A-101 is appealing concept for SK treatment

- Topical, non-invasive
- Minimal discomfort; no need for anesthesia
- Reduced risk of pigmentary changes and scarring
- Ability to treat larger numbers of lesions
- Ability to hand off to ancillary staff

Background

- Developed a proprietary formulation of 40.0% H_2O_2
- Conducted formal dose-ranging studies
- MOA: drives apoptotic and necrotic cell death



Inventor's Proof of Concept
(with his initial formulation)

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Summary of Completed Phase 2 Trials for SK

Trial	SK Lesion Area	Date Completed	Trial Design	Trial Outcome
SEBK-201 (n=35) Phase 2	Trunk (Back)	June 2014	• Single center, intra-subject • Four lesions treated • A-101 concentrations: 25.0%, 32.5%, 40.0% • 1 or 2 applications • Duration: 78 days	• Efficacy: 32.4% clear; 67.7% clear or near clear with 40% concentration • Favorable safety profile
SEBK–202 (n=172) Phase 2	Trunk and Extremities	December 2014	• Multicenter, parallel group • Four lesions treated • A-101 concentrations: 32.5%, 40.0% • 1 or 2 applications • Duration: 106 days	• Efficacy: Demonstrated statistically significant clearance of all 4 lesions in top dose group (Phase 3 primary end point) • Favorable safety profile
SEBK–203 (n=119) Phase 2	Face	March 2015	• Multicenter, parallel group • One lesion treated • A-101 concentrations: 32.5%, 40.0% • 1 or 2 applications • Duration: 106 days	• Efficacy: Statistically significant clearance • Favorable safety profile

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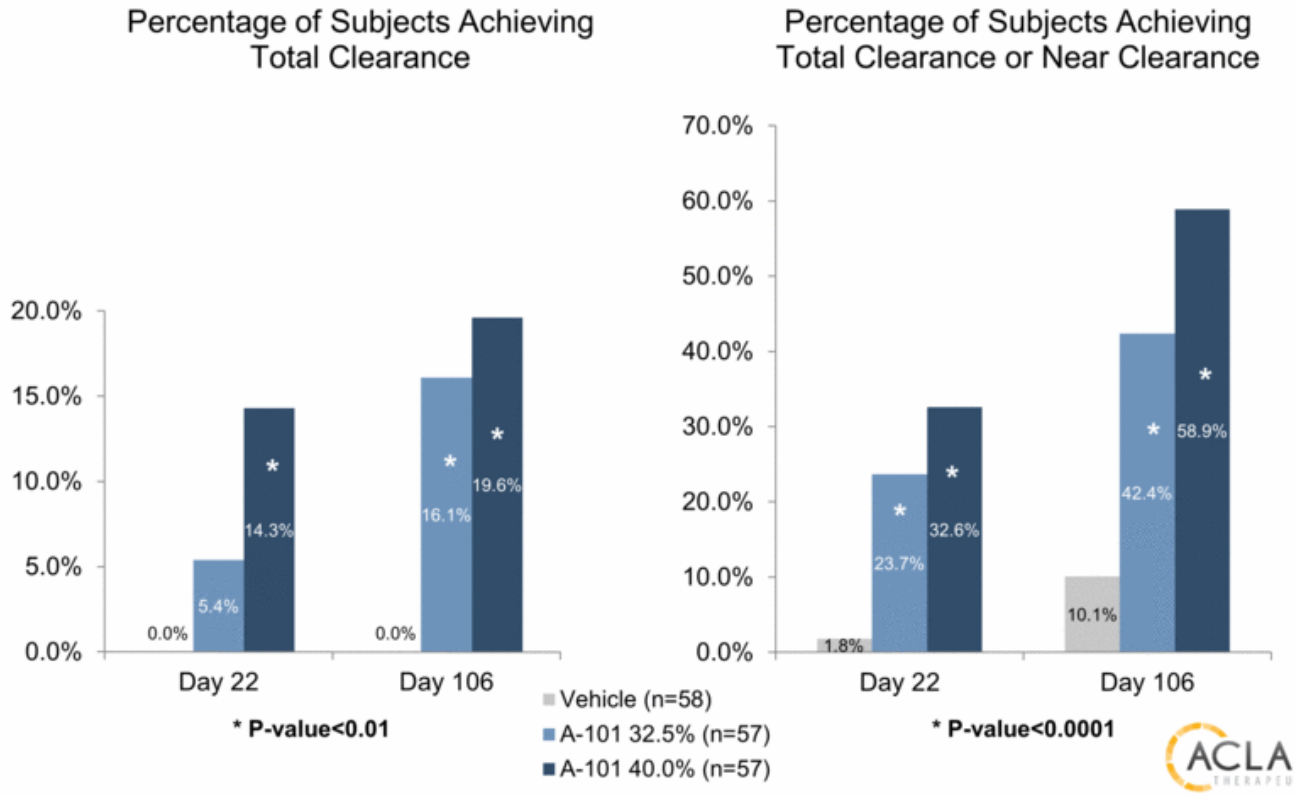
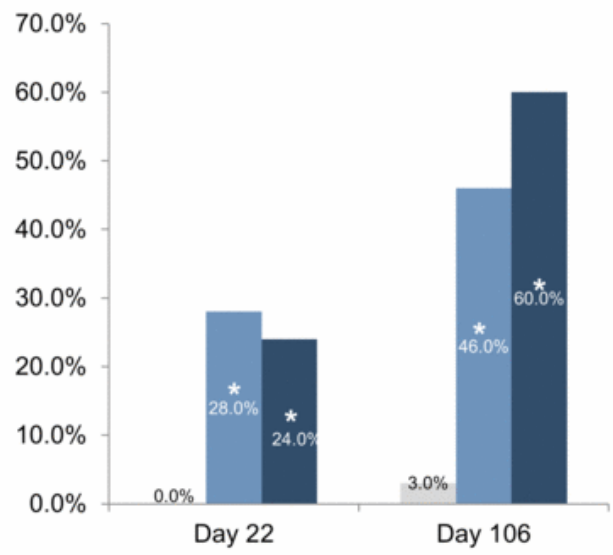
A-101 Phase 2 Trunk/Extremities Study:
PLA Responder Analysis



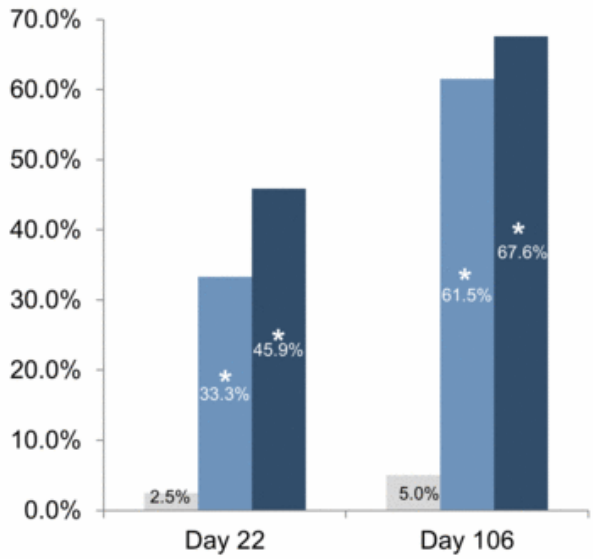
A-101 Phase 2 Face Study:
PLA Responder Analysis

