
**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 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): April 4, 2019

Aclaris Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of incorporation)

001-37581
(Commission File Number)

46-0571712
(IRS Employer
Identification No.)

**640 Lee Road, Suite 200
Wayne, PA 19087**
(Address of principal executive offices, including zip code)

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

N/A
(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))

Indicate by check mark whether the registrant is an emerging growth Company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure.

On April 4, 2019, management of Aclaris Therapeutics, Inc. (the “*Company*”) will host investor meetings during the William Blair & Company 3rd Annual Late-Stage Therapeutics Conference in New York, New York. The investor meetings will include a slide presentation. A copy of this slide presentation is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

In accordance with General Instruction B.2. of Form 8-K, the information in this Item 7.01 and Exhibit 99.1 hereto, shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liability of that section, nor shall it be deemed incorporated by reference in any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, regardless of any incorporation language in such a filing, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit Number</u>	<u>Exhibit Description</u>
99.1	Company 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: April 4, 2019

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

EMPOWERING PATIENTS THROUGH
REVELATIONARY
SCIENCE



Company Overview

Dr. Neal Walker
President and CEO
April 2019



Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this presentation that do not describe historical facts may constitute forward-looking statements as that term is defined in the Private Securities Litigation Reform Act of 1995. These statements may be identified by words such as "believe", "expect", "may", "plan," "potential," "will," and similar expressions, and are based on Aclaris' current beliefs and expectations. These forward-looking statements include expectations regarding Aclaris' development of its drug candidates, including the timing for initiation and completion of clinical trials, the availability of data from these trials and the timing of its regulatory submissions related to these trials, and the growth opportunity for ESKATA and RHOFADÉ. These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. Risks and uncertainties that may cause actual results to differ materially include uncertainties inherent in the conduct of clinical trials, Aclaris' reliance on third parties over which it may not always have full control, and other risks and uncertainties that are described in the Risk Factors section of Aclaris' Annual Report on Form 10-K for the year ended December 31, 2018, and other filings Aclaris makes with the U.S. Securities and Exchange Commission from time to time. These documents are available under the "SEC filings" section of the Investors page of Aclaris' website at <http://www.aclaristx.com>. Any forward-looking statements speak only as of the date of this presentation and are based on information available to Aclaris as of the date of this presentation, and Aclaris assumes no obligation to, and does not intend to, update any forward-looking statements, whether as a result of new information, future events or otherwise.

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.

Corporate Strategy: Building a Fully-Integrated Biopharmaceutical Company



LEADERSHIP

- Physician-founded
- Key leadership with track record of executing across multiple development and commercial stage companies
- Kinome experts - chemists and biologists; combined 300+ years of drug discovery experience

Leverage core expertise in drug development and kinase inhibition to develop small molecule therapeutics



12 ACTIVE
CLINICAL TRIALS



2 FDA-APPROVED
MEDICINES



KINect™ PLATFORM
Proprietary discovery engine

Pipeline

Program	Indication(s)	Preclinical	Phase 1	Phase 2	Phase 3	
A-101(45%) <i>Topical</i>	Common Warts	▶				
ATI-502 JAK1/JAK3 Inhibitor <i>Topical</i>	Alopecia Areata	▶				
	Vitiligo	▶				
	Androgenetic Alopecia	▶				
	Atopic Dermatitis	▶				
ATI-501 JAK1/JAK3 Inhibitor <i>Oral</i>	Alopecia Areata	▶				
ATI-450 MK2 Pathway Inhibitor <i>Oral</i>	RA, Psoriasis, Hidradenitis Suppurativa, CAPS, Pyoderma Gangrenosum, Other	▶				
ATI-1777 JAK1/JAK3 Inhibitor <i>Soft Topical</i>	Atopic dermatitis, Vitiligo, Alopecia Areata	▶				
ITK/JAK3 Inhibitor <i>Soft Topical</i>	Psoriasis, Inflammatory Dermatoses	▶				
ITK/JAK3 Inhibitor <i>Oral</i>	Psoriasis, Inflammatory Dermatoses	▶				
ITK/JAK3 Inhibitor <i>Oral, gut-restricted</i>	Ulcerative colitis / Crohn's Disease	▶				
MK2 Pathway Inhibitor <i>Oral</i>	Oncology	▶				

RA = rheumatoid arthritis, CAPS = cryopyrin-associated periodic syndromes

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Conditions with Significant Treatment Gaps

SEBORRHEIC KERATOSIS (SK)

83+MM people in U.S.*1

ESKATA® (hydrogen peroxide) topical solution, 40% (w/w), first FDA-approved topical treatment for raised SKs in adults



ALOPECIA AREATA (AA)

5-7MM people in U.S.

have or will develop AA^{2,7}
Currently available Rx treatment options often used off-label and have significant limitations⁷



VERRUCA VULGARIS (COMMON WARTS)

19-22MM people in U.S.^{2,3}

Currently available treatments have modest therapeutic effect and significant limitations⁴



ANDROGENETIC ALOPECIA (MALE / FEMALE PATTERN HAIR LOSS)

~50MM men / ~30MM women

in U.S. affected by AGA hair loss⁸



VITILIGO

1-2% of global population impacted⁵

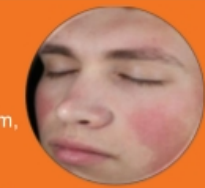
No FDA-approved medication to repigment the skin⁵



ROSACEA

16+MM people in U.S.⁹

RHOFADE® (oxymetazoline hydrochloride) cream, 1% FDA-approved for the topical treatment of persistent facial erythema (redness) associated with rosacea in adults, a symptom experienced in about 71% of patients with rosacea⁹



*Includes all types of SKs ¹Bickers et al. The Burden of Skin Disease. *J Am Acad Dermatology*. 2006;55:490-500. ²Data on file, Aclaris Therapeutics, Inc. ³Nguyen et al. Laser Treatment of Nongenital Verrucae A Systematic Review. *JAMA Dermatology*. 2016;152(9):1025-1033. ⁴Kwok et al. Topical treatments for cutaneous warts (Review). *Cochrane Database of Systematic Reviews*. 2012. Art. No.: CD001781. ⁵Fitzpatrick T, et al. <http://www.avrf.org/facts/frequently-asked-questions.html>. Last accessed March 30, 2019. ⁶<https://www.asdreports.com/news-217/vitiligo-therapeutics-market-expected-show-moderate-growth-up-2019>. Last accessed March 30, 2019. ⁷National Alopecia Areata Foundation. <https://www.naaf.org/alopecia-areata>. Last accessed March 30, 2019. ⁸National Institute of Health Androgenetic Alopecia. <https://ghr.nlm.nih.gov/condition/androgenetic-alopecia#statistics>. Last accessed March 30, 2019. ⁹National Rosacea Society. <https://www.rosacea.org/rosacea-review/2010/summer/new-survey-uncovers-wide-range-of-potential-signs-and-symptoms>. Last accessed on March 30, 2019.

