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): June 5, 2019

Aclaris Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-37581**	**46-0571712**
(State or other jurisdiction of incorporation)	(Commission File Number)	(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))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.00001 par value	ACRS	The Nasdaq Stock Market, LLC

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 June 5, 2019, management of Aclaris Therapeutics, Inc. (the "***Company***") will present a company overview at the Jefferies 2019 Global Healthcare Conference at 3:30 PM ET at the Grand Hyatt Hotel in New York, New York. The presentation 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

Exhibit Number	Exhibit Description
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.

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

Date: June 5, 2019

EMPOWERING PATIENTS THROUGH
REVELATIONARY
SCIENCE

Company Overview

Dr. Neal Walker
President and CEO
June 2019

aclaris THERAPEUTICS

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 RHOFADE. 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

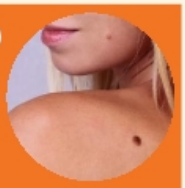
Program	Indication(s)	Preclinical	Phase 1	Phase 2	Phase 3
A-101(45%) *Topical*	Common Warts				
ATI-502 JAK1/JAK3 Inhibitor *Topical*	Alopecia Areata				
	Vitiligo				
	Androgenetic Alopecia				
	Atopic Dermatitis				
ATI-501 JAK1/JAK3 Inhibitor *Oral*	Alopecia Areata				
ATI-450 MK2 Pathway Inhibitor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

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

aclaris THERAPEUTICS

Conditions with Significant Treatment Gaps

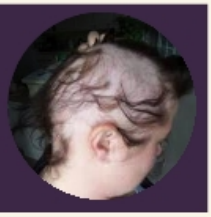
SEBORRHEIC KERATOSIS (SK)



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

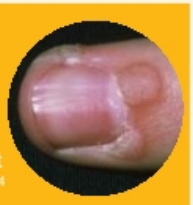
ALOPECIA AREATA (AA)



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 limitations[7]

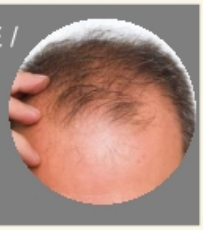
VERRUCA VULGARIS (COMMON WARTS)



19-22MM people in U.S.[2,3]

Currently available treatments have modest therapeutic effect and significant limitations[4]

ANDROGENETIC ALOPECIA (MALE / FEMALE PATTERN HAIR LOSS)



~50MM men / ~30MM women

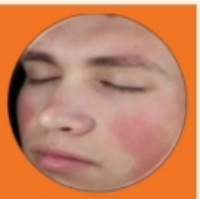
in U.S. affected by AGA hair loss[8]

VITILIGO

1-2% of global population impacted[5]

No FDA-approved medication to repigment the skin[6]

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 rosacea[9]

*Includes all types of SKs [1]Bickers et al. The Burden of Skin Disease. *J Am Acad Dermatology*. 2006;55:490-500.[2]Data on file, Aclaris Therapeutics, Inc. [3]Nguyen et al. Laser Treatment of Nongenital Verrucae A Systematic Review. *JAMA Dermatology*. 2016;152(9):1025-1033.[4]Kwok et al. Topical treatments for cutaneous warts (Review). Cochrane Database of Systematic Reviews.2012. Art. No.: CD001781. [5]Fitzpatrick 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. [7]National Alopecia Areata Foundation. https://www.naaf.org/alopecia-areata. Last accessed March 30, 2019.[8]National Institute of Health Androgenetic Alopecia. https://ghr.nlm.nih.gov/condition/androgenetic-alopecia#statistics. Last accessed March 30, 2019. [9]National 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.

aclaris THERAPEUTICS

COMMERCIAL PORTFOLIO

RHOFADE® (oxymetazoline HCl) cream, 1%
ESKATA® (hydrogen peroxide) topical solution, 40% (w/w)

aclaris THERAPEUTICS

RHOFADE Cream

- National Rosacea Society estimates more than 16 million Americans are affected by rosacea[1]
- Persistent facial erythema (PFE) is the most common sign or symptom of rosacea, experienced in about 71% of rosacea patients according to a survey conducted by this same Society[1]
- 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

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.

The most common side effects of RHOFADE® Cream include application-site reactions of: skin reactions (dermatitis), worsening of rosacea pimples, itching, redness, and pain.