Percentage of Subjects With Target Lesion Clear



* P-value<0.001

Percentage of Subjects With Target Lesion Clear or Near-Clear



* P-value<0.001

Vehicle (n=40)
A-101 32.5% (n=39)
A-101 40.0% (n=37)

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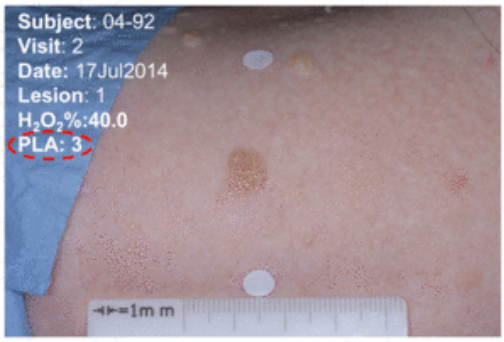
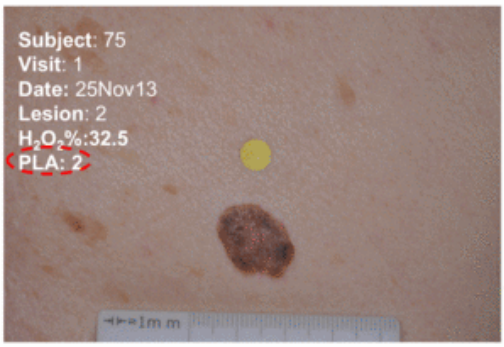
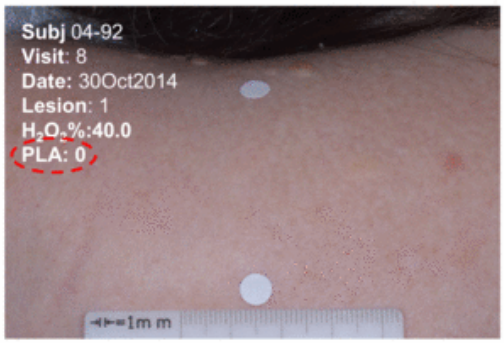
Grading of SKs using PLA Scale in Clinical Trials

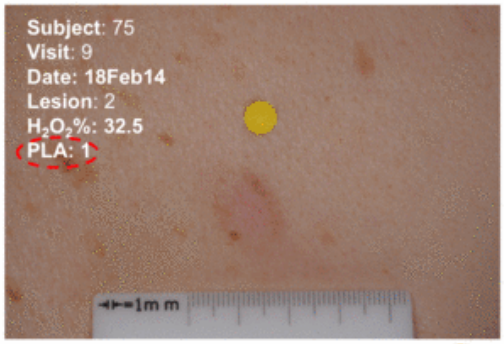
Pre-Treatment with A-101





Post-Treatment with A-101





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A-101 Next Steps: Phase 3 Overview

- A-101 40.0% is being used for Phase 3 clinical testing
- Initiated Phase 3 program – January 2016
  - Pivotal trials (SEBK-301/302): Two identical Phase 3 trials
    - 4 lesions treated in total with at least one on face and one on trunk or extremities
    - Primary endpoint: Proportion of subjects with clear on PLA scale
    - 3 month drug-free follow-up
  - Open-label (SEBK-303): 4 SK lesions
    - Up to four applications
- Phase 3 Data - 4Q 2016
- Plan to submit NDA – 1Q 2017

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A-101 Commercialization Strategy

Buy and Bill Model	• Cash pay, minimally invasive procedure • Lower cost relative to other aesthetic treatments (Botox®, Fillers, Laser treatments)
Concentrated Prescriber Base	• 5,000 dermatologists in US, accounting for over 70% of procedures performed • Concentrated call point allows for high reach and frequency
Disease Awareness	• Disease state awareness initiatives • KOL engagement, conference presentations and publications
Commercial Launch	• 50-60 person specialty sales team focused on high tier targets • Comprehensive promotional campaign to include peer-influence programs
Patient Engagement	• Campaigns focused on driving awareness and furthering interest in treatment options

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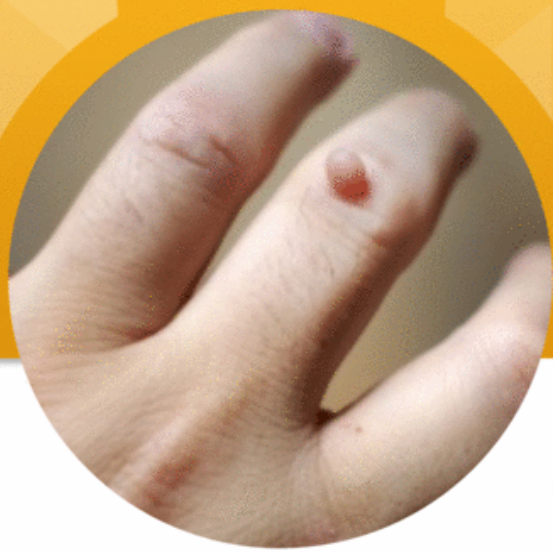
A-101
CANDIDATE FOR COMMON WARTS



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Existing Patient Base Offers Significant Market Potential

[1] IMS National Disease and Therapeutic Index 2016.
[2] Bruggnik et al, Natural Course of Cutaneous Warts Among Primary Schoolchildren: A Prospective Cohort Study 2013, *Annals of Family Medicine*;11:5,2013;437-441.
[3] Lipke M., An Armamentarium of Wart Treatments, *Clinical Medicine & Research*,4:4, 2006; 273–293.

Summary of A-101 Phase 2 Wart Clinical Trial Results

Trial	Common Wart Area	Topline Data	Trial Objective and Design	Trial Outcome
WART–201 (n=98) Phase 2	Trunk and Extremities	August 2016	• Multicenter, parallel group • One wart treated • A-101 concentrations: 40%, 45% compared to vehicle • 8 applications • Duration: 56 days	• Efficacy: Statistically significant clearance with 45% concentration • Favorable safety profile

Primary Endpoint:

Mean change from baseline in the Physician's Wart Assessment (PWA) score at Visit 10 using a analysis of covariance

Secondary Endpoints:

Responder analysis: The proportion of subjects whose target wart is judged to be clear on the PWA at Visit 10.
Responder analysis: The proportion of subjects whose target wart is judged to be clear or mild on the PWA at Visit 10.