COMMERCIAL PORTFOLIO

RHOFADE[®] (oxymetazoline HCl) cream, 1%

ESKATA[®] (hydrogen peroxide) topical solution, 40% (w/w)



RHOFADE Cream

Rhofade
(oxymetazoline HCl)
cream, 1%

ABOUT RHOFADE CREAM

RHOFADE cream reduced persistent facial redness due to rosacea in adults all day, through 12 hours on day 29.¹

BEFORE **AFTER**

Illustration only. On day 29, results seen in 12%–18% of people using RHOFADE cream vs 5%–9% of people using vehicle cream. Individual results may vary.

TAKE THE NEXT STEP

Find a dermatologist, savings, and condition information.

INDICATION
RHOFADE cream is indicated for the topical treatment of persistent facial erythema associated with rosacea in adults.

IMPORTANT SAFETY INFORMATION AND WARNINGS

WARNINGS AND PRECAUTIONS

Potential Impacts on Cardiovascular Disease

Alpha-adrenergic agonists may impact blood pressure. RHOFADE cream should be used with caution in patients with severe or unstable or uncontrolled cardiovascular disease, orthostatic hypotension, and uncontrolled hypertension or hypotension. Advise patients with cardiovascular disease, orthostatic hypotension, and/or uncontrolled hypertension/hypotension to seek immediate medical care if their condition worsens.

- National Rosacea Society estimates more than 16 million Americans are affected by rosacea¹
- Persistent facial redness is the most common sign or symptom of rosacea, experienced in about 71% of rosacea patients according to a survey conducted by this same Society¹
- RHOFADE Growth Opportunity:
 - Increase prescribing by current RHOFADE prescribers
 - Recapture lost share from HCPs who decreased their prescribing in 2018
 - Capitalize on untapped potential within rosacea-treating HCPs who are not yet prescribing a medication to treat PFE

¹National Rosacea Society, <https://www.rosacea.org/rosacea-review/2010/summer/new-survey-uncovers-wide-range-of-potential-signs-and-symptoms>. Last accessed on March 30, 2019.

83+MM People in the US with SK¹

18+MM visits to Derm for SK²

8+MM SK treatments²

Reasons for Not Removing SKs Include³:

- High risk of **scarring**
- High risk of **hypopigmentation**
- Want to avoid **cutting, freezing or burning**
- Moved to second position in the detail schedule
- Sales team focused on top 10 ESKATA accounts based on productivity in each territory, with the objective of increasing utilization
- Received recent European approvals for ESKATA / ESKERIELE and in active discussions with potential commercial partners



*Includes all types of SKs ¹Bickers et al. The Burden of Skin Disease. *J Am Acad Dermatology*. 2006;55:490-500. ²Data on File. Aclaris Therapeutics, Inc. Burke Screener of 594 dermatologists. 2014. ³Data on File. Aclaris Therapeutics, Inc. In-Office SK Treatment Study. Final Report. 2016.

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A-101 (hydrogen peroxide)
45% Topical Solution
Phase 3 Candidate For
Common Warts



Common Warts - Patient/Physician Surveys



People with Common Warts in the US

19–22 M^{1,2}



61%

treated by
**Primary Care
Physicians**
(2.5 avg. visits)¹

39%

treated by
Dermatologists
(2.6 avg. visits)
31% of pts are referrals¹

- 50% of all patient visits for warts are for common warts³
- 3x more patient visits than genital warts³
- 50% of patients report moderate to extreme discomfort⁴
- 39% of patients say warts impact social/leisure activities⁴
- Unmet Needs¹:
 - Would prefer pain-free treatments which work faster and do not have unwanted side effects

¹Data on file, Aclaris Therapeutics, Inc.

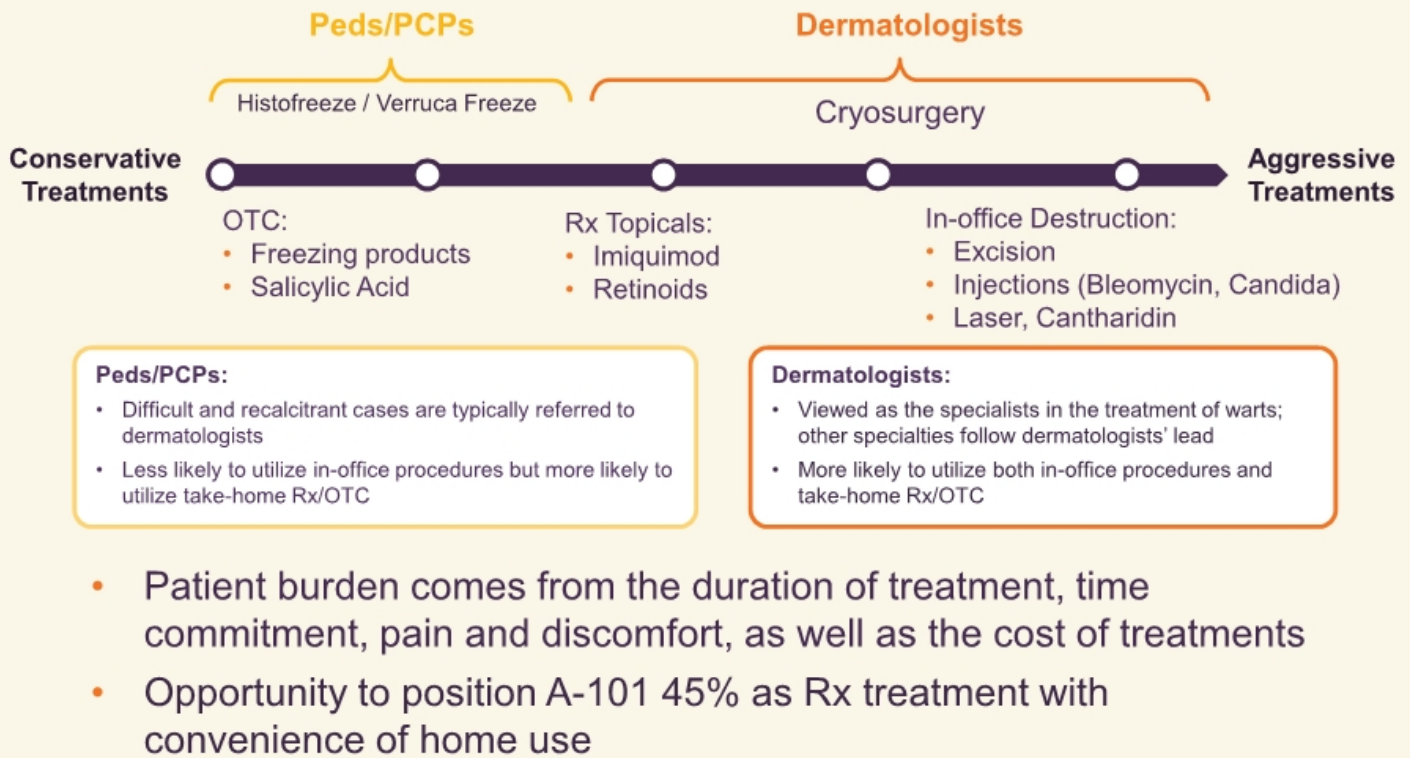
²Nguyen et al. Laser Treatment of Nongenital Verrucae A Systematic Review. *JAMA Dermatology*. 2016;152(9):1025-1033.