[1]National 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.

aclaris THERAPEUTICS

Core Intellectual Property: RHOFADE

- **Three-year CI market exclusivity until January 18, 2020**
- **Five Orange Book Patents**
  - **USP No. 7,812,049 (Exp 5/2/28 with 1562 days PTA)**
    - Method of treating erythema resulting from rosacea comprising administering topically a composition comprising about 0.05-30% of oxymetazoline as the sole active agent
    - Exclusively licensed from Allergan
  - **USP No. 8,420,688 (Exp 8/02/24 with 193 days PTA)**
    - Same as '049, but recites "therapeutically effective amount" of oxymetazoline
    - Exclusively licensed from Allergan
  - **USP No. 8,815,929 (Expires: 1/22/24)**
    - Same as '688, but recites oxymetazoline and other alpha-1 agonists
    - Exclusively licensed from Allergan
  - **USP No. 8,883,838 (Exp 12/1/31)**
    - A cream composition with certain % of oxymetazoline, % of certain emollient/emulsifier/excip/ etc. (the stabilized cream)
  - **USP No. 9,974,773 (Exp 6/11/35)**
    - Method of treating facial erythema associated with rosacea comprising topically administering once daily to the site of erythema on the face of the patient a pharmaceutical composition comprising 1.0% or 1.5% w/w oxymetazoline HCl thereof as the sole active ingredient
- **Pending applications**
  - Families related to Orange Book listed patents have pending applications in the U.S.
  - Pending applications are directed to, for example, methods of treating facial erythema using 1.0% oxymetazoline administered once daily; cream formulations of oxymetazoline; method of treating erythema, telangiectasia or inflammatory lesions associated with rosacea comprising topically administering formulations of oxymetazoline
  - Corresponding pending/issued applications in major international jurisdictions

ESKATA

83+MM People in the US with SK*[1]

18+MM visits to Derm for SK[2]

8+MM SK treatments[2]

Reasons for Not Removing SKs Include[3]:

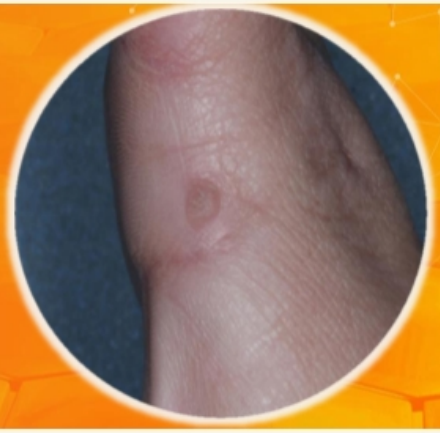
- High risk of **scarring**
- High risk of **hypopigmentation**
- Want to avoid **cutting, freezing** or **burning**

- Moved to second position in the detail schedule
- Sales team focused on top 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 [1]Bickers et al. The Burden of Skin Disease. *J Am Acad Dermatology*. 2006;55:490-500. [2]Data on File. Aclaris Therapeutics, Inc. Burke Screener of 594 dermatologists. 2014. [3]Data on File. Aclaris Therapeutics, Inc. In-Office SK Treatment Study. Final Report. 2016.

aclaris THERAPEUTICS

A-101 (hydrogen peroxide) 45% Topical Solution (Investigational Drug Candidate) - Phase 3 for the Treatment of Common Warts

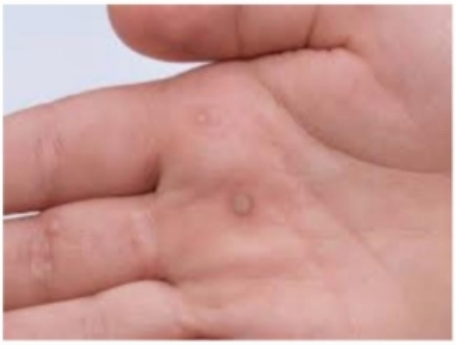


aclaris THERAPEUTICS

Common Warts - Patient/Physician Surveys

People with Common Warts in the US

19–22 MM[1,2]



61% treated by **Primary Care Physicians** (2.5 avg. visits)[1]

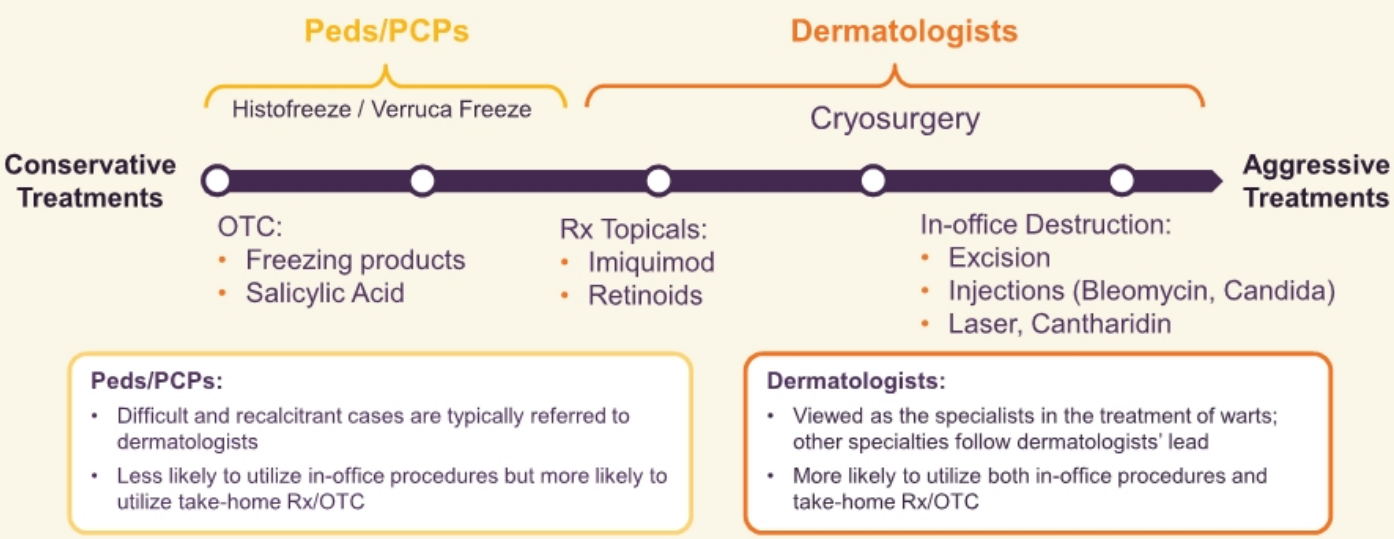
39% treated by **Dermatologists** (2.6 avg. visits) 31% of pts are referrals[1]