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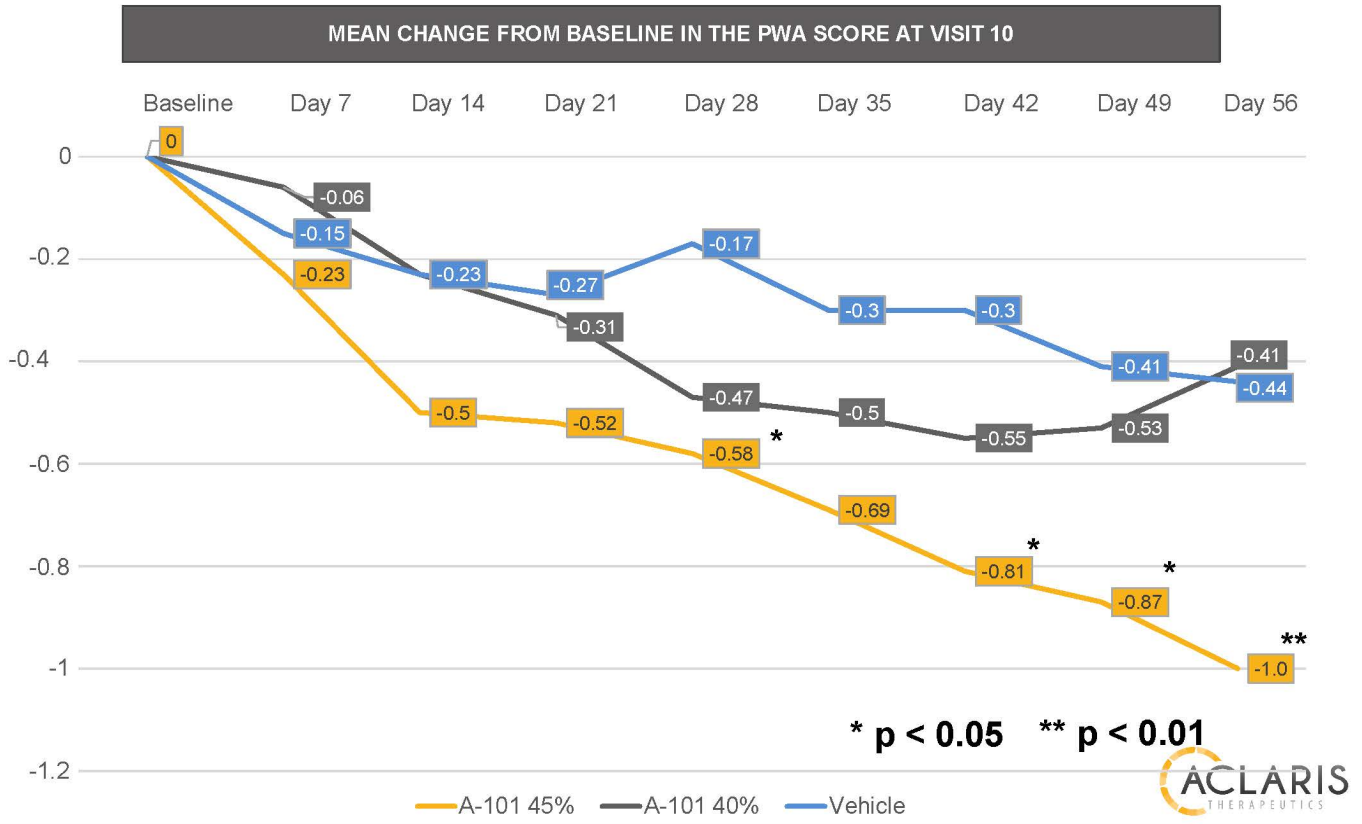
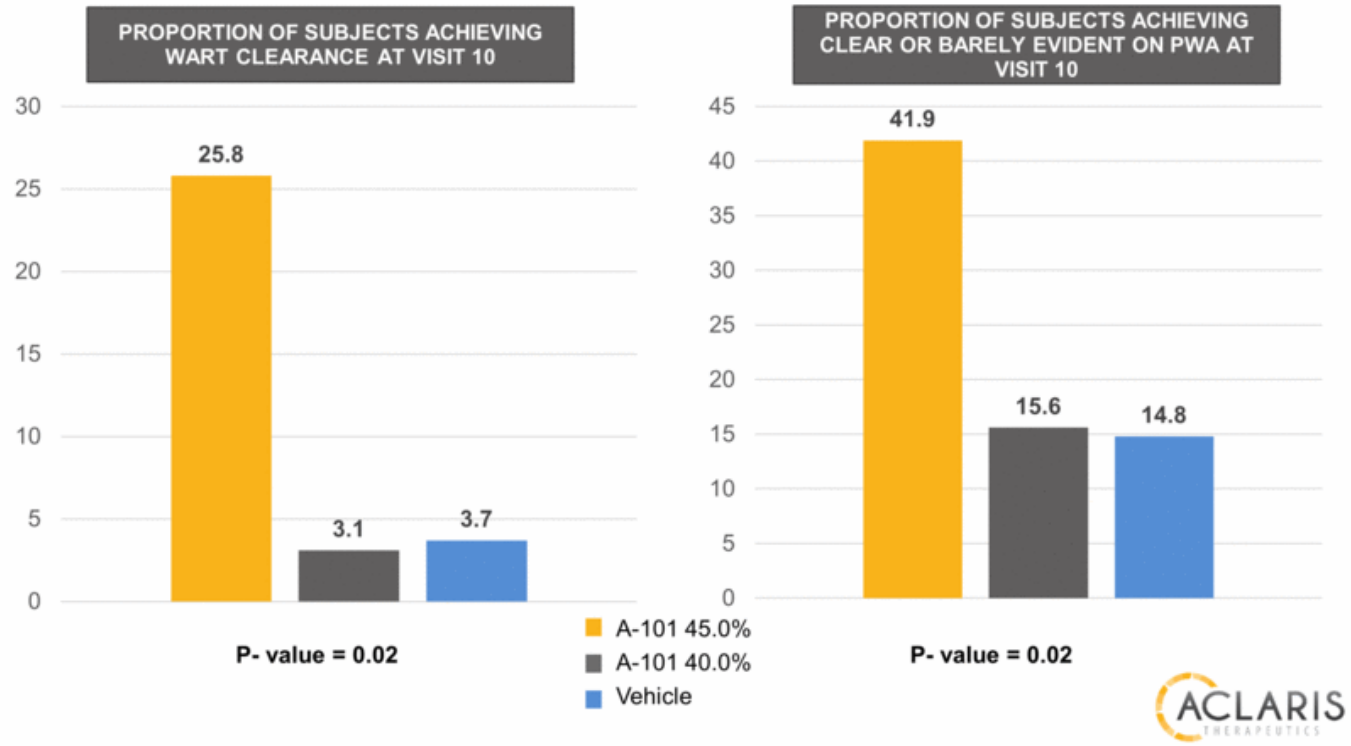
Both Statistical and Clinical Significance Achieved on Primary Endpoint with A-101 45% Concentration