³IMS National Disease and Therapeutic Index 2016.

⁴Lipke M., An Armamentarium of Wart Treatments, *Clinical Medicine & Research*, 4:4, 2006; 273–293.

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Common Warts: Treatment Paradigm



Source: Burke Market Research, January 2016

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Summary of WART-203 Phase 2 Trial Results

Trial	Trial Design	Trial Outcome
WART-203 (N=159)	<ul style="list-style-type: none">• A randomized, double-blind, vehicle-controlled, parallel-group study of investigational drug A-101 45% topical solution in subjects with 1-6 common warts• Self-treated twice weekly for a total of 16 treatments	<ul style="list-style-type: none">• Efficacy: Statistically significant results on all primary and secondary endpoints• Favorable safety profile

Primary Endpoint:

- Mean change from baseline in the Physician's Wart Assessment (PWA)TM score on target wart at day 56 (visit 10) using an analysis of covariance.

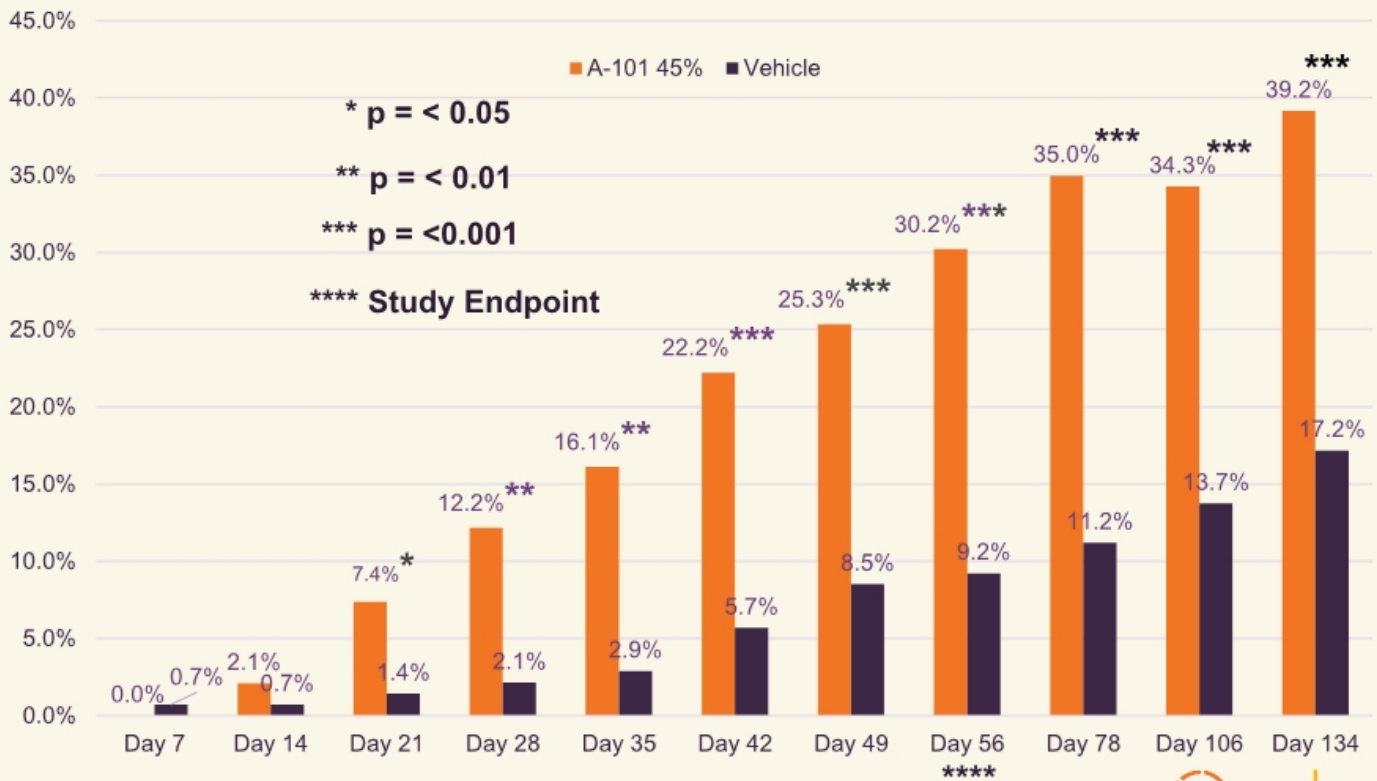
Secondary Endpoints:

- The proportion of subjects whose target wart is judged to be clear (PWA=0) at day 56.
- The proportion of subjects with all treated wart(s) clear, stratified by baseline number of warts at day 56.
- The percentage of all treated warts that were clear at day 56.