- 50% of all patient visits for warts are for common warts[3]
- 3x more patient visits than genital warts[3]
- 50% of patients report moderate to extreme discomfort[4]
- 39% of patients say warts impact social/leisure activities[4]
- Unmet Needs[1]:
  - Would prefer pain-free treatments which work faster and do not have unwanted side effects

[1]Data on file, Aclaris Therapeutics, Inc.
[2]Nguyen et al. Laser Treatment of Nongenital Verrucae A Systematic Review. *JAMA Dermatology*. 2016;152(9):1025-1033.
[3] IMS National Disease and Therapeutic Index 2016.
[4] Lipke M., An Armamentarium of Wart Treatments, *Clinical Medicine & Research*,4:4, 2006; 273–293.

aclaris THERAPEUTICS

Common Warts: Treatment Paradigm



Peds/PCPs:

- Difficult and recalcitrant cases are typically referred to dermatologists
- Less likely to utilize in-office procedures but more likely to utilize take-home Rx/OTC

Dermatologists:

- Viewed as the specialists in the treatment of warts; other specialties follow dermatologists' lead
- More likely to utilize both in-office procedures and take-home Rx/OTC

- Patient burden comes from the duration of treatment, time commitment, pain and discomfort, as well as the cost of treatments
- Opportunity to position A-101 45% as Rx treatment with convenience of home use

Source: Burke Market Research, January 2016

aclaris THERAPEUTICS

Summary of WART-203 Phase 2 Trial Results

Trial	Trial Design	Trial Outcome
WART–203 (N=159)	• 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	• 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)™ score on target wart at day 56 (visit 10) using an analysis of covariance.

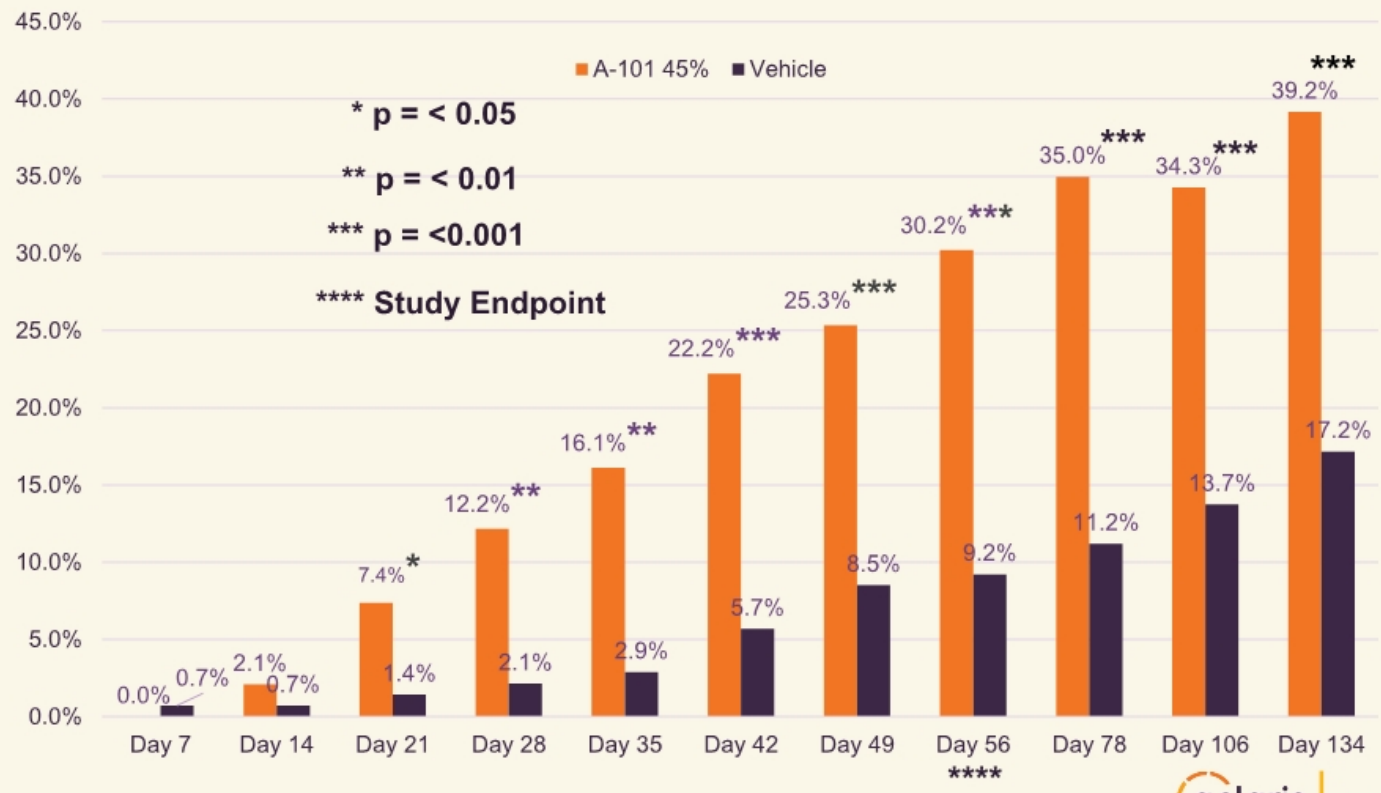
Secondary Endpoints:

- 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.

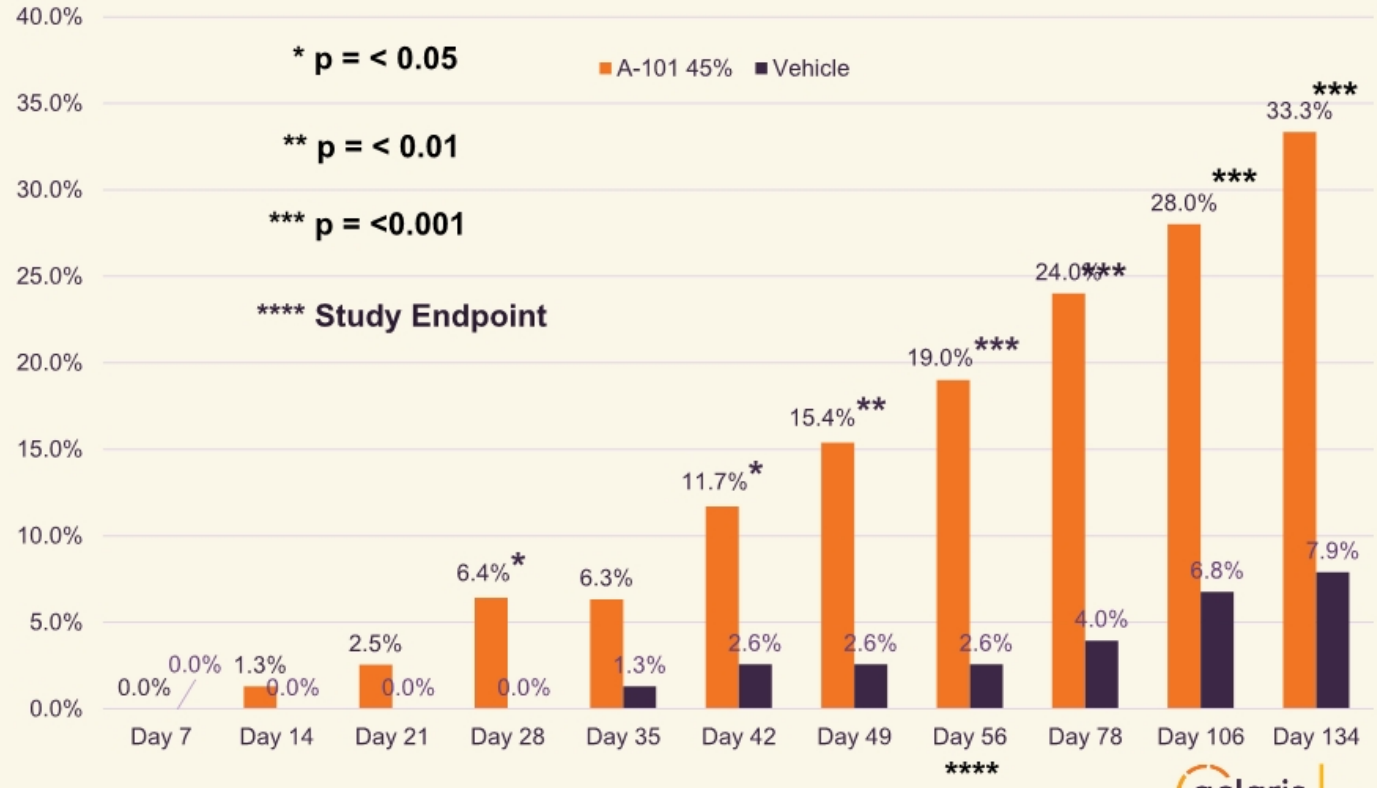
Current Status

- 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)