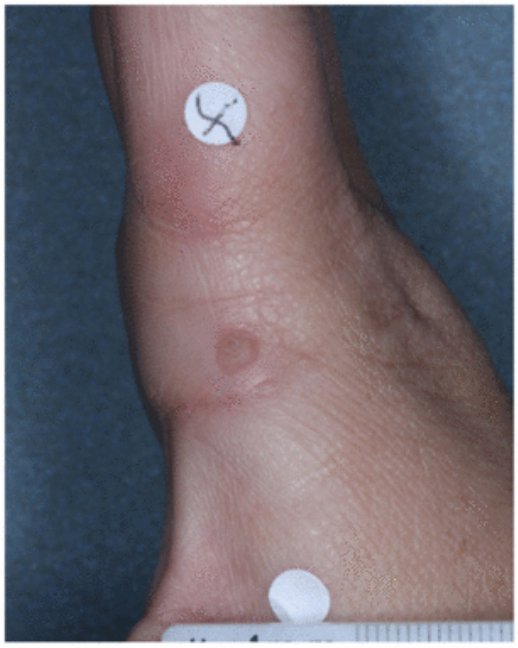
Statistical Significance Achieved on Secondary Endpoints in Clearance of Common Warts with A-101 45% Concentration

Responder Analysis



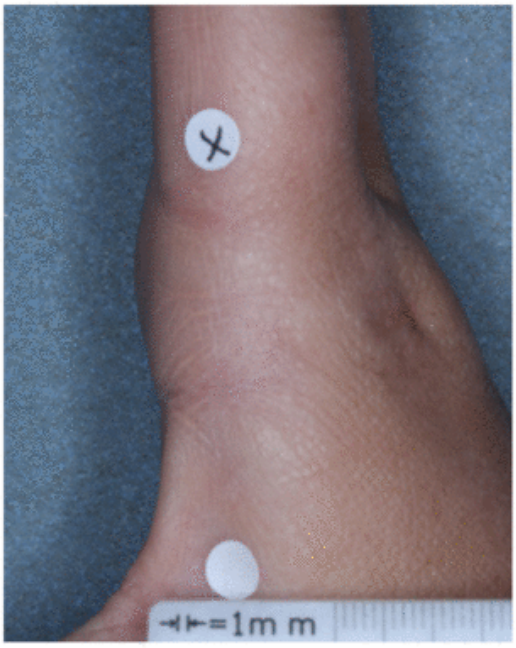
Patient Treated with A-101 45% Concentration in study WART-201

Pre-Treatment with A-101



Visit 2 (PLA 3)

Post-Treatment with A-101



Visit 10 (PLA 0)

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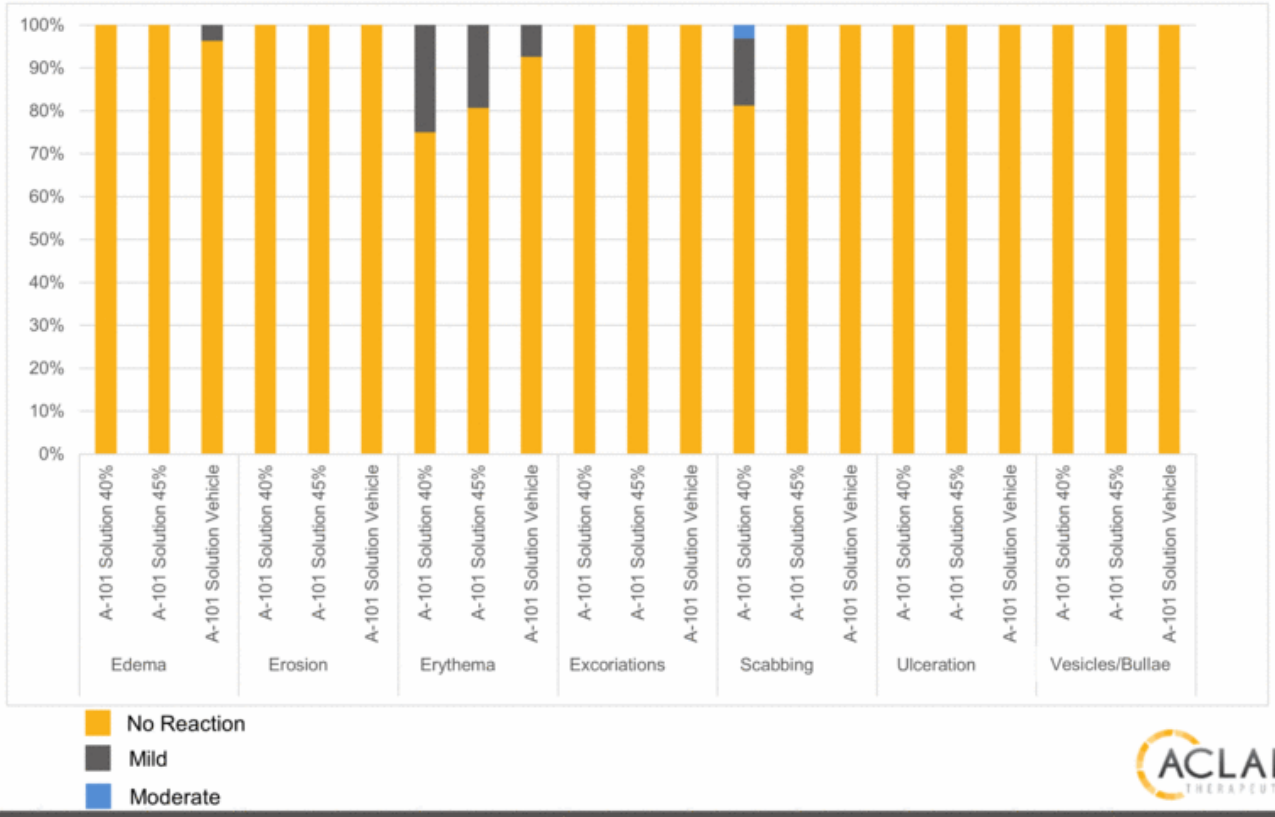
Skin Reactions Similar to Vehicle at Visit 10; Favorable Safety Profile



Based on Results, A-101 45% Concentration Considered for Further Development as Treatment for Common Warts

45% Concentration of A-101 Observed to be Safe and Effective

Statistical Significance	• Achieved both statistical and clinical significance on the primary endpoint • Achieved statistical significance in complete clearance of the warts
Safety Profile	• Favorable safety profile was observed under the conditions of this study • Occasional mild, transient local skin reactions observed during treatment; skin reactions were similar to vehicle
Next steps	• Develop A-101 45% Concentration as the commercial dosage form for common warts • Develop as RX drug for patient to use at home

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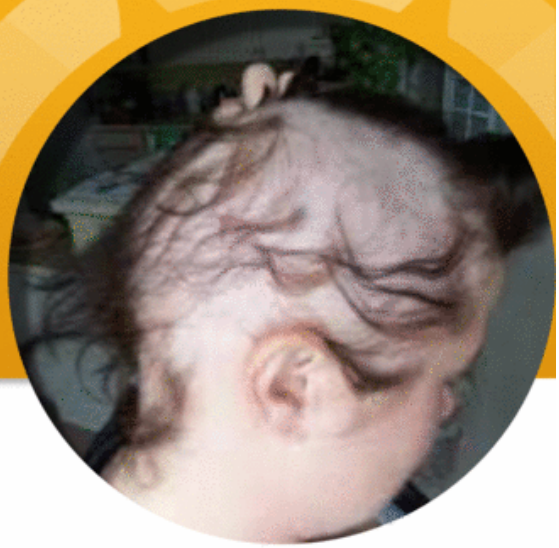
ATI-50001/ATI-50002 Candidates for Alopecia Areata