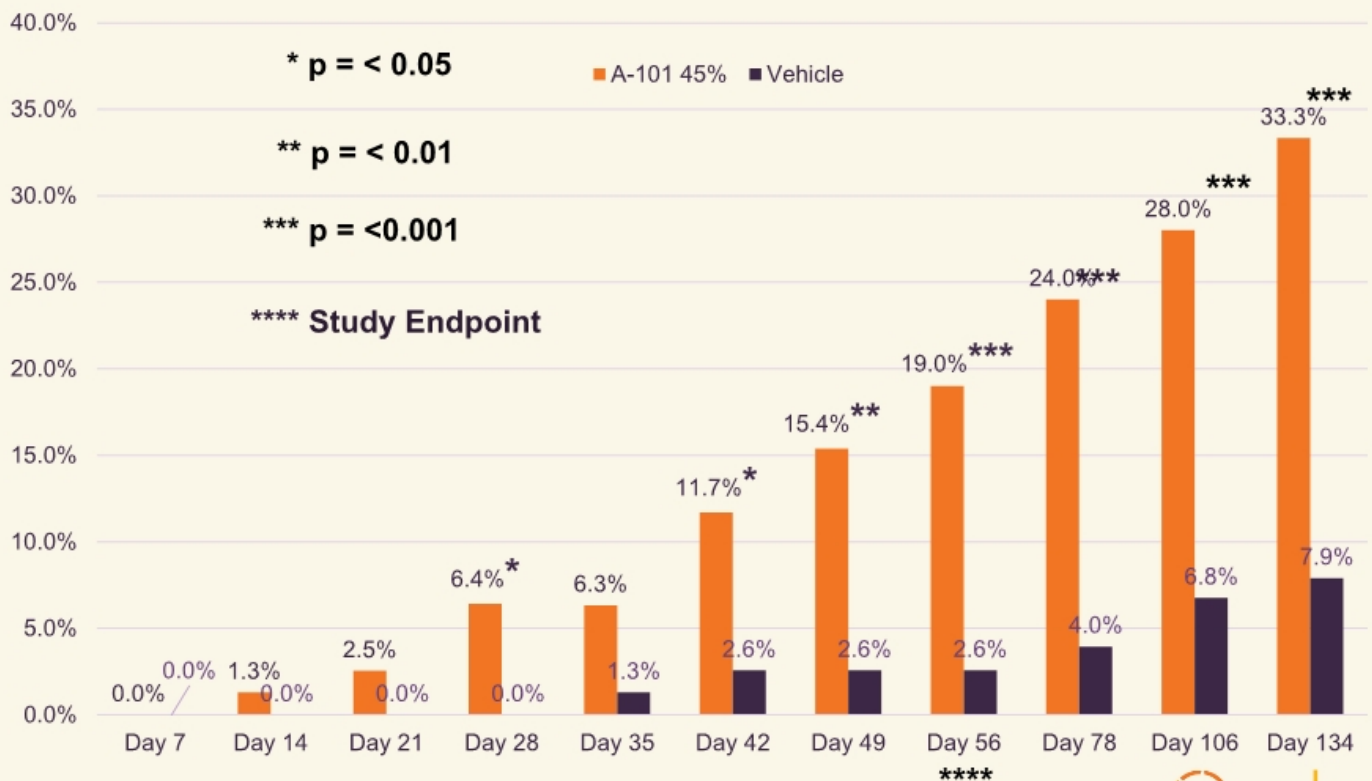
Current Status

- Phase 3 Data expected 2H19.

WART-203: The Percentage of All Treated Warts that are Clear on the PWA for Each Post-baseline Visit (N=159)



WART-203: Proportion of Subjects with all treated Wart(s) (1-6) Clear, Stratified by Baseline Number of Warts, at each Post-Baseline Visit (N=159)



Inflammation and Immunology Platform

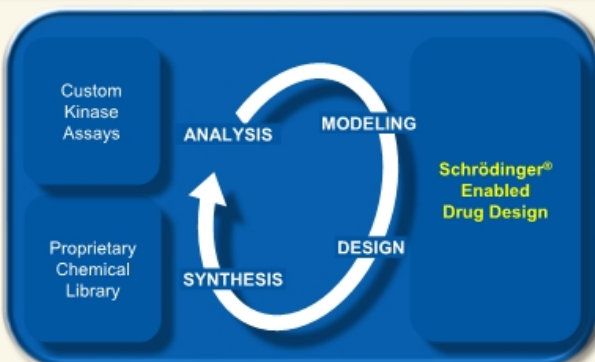
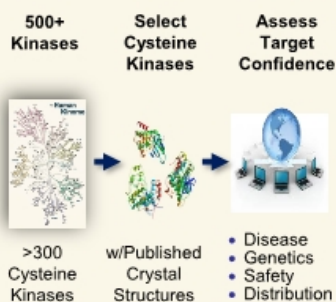


KINect™ Platform – Developing Better Kinase Drug Candidates Rapidly & Efficiently

TARGET SELECTION & VALIDATION

KINect™ Platform – LEAD GENERATION

ASSET GENERATION



Proprietary Portfolio

- Project 1
- Project 2
- Project 3

Strategic Partner(s)

- Project 1
- Project 2
- Project 3

Leveraging key opinion leaders, data in public domain and internal validation

High affinity/selective drug scaffolds more rapid target to candidate selection

PEOPLE

- Co-inventors of tofacitinib and former leaders of Pfizer kinase program (including JAK inhibitors)
- Kinome experts - chemists and biologists; combined 300+ years of drug discovery experience
- Significant experience in small molecule drug discovery through Phase 2

The Kinase Opportunity: Rational Targeted Drug Discovery

Creating New Medicines Targeting Previously Inaccessible Parts of the Kinome

KINect™ Technology Platform

Proprietary chemical library and integrated capabilities for interrogating the Kinome

- Solves challenges encountered in the class
 - Selectivity
 - Biochemical efficiency
- Validity of targeting kinases is commercially established
- Plethora of validated kinase targets are inadequately drugged
- KINect™ platform allows rational targeting of validated kinase targets

Kinase Drugs Represented \$240B in Aggregate Global Sales from 2011-2015¹



500 member class, representing 2% of the human genome

¹ https://www.nature.com/nrd/posters/druggablegenome/nrd_druggablegenome.pdf. Last Accessed March 30, 2019
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Portfolio and IP Estate:

ATI-501 (oral) and ATI-502 (topical) – Selective JAK 1/3 inhibitor

Additional topical JAK inhibitors in development

- Known MOA and observed biological response in humans
- Promoted hair regrowth in mouse model¹
- Broad IP estate - Methods of use covering JAK inhibitors for the treatment of:
 - Alopecia areata
 - Androgenetic alopecia (male and female pattern hair loss)

ATI-501 JAK1/JAK3 inhibitors

Oral treatment for alopecia totalis and alopecia universalis

ATI-502 JAK1/JAK3 inhibitors

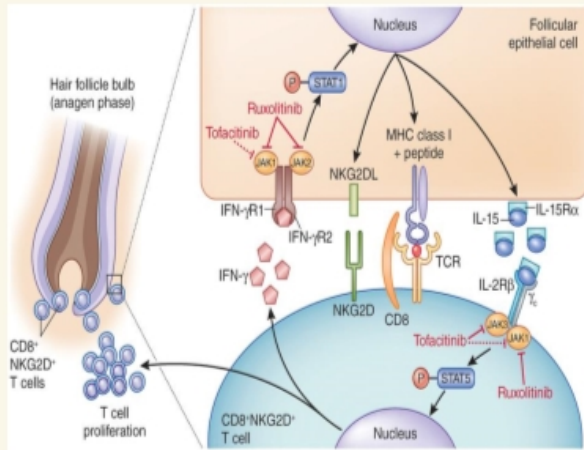
Topical treatment for hair loss disorders: patchy alopecia areata and androgenetic alopecia

ATI-1777 JAK1/JAK3 inhibitors

“Soft Topical” treatment for atopic dermatitis, alopecia areata, and vitiligo

¹ Data on File. Aclaris Therapeutics, Inc.

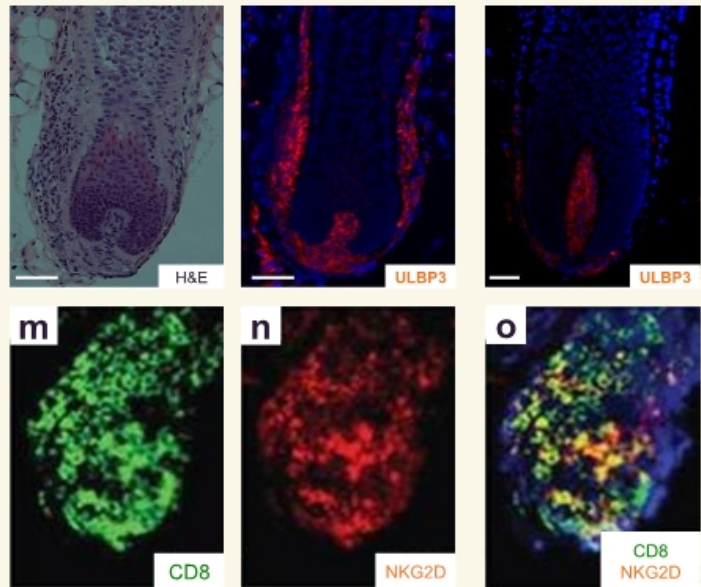
Mechanism of JAK Inhibitors in Alopecia Areata



Divito & Kupper, Nature Medicine 20, 989–990 (2014).