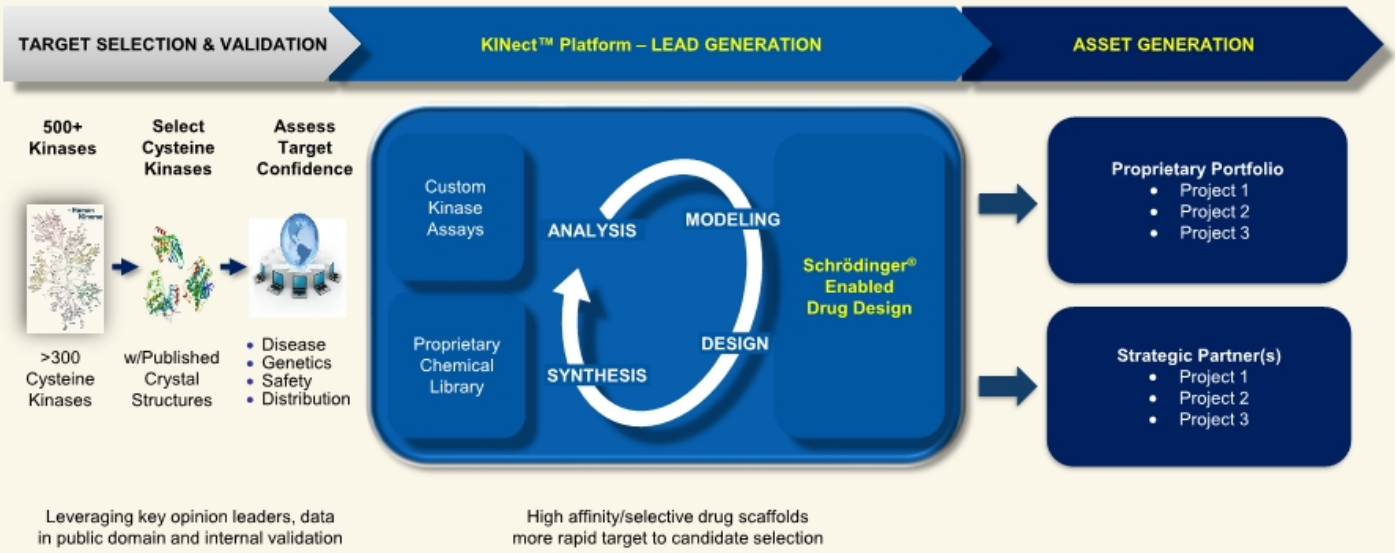


WART-203: Proportion of Subjects with all treated Wart(s) (1-6) Clear, Stratified by Baseline Number of Warts, at each Post-Baseline Visit (N=159)



Inflammation and Immunology Platform

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



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

aclaris THERAPEUTICS

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 2011-2015[1]

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

aclaris THERAPEUTICS

Investigational Selective JAK 1/3 Inhibitors

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 model[1]
- 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

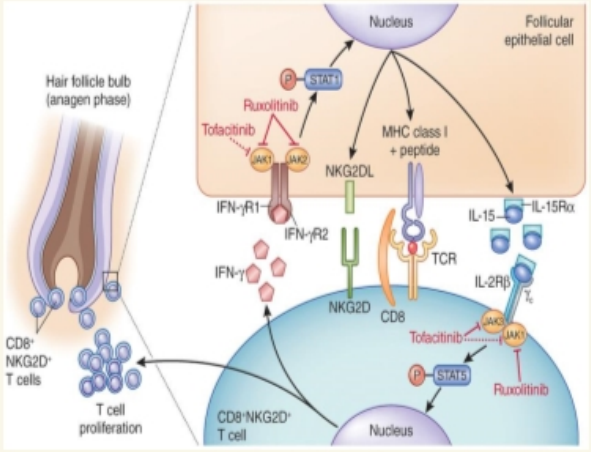
Topical treatment for hair loss disorders: patchy alopecia areata and androgenetic alopecia

ATI-1777 JAK1/JAK3 inhibitors

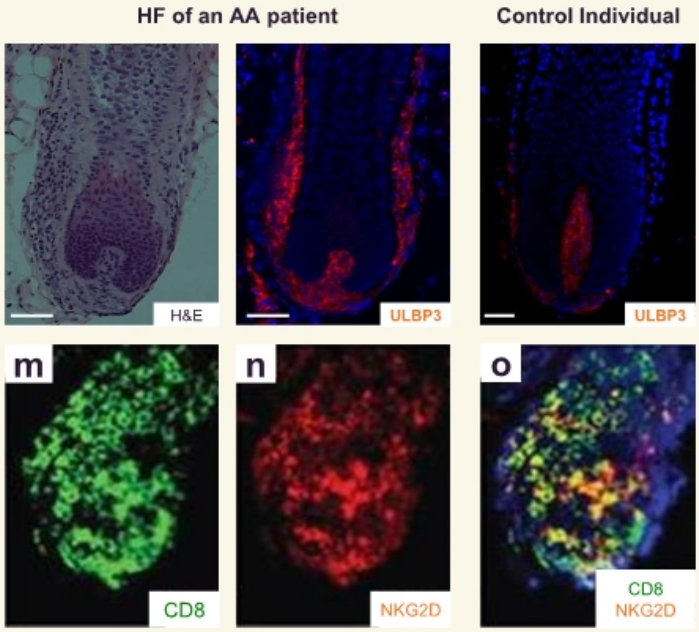
"Soft Topical" treatment for atopic dermatitis, alopecia areata, and vitiligo

[1] Data on File. Aclaris Therapeutics, Inc.