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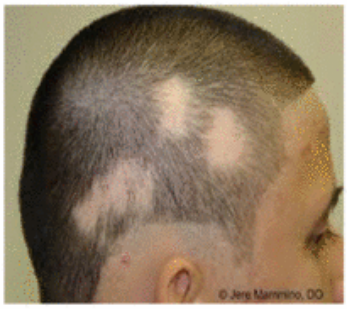
Alopecia Areata (AA) Background



AA – Patchy

Alopecia Universalis

- AA is an autoimmune condition, characterized by patchy, non-scarring hair loss on the scalp and body
- Large unmet need: >6.6 million people in the U.S. have had or will develop AA at some point in their lives
  - 2/3 of affected individuals ≤30 years old at disease onset
  - 25-50% of patients have persistent patchy AA
  - 14%-25% of patients progress to totalis or universalis
- Current off label treatments include topical steroids, steroid injections, and minoxidil
- Recent translational research work by Dr. Angela Christiano
  - Furthered genetic understanding of disease
  - Identified JAK inhibitors as a potential treatment for AA

Potential to be First FDA-Approved Drug for AA

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ATI-50001/ATI-50002: JAK Inhibitors in Alopecia Areata

- Lead asset: Selective JAK 1/3 inhibitor from Rigel
  - Exclusive, worldwide license and development collaboration
  - Oral and topical rights
  - Known mechanism of action and biological response in humans
  - Promoted hair regrowth in mouse model of AA
- Drug Candidates:
  - ATI-50001 for oral administration in Alopecia Totalis and Alopecia Universalis
  - ATI-50002 for topical administration in Patchy Alopecia Areata
- Development Strategy
  - Planned submission of IND: 2H 2016
  - Initiation of clinical trial: 1H 2017

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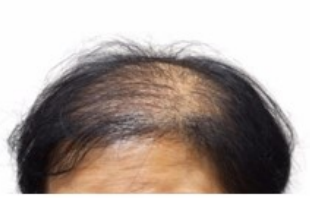
Business Development Transactions

- Vixen (Columbia University IP) and Key Organics/JAKPharm
  - Broadens our IP estate
    - Methods of use covering JAK inhibitors for the treatment of:
      - Alopecia Areata
      - Androgenetic alopecia (female and male pattern hair loss)
      - Additional hair loss disorders
  - Next generation JAK inhibitors
    - Covalently bound highly selective JAK3 inhibitors

Additional Potential Indications

- Androgenic alopecia (male and female pattern hair loss)
  - AGA is the most common cause of hair loss and is experienced by 70% of men and 40% of women at some point in their lives[1]
  - In 2012, 35 million men and 21 million women suffered hair loss[2]
  - Topical JAK inhibitor

Male with AGA



Female with AGA

- Vitiligo
  - Vitiligo impacts 1% to 2% of the overall global population irrespective of sex, race, or age[3]
  - Disease onset occurs in about one-half of sufferers between the ages of 10 and 30[3]
  - Oral and topical JAK inhibitor

[1] Cassiopea. Androgenic Alopecia.
[2] Bergeson, L. The Truth About Hair Loss and Baldness Cures. 11.08.2014.
[3] Fitzpatrick T., et al. Vitiligo Facts. American Vitiligo Research Foundation Inc.

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Milestones

Milestone	2016				2017			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
A-101 SK								
Phase 3 Trials Initiated								
Phase 3 Data								
Submit NDA								
Submit MAA								
A-101 Common Warts								
Phase 2 Data								
ATI-50001/ATI-50002 Alopecia Areata								
Submit IND								
Commence POC trial								

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THANK YOU

www.aclaristx.com

Verruca Vulgaris (Common Warts) Market Opportunity

September 2016

Summary of A-101 Phase 2 Wart Clinical Trial Results

Trial	Common Wart Area	Topline Data	Trial Objective and Design	Trial Outcome
WART–201 (n=98) Phase 2	Trunk and Extremities	August 2016	• Multicenter, parallel group • One wart treated • A-101 concentrations: 40%, 45% compared to vehicle • 8 applications • Duration: 56 days	• Efficacy: Statistically significant clearance with 45% concentration • Favorable safety profile

Primary Endpoint:

Mean change from baseline in the Physician's Wart Assessment (PWA) score at Visit 10 using a analysis of covariance

Secondary Endpoints:

Responder analysis: The proportion of subjects whose target wart is judged to be clear on the PWA at Visit 10.
Responder analysis: The proportion of subjects whose target wart is judged to be clear or mild on the PWA at Visit 10.