HF of an AA patient

Control Individual



Christiano Laboratory, Columbia University

ATI-502-AUATB-201 – Topical Proof of Concept

Baseline

Follow up

33/M



(250 Days on Drug)

23/F



(268 Days on Drug)

45/F



(250 Days on Drug with a 47 day gap)

*Hair regrowth continues in 3 of the 5 patients who were on drug longer than 6 months

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Alopecia Areata - Patient/Physician Surveys



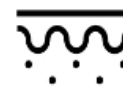
Patients with Alopecia Areata in the US

5-7 M¹²



42%

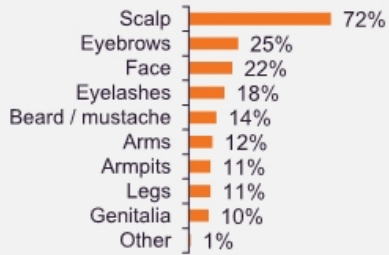
treated by
**Primary Care
Physicians**
(6.7 avg. visits)¹



54%

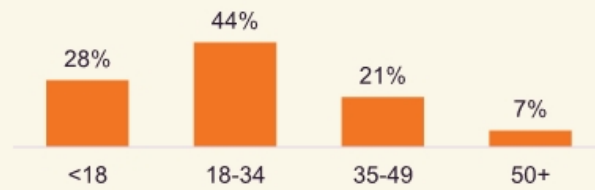
treated by
Dermatologists
(7.1 avg. visits)
43% of pts are referrals¹

COMMON BODY LOCATIONS¹



AGE & OTHER DEMOGRAPHICS¹

Average age = 25.7 years



¹Data on file, Aclaris Therapeutics, Inc.

²National Alopecia Areata Foundation. <https://www.naaf.org/alopecia-areata>.