Mechanism of JAK Inhibitors in Alopecia Areata

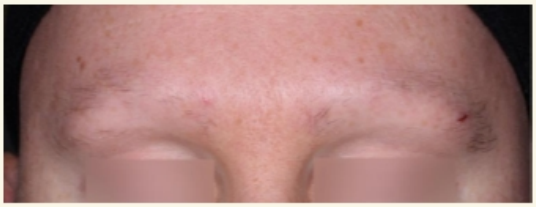
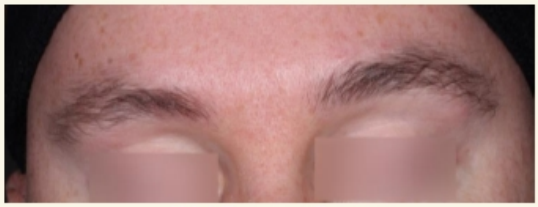
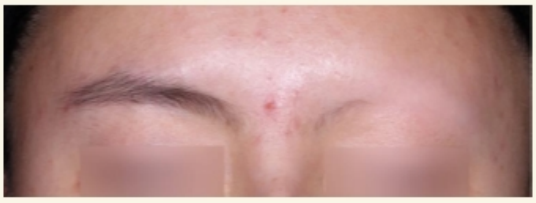
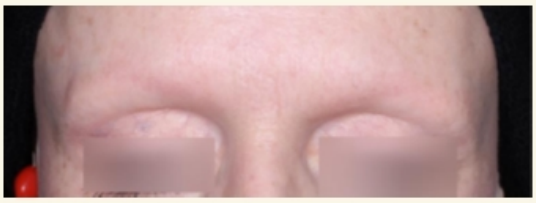


Divito & Kupper, *Nature Medicine* 20, 989–990 (2014).



Christiano Laboratory, Columbia University

ATI-502 – Topical Proof of Concept

	Baseline	Follow up
33/M		 (334 Days on Drug)
23/F		 (353 Days on Drug)
45/F		 (385 Days on Drug with a 47 day gap)

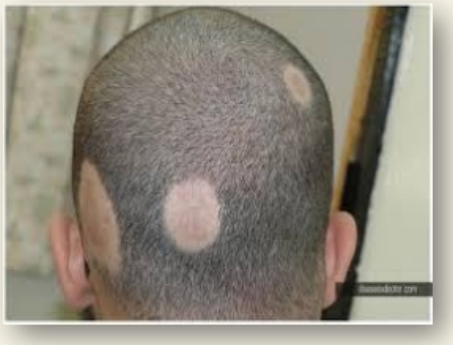
- Of the 8 patients who received at least 6 months of drug, 3 had evidence of eyebrow hair regrowth (defined by at least a 2 grade categorical shift in eyebrow score in at least 1 eyebrow [scale 1-5]).
- The 3 patients pictured above were the only patients who completed ~12 months of drug treatment.

aclaris THERAPEUTICS

Alopecia Areata - Patient/Physician Surveys

Patients with Alopecia Areata in the US

5–7 MM[12]



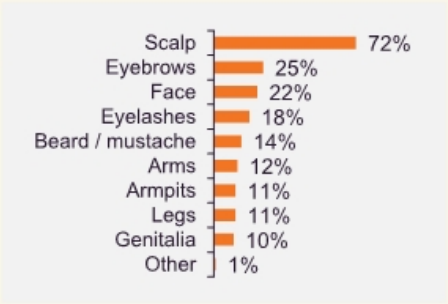
42%

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

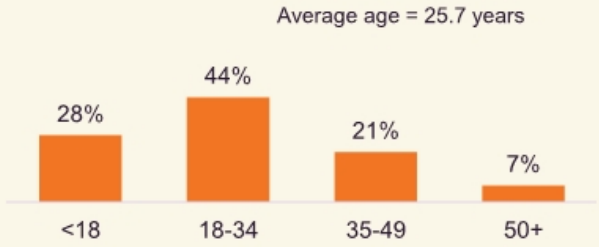
54%

treated by **Dermatologists** (7.1 avg. visits)
43% of pts are referrals[1]

COMMON BODY LOCATIONS[1]