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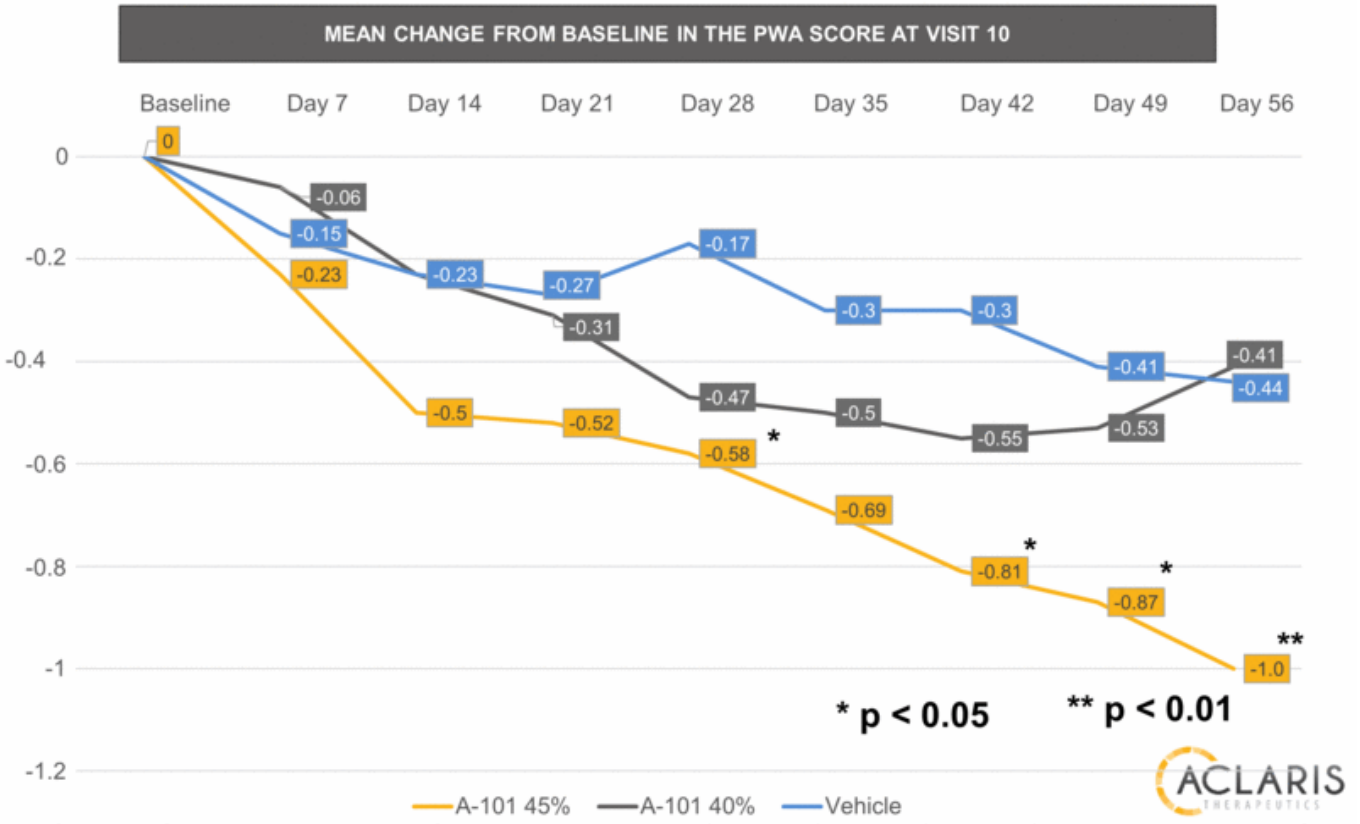
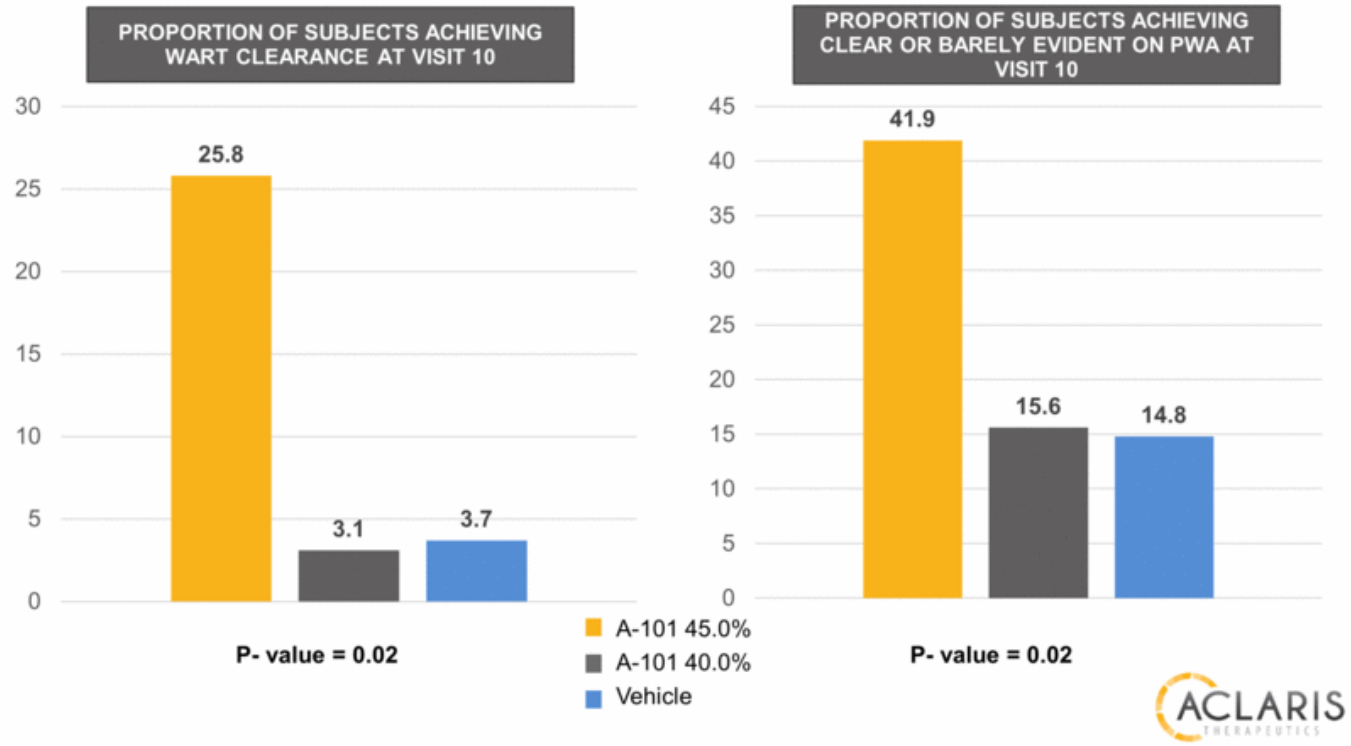
Both Statistical and Clinical Significance Achieved on Primary Endpoint with A-101 45% Concentration



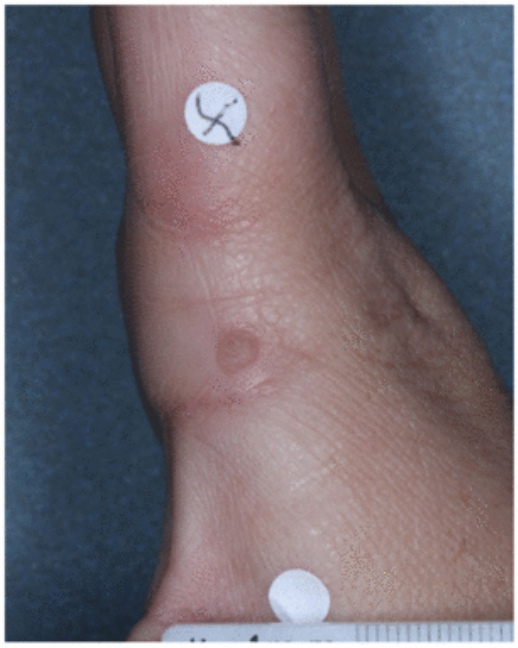
Statistical Significance Achieved on Secondary Endpoints in Clearance of Common Warts with A-101 45% Concentration

Responder Analysis



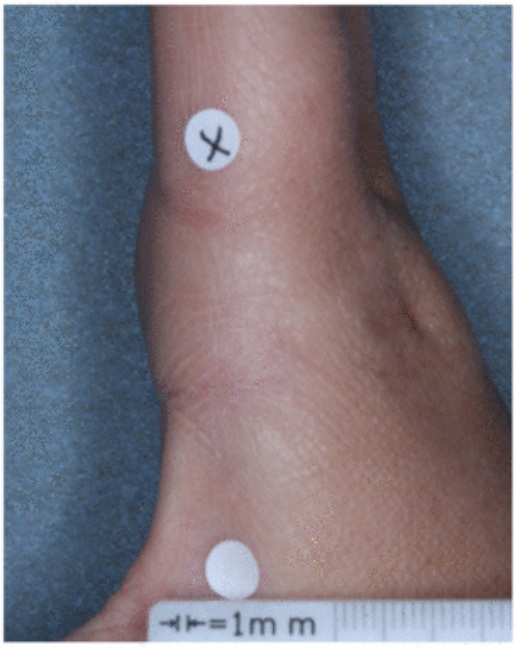
Patient Treated with A-101 45% Concentration in study WART-201