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Spectrum of Hair Loss

24%



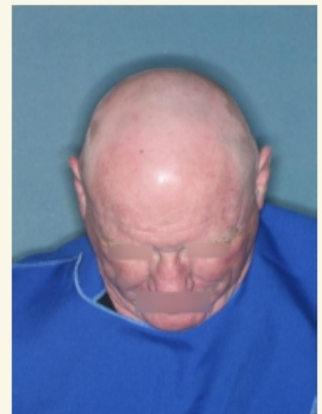
34%



43%



51%

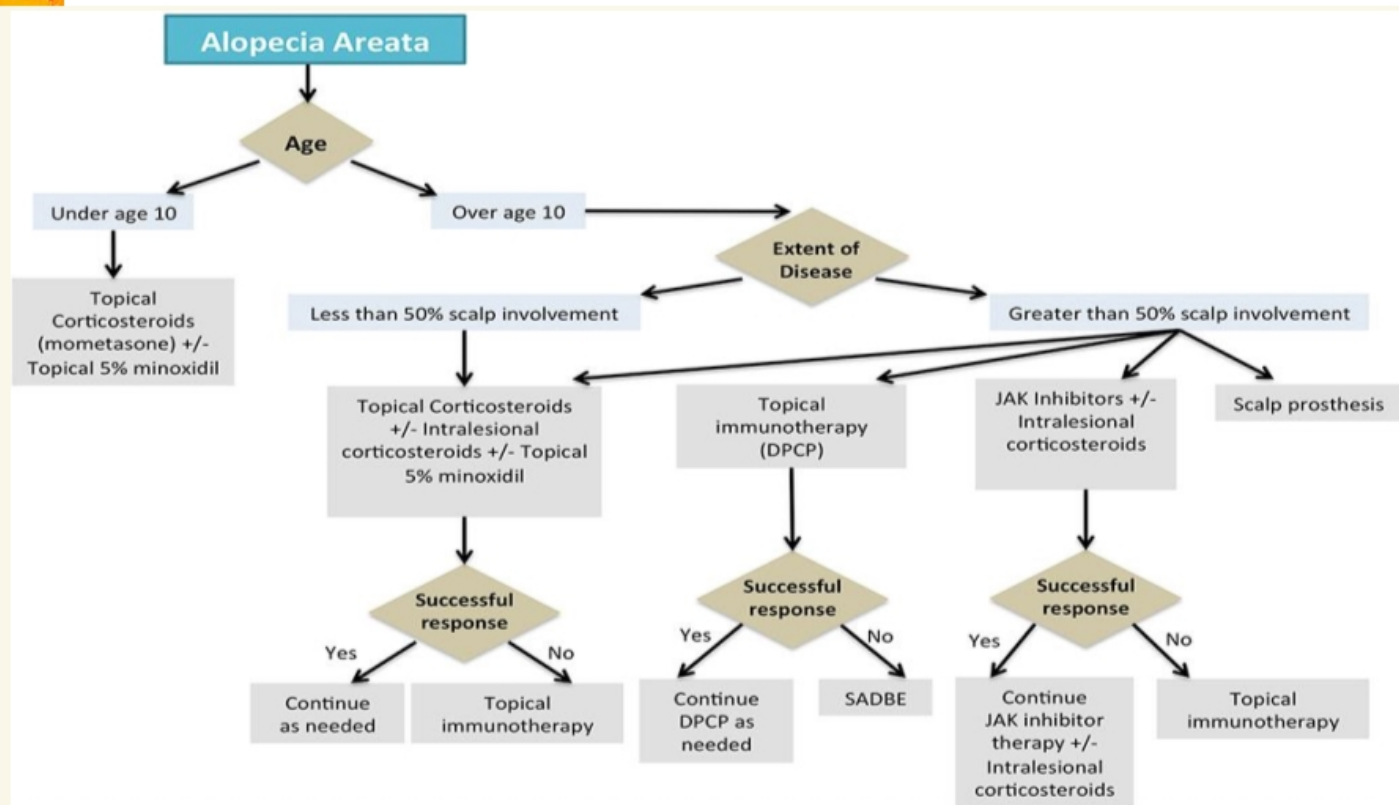


100%

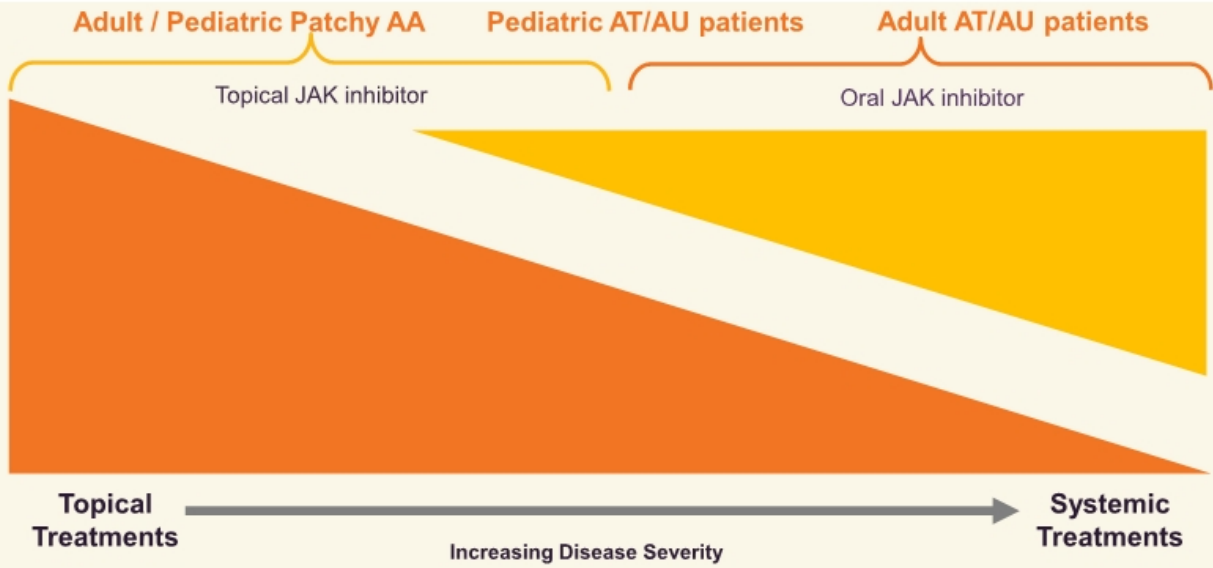


- 25-52% of patients have persistent patchy AA¹
- 14-25% of patients progress to alopecia totalis or universalis¹

Current treatment paradigm



Alopecia Areata: Potential Treatment Paradigms



INDUCTION:

Topical JAK inhibitor may be efficacious in patients with less severe patchy AA
Oral JAK inhibitor may be best option in patients with more severe AT/AU phenotypes

MAINTENANCE:

AT/AU patients may be able to maintain hair with topical JAK inhibitor
Concomitant topical therapy may decrease reliance on longer term oral therapy in some patients

Androgenetic Alopecia (AGA)



Androgenetic Alopecia (AGA): Male/Female pattern hair loss

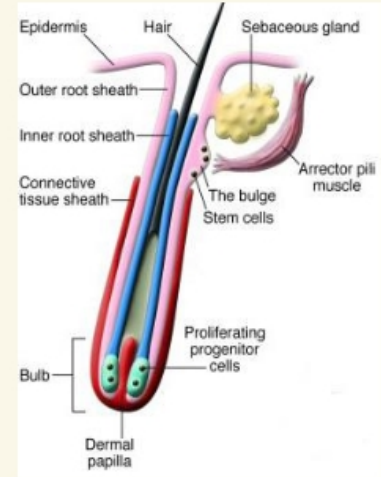
- AGA is a genetic disorder and the most common cause of hair loss¹
- Experienced by 70% of men and 40% of women at some point in their lives¹; affects ~50 million men and ~30 million women in the US²
- Affected individuals highly motivated to seek treatment¹
- Potential benefits of topical JAK inhibitor in AGA:
 - ✓ New mechanism of action
 - ✓ Minimal systemic side effects
 - ✓ Non-hormonal
 - ✓ Novel option women with AGA



Male with AGA



Female with AGA



Cotsarelis, J Clin Invest. 2006;116(1):19-22.

¹ McElwee J., et al. Promising Therapies for Treating and/or Preventing Androgenic Alopecia. Medscape. 2012

² National Institute of Health Androgenetic Alopecia. <https://ghr.nlm.nih.gov/condition/androgenetic-alopecia#statistics>. Last accessed March 30, 2019.

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ATI-450 (MK2 Inhibitor)