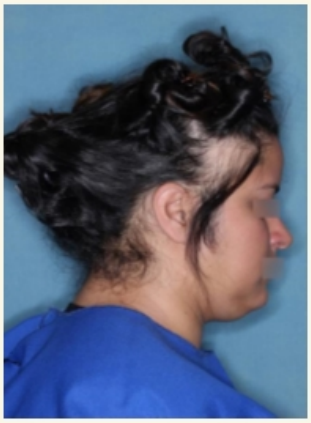
AGE & OTHER DEMOGRAPHICS[1]



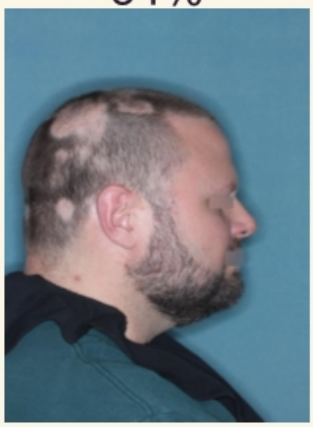
[1]Data on file, Aclaris Therapeutics, Inc.
[2]National Alopecia Areata Foundation. https://www.naaf.org/alopecia-areata.

Spectrum of Hair Loss

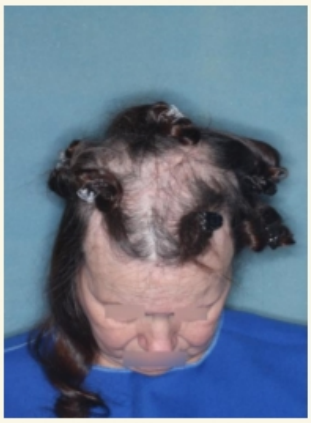
24%



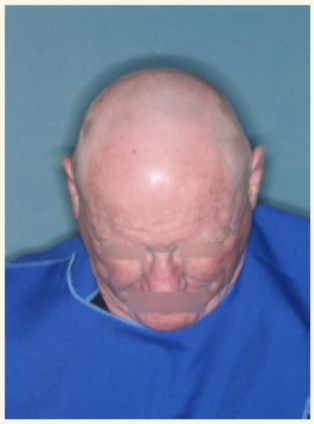
34%

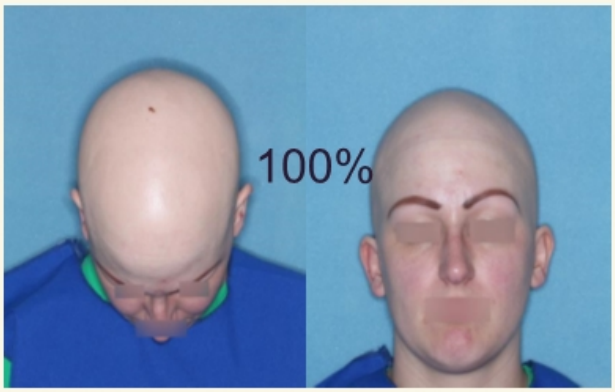


43%



51%



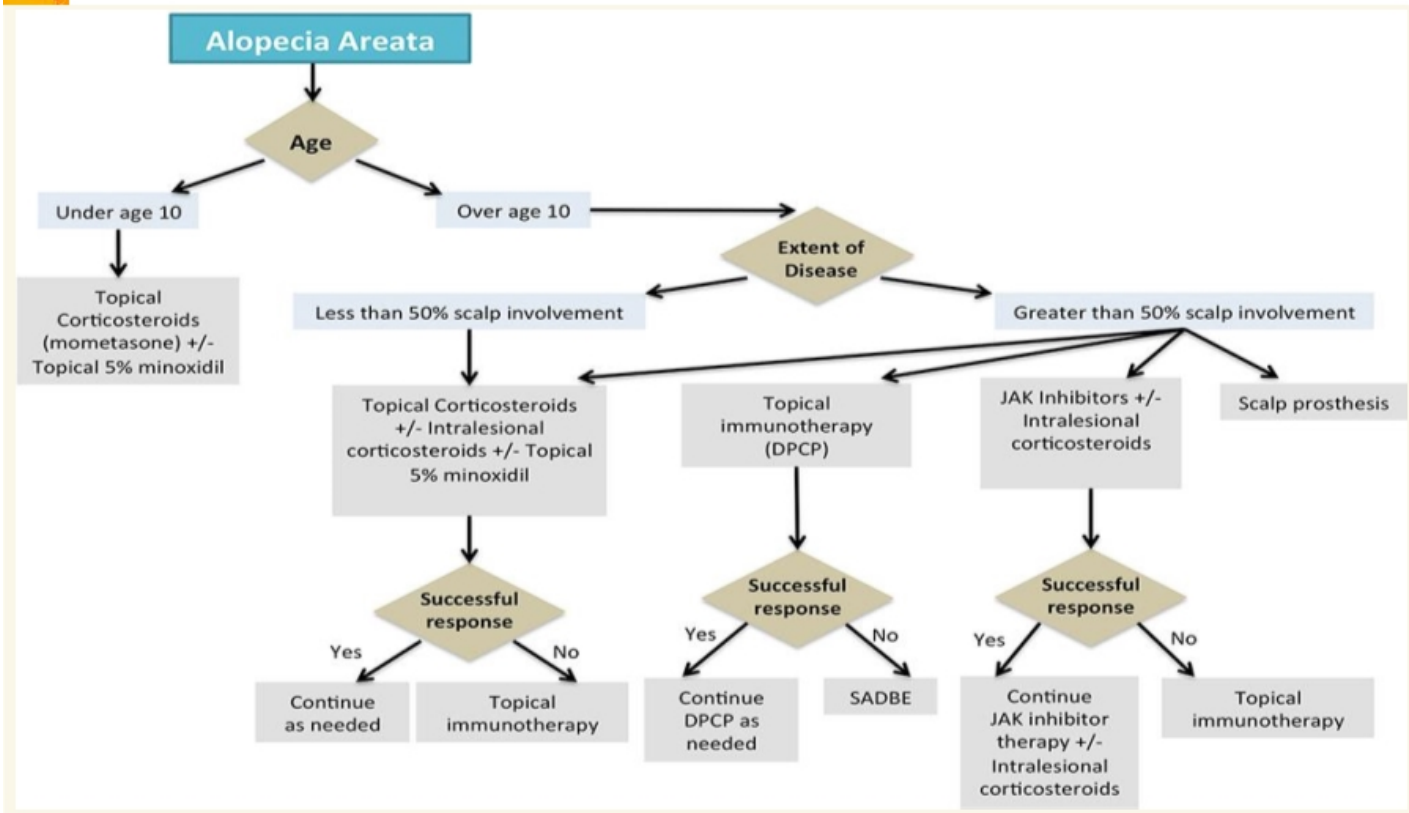


- 25-52% of patients have persistent patchy AA[1]