Pre-Treatment with A-101



Visit 2 (PLA 3)

Post-Treatment with A-101



Visit 10 (PLA 0)

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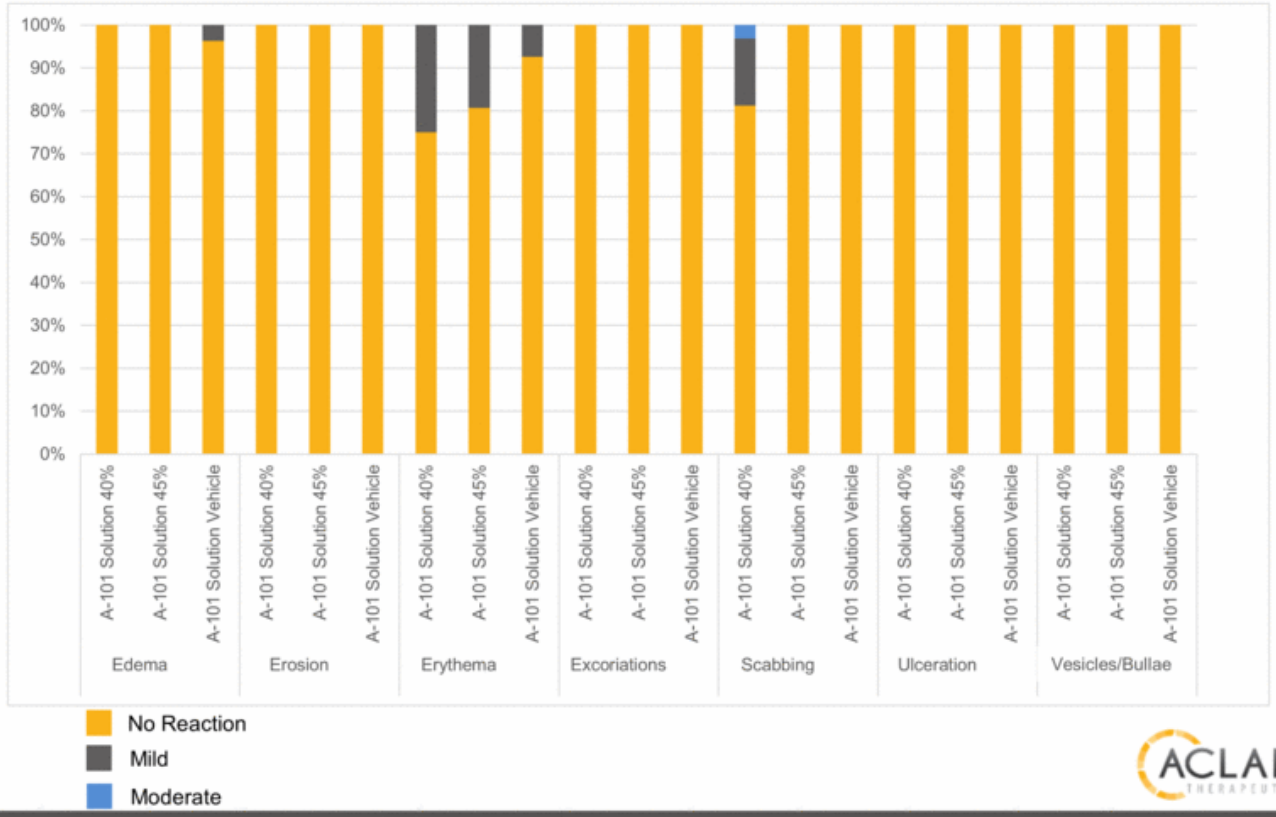
Skin Reactions Similar to Vehicle at Visit 10; Favorable Safety Profile



Based on Results, A-101 45% Concentration Considered for Further Development as Treatment for Common Warts

45% Concentration of A-101 Observed to be Safe and Effective

Statistical Significance	• Achieved both statistical and clinical significance on the primary endpoint • Achieved statistical significance in complete clearance of the warts
Safety Profile	• Favorable safety profile was observed under the conditions of this study • Occasional mild, transient local skin reactions observed during treatment; skin reactions were similar to vehicle
Next steps	• Develop A-101 45% Concentration as the commercial dosage form for common warts • Develop as RX drug for patient to use at home

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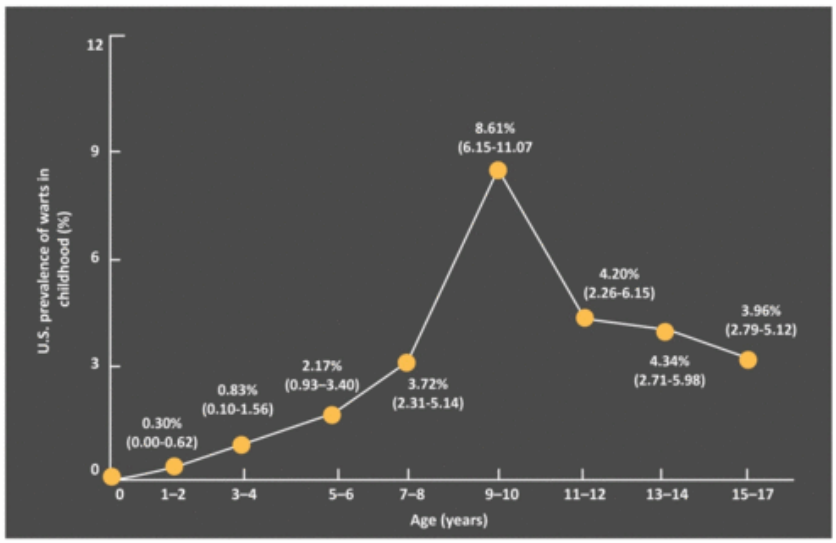
Verruca Vulgaris (Common Warts): Common Skin Disease

ABOUT COMMON WARTS:

- Etiology – keratinocytes infected by human papillomavirus (HPV); manifests as common warts, plantar warts or genital warts
- Virus spreads via direct contact or contact with environment
- U.S. population-based prevalence estimates in adults are lacking[1]
- Children have increased risk due to immature immunologic response and frequent skin-to-skin contact with peers
  - U.S. prevalence of warts in children reported at 3.3%[1]
  - In the U.S. , in children ages 9-10, the estimated prevalence of warts. is 8.6%



[1] Silverberg et al, The US Prevalence of Common Warts in Childhood: A Population-Based Study, *Journal of Investigative Dermatology*; 2013; 133, 2788–2790.