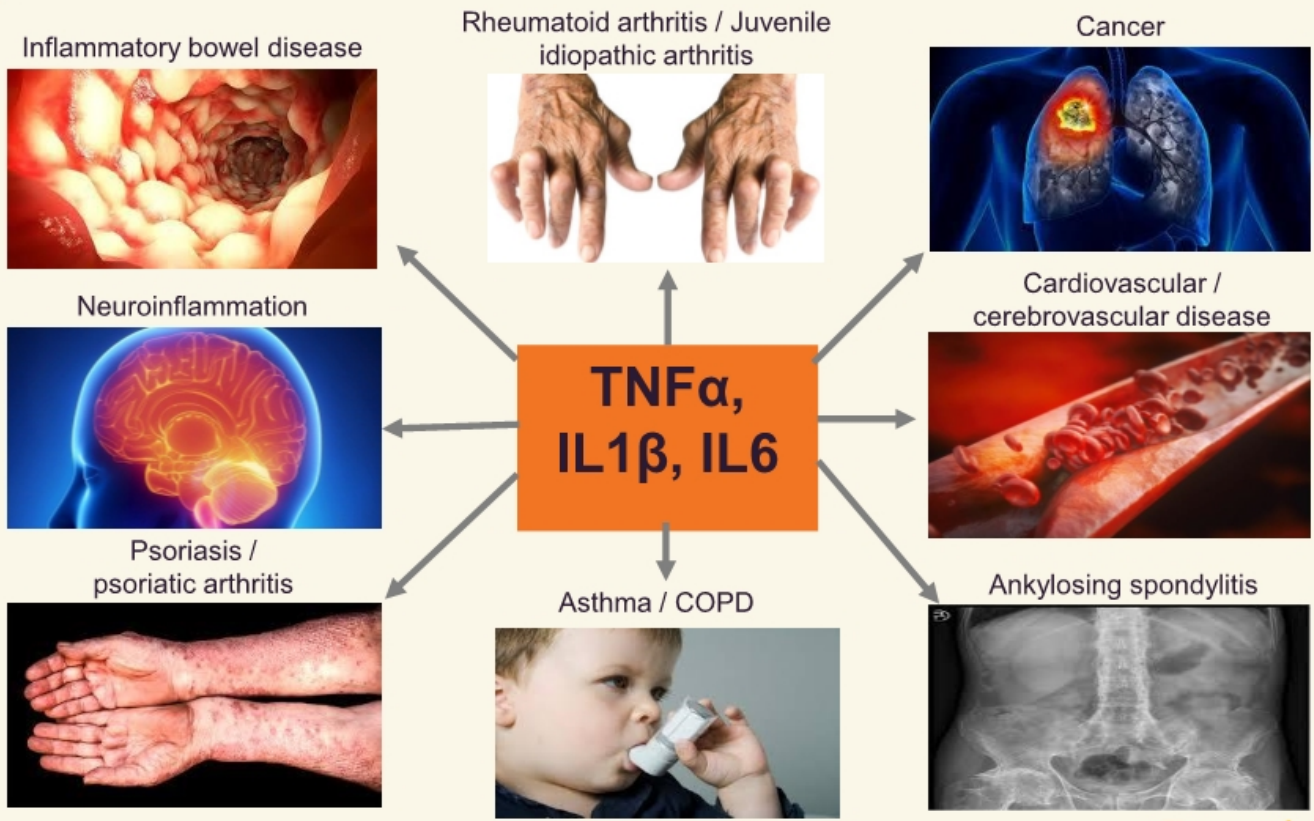
MK2 Pathway Inhibitor (MK2 PI) ATI-450

- Pharmacologically unique MOA
- MK2 pathway inhibitors target the production and activity of key inflammatory cytokines including TNF α , IL-1 α , IL-1 β and IL-6
- ATI-450 inhibits the cytokine targets of established biologics:
 - Anti-TNFs: Humira[®], Enbrel[®], Remicade[®]
 - RA, psoriasis, psoriatic arthritis, IBD, ankylosing spondylitis
 - Anti-IL1s: Kineret[®], Ilaris[®], Arcalyst[®]
 - CAPS, Still's disease, SJIA, cardiovascular disease
 - Anti-IL6: Kevzara[®], Actemra[®]
 - RA, Castleman's disease
- Aclaris is developing MK2 pathway inhibitors for chronic inflammatory disease and autoimmune disease

MK2 = mitogen-activated protein kinase-activated protein kinase 2 (MAPKAPK2)

RA = rheumatoid arthritis; IBD = inflammatory bowel disease; SJIA = systemic juvenile idiopathic arthritis

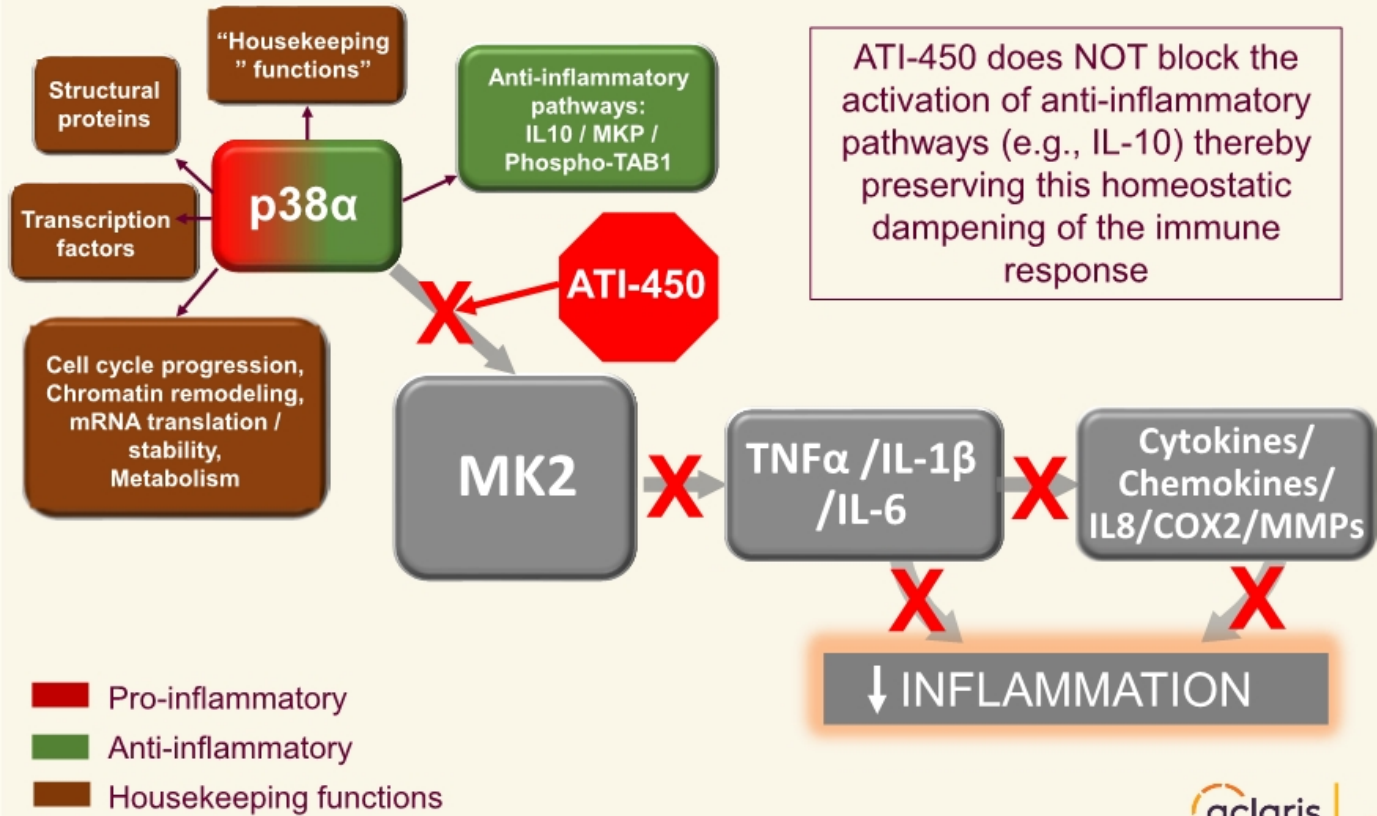
MK2-driven cytokines are central to many diseases



Singh RK, et al. *Pharmacol Reports*. 2017; 69:746-756.

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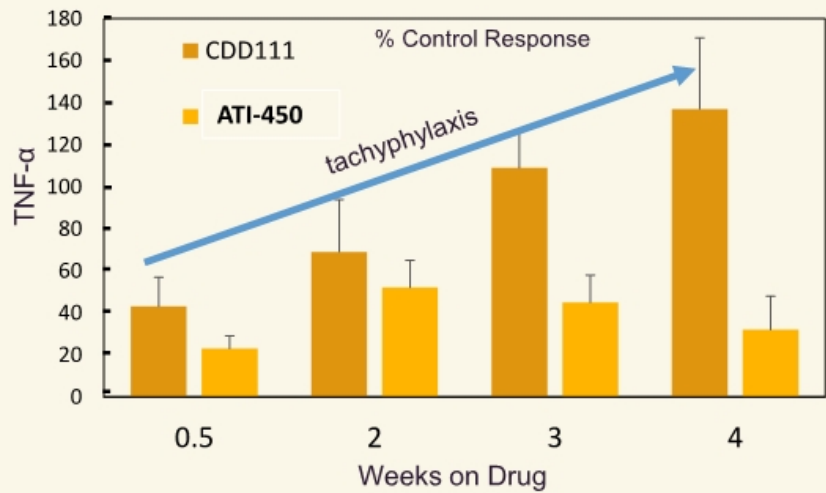
ATI-450 Inhibits the Expression of Key Inflammatory Cytokines: TNF α , IL-1 β and IL-6



Mouse LPS-Induced TNF α Production

ATI-450 demonstrated durable response (no tachyphylaxis)