Patient Desire for Treatment

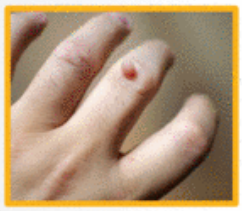
- 50% of patients report discomfort[1]
- 39% of patients say warts impact social/leisure activities[1]
- Perceived social stigma,[2] possibly due to contagious nature
- Warts can persist for years
  - In children, up to 2/3 of warts may resolve within two years[3]
  - Warts that do not clear within a year are unlikely to do so without treatment[4]
- OTC topical treatments containing salicylic acid are first-line and most common therapy[1]
  - Promote exfoliation; stimulate host immunity
  - Slow to work; require frequent application for up to 12 weeks[2]
  - Marginally effective; 1.6 times more likely to clear treated warts than placebo[4]
- Two million patients seek treatment from HCP annually[5]

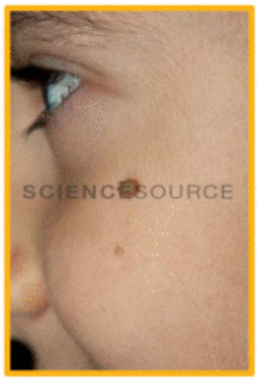
[1] Lipke M., An Armamentarium of Wart Treatments, *Clinical Medicine & Research*,4:4, 2006; 273–293.
[2] Mulhem et al, Treatment of Nongenital Cutaneous Warts, *American Family Physician*; 84:3, 2011; 288-293 .
[3] Bruggnik et al, Cryotherapy with liquid nitrogen versus topical salicylic acid application for cutaneous warts in primary care: randomized controlled trial, *Canadian Medical Association Journal*; 182:15, 2010; 1624-1630.
[4] Kwok et al, Topical treatments for cutaneous warts (Review),*Cochrane Database of Systematic Reviews*, 9, 2012; Art. No.: CD001781.
[5] IMS National Disease and Therapeutic Index 2016.
[6] Patient interview.

Treatment Guidelines for Common Warts

TREATMENT GUIDELINES RECOMMEND PHYSICIAN INTERVENTION FOR COMMON WARTS IF:[1]

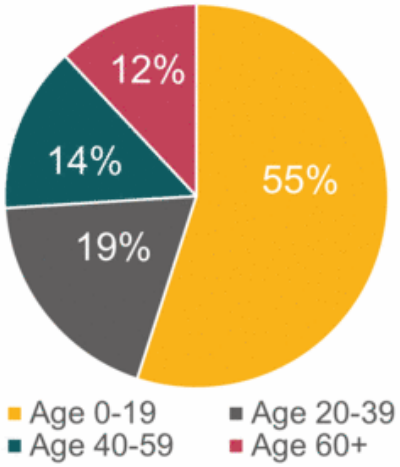
- Patient wishes to prevent spread to self or to others
- Patient complains of pain, bleeding, itching, burning
- Disabling or disfiguring lesions present
- Numerous or very large lesions present
- Patient is immunocompromised
- Patient desires therapy





A high percentage of patients with warts are children

Patient Visits by Age[2]

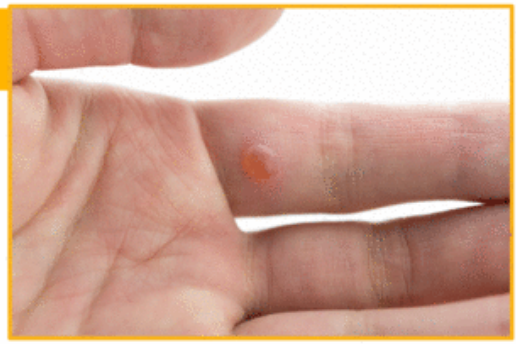


[1] Lipke M., An Armamentarium of Wart Treatments, *Clinical Medicine & Research*,4:4, 2006; 273–293.
[2] IMS National Disease and Therapeutic Index 2016.

Significant Unmet Need Exists

COMMON WART TREATMENTS CURRENTLY USED BY PHYSICIANS…[1]

- About 45% of patients treated by a physician receive cryosurgery
- Other in-office treatments (e.g., surgery, cautery, intralesional bleomycin injections)
- Off-label uses of Rx drugs (e.g., imiquimod)
- Over-the-counter treatments (e.g., salicylic acid)



…HAVE SIGNIFICANT LIMITATIONS[2,3,4,5]

- May be painful; challenge to treat children
- May cause scarring
- May cause dyspigmentation (hypo or hyper)
- Lack of rigorous clinical studies
- Slow to work
- Recurrence rate is high

[1] IMS National Disease and Therapeutic Index 2016.
[2] Lipke M., An Armamentarium of Wart Treatments, *Clinical Medicine & Research*,4:4, 2006; 273–293.
[3] Sterling et al, British Association of Dermatologists' guidelines for the management of cutaneous warts 2014, *British Journal of Dermatology*, 171, 2014; 696-712.
[4] Kwok et al, Topical treatments for cutaneous warts (Review), *Cochrane Database of Systematic Reviews*, 9, 2012; Art. No.: CD001781.
[5] Mulhem et al, Treatment of Nongenital Cutaneous Warts, *American Family Physician*; 84:3, 2011; 288-293

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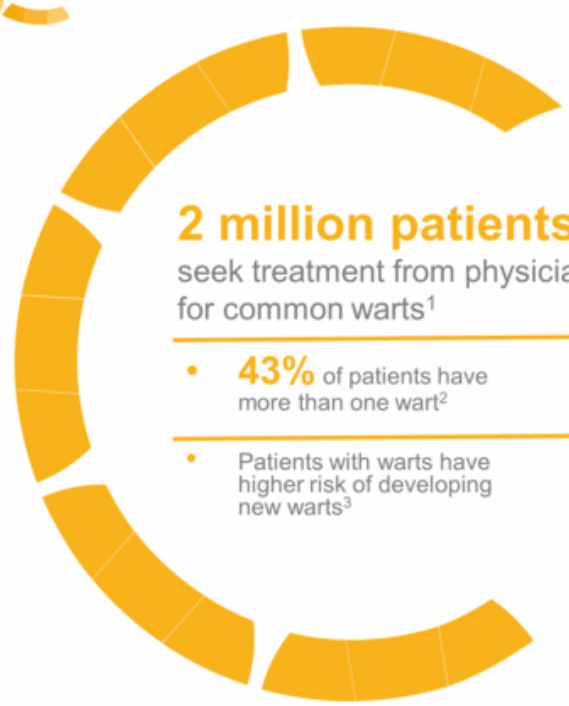
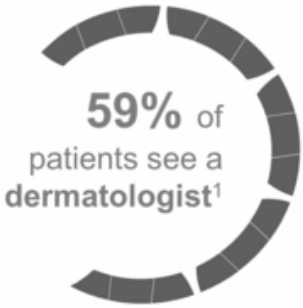
Current Patient Base



2 million patients
seek treatment from physicians for common warts[1]

- **43%** of patients have more than one wart[2]
- Patients with warts have higher risk of developing new warts[3]



59% of patients see a **dermatologist**[1]

25% see a **pediatrician**[1]

11% see a **family/general practitioner**[1]

[1] IMS National Disease and Therapeutic Index 2016.
[2] Bruggnik et al, Natural Course of Cutaneous Warts Among Primary Schoolchildren: A Prospective Cohort Study 2013, *Annals of Family Medicine*;11:5,2013;437-441.
[3] Lipke M., An Armamentarium of Wart Treatments, *Clinical Medicine & Research*,4:4, 2006; 273–293.

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THANK YOU

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