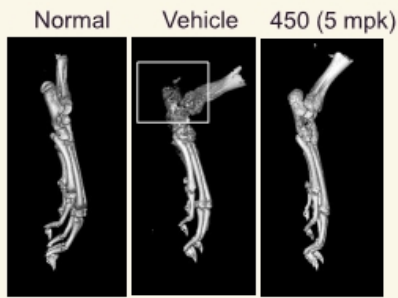
- Global p38 inhibitor CDD-111 lost inhibition over time
- **This investigational MK2 pathway inhibitor ATI-450 demonstrated durable responses in this model (no tachyphylaxis)**



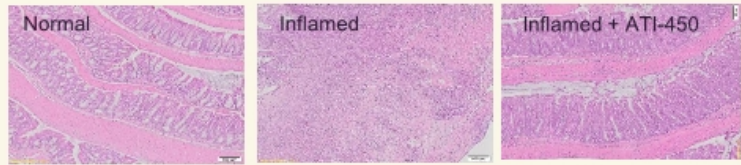
- Conventional p38 (CDD-111) and MK2PI (ATI-450) administered to mice in feed starting day 1 and continuing through day 28
- At the time point indicated, mice were LPS challenged and blood TNF α levels determined

In vivo Results of MK2 Pathway Inhibitor ATI-450

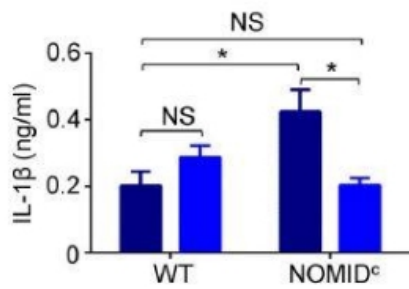
Joint Protection in Rat Arthritis Model¹



Blockade of Gut Inflammatory Infiltrate in Murine Adoptive Transfer Ulcerative Colitis Model³

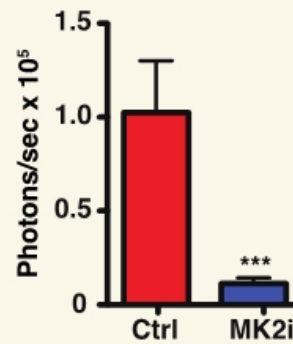


Cytokine Modulation in Orphan Autoinflammatory Disease (CAPS)¹



Reduction in Breast Cancer Bone Metastasis in Mice²

Bone Metastasis

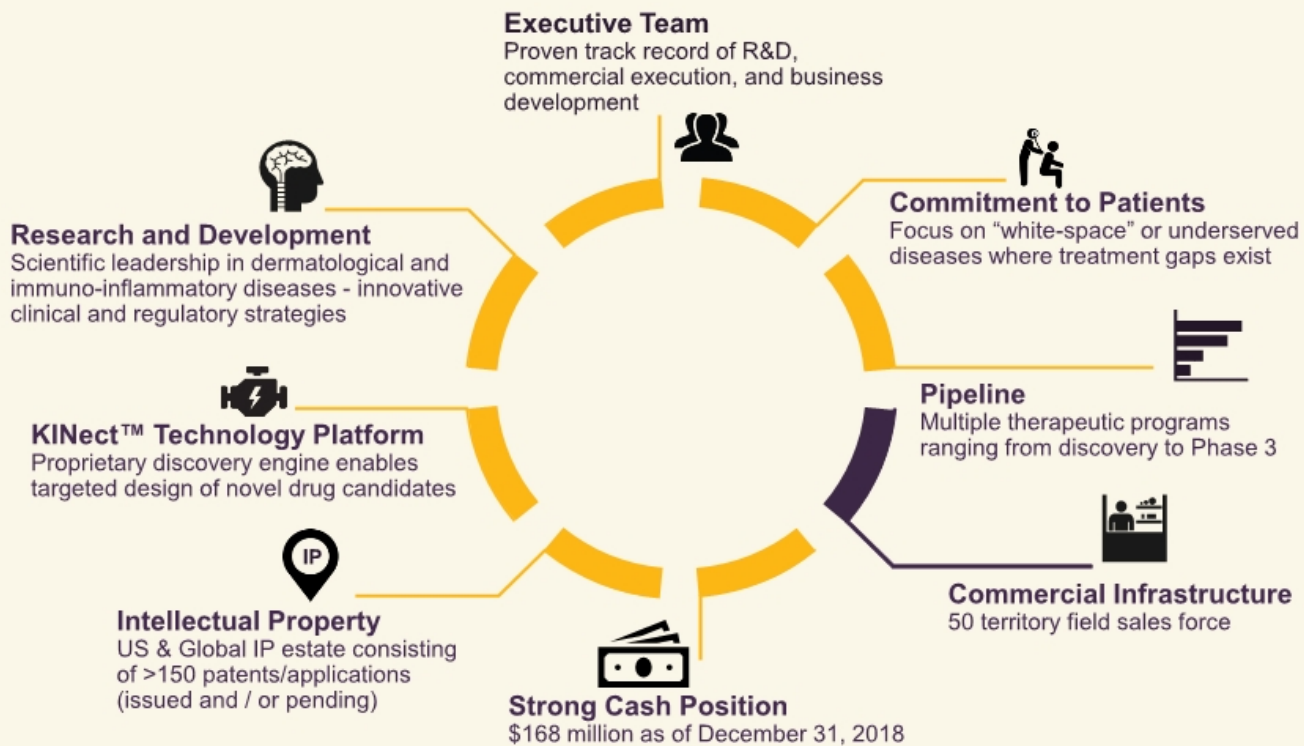


¹ Wang C, et al. J Exp Med. 2019;215(5):1315-1325.

² Murali B, et al. Cancer Res. 2019;79(19):5618-5630.

³ Data on File. Aclaris Therapeutics, Inc.

Fully Integrated Biopharmaceutical Company



Milestone	2019				2020			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
A-101 45% Common Warts								
Phase 3 Data								
Submit NDA								
ATI-501/ATI-502 (Oral/Topical JAK Inhibitor)								
ATI-501 - Phase 2 AT/AU Dose Range Data								
ATI-501 - AT/AU End of Phase 2 FDA mtg								
ATI-502 - Phase 2 Patchy AA Dose Range Data								
ATI-502 – Initiate Phase 3 Patchy AA Trial								
ATI-502 - Phase 2 Open Label Vitiligo Data ¹								
ATI-502 - Phase 2 Open Label AGA Data ²								
ATI-502 - Initiate Phase 2B AGA Trial								
ATI-502 - Phase 2 Open Label Atopic Dermatitis Data								
Inflammation / Immunology								
ATI-450 (MK2 Inhibitor) - Submit IND								
ATI-450 (MK2 Inhibitor) - Initiate Phase 1/2A Trials								
ATI-450 (MK2 Inhibitor) - Phase 1/2A Data								
ATI-1777 (Soft JAK) – Submit IND								
ATI-1777 (Soft JAK) - Initiate Phase 1/2A Trials								

¹ VITI-201: 6-month data interim expected second quarter of 2019; 12-month data expected fourth quarter of 2019

² AGA-201: 6-month data expected second quarter of 2019; 12-month data expected fourth quarter of 2019

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THANK YOU



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