- 14-25% of patients progress to alopecia totalis or universalis[1]

[1]MacDonald, et al. Guidelines for the Management of Alopecia Areata. *Brit J Derm.* 2003
*Pictures from data on file

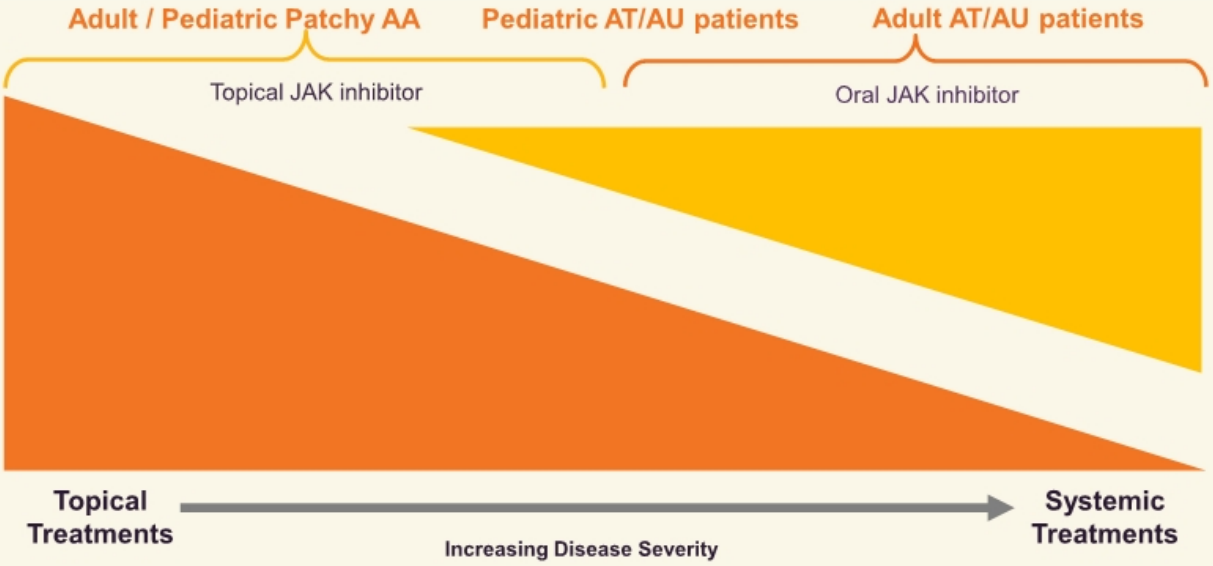
aclaris THERAPEUTICS

Current treatment paradigm



https://www.naaf.org/alopecia-areata/alopecia-areata-treatments. Last accessed March 30, 2019.

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

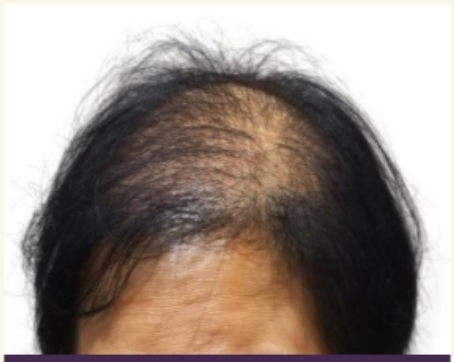
aclaris THERAPEUTICS

Androgenetic Alopecia (AGA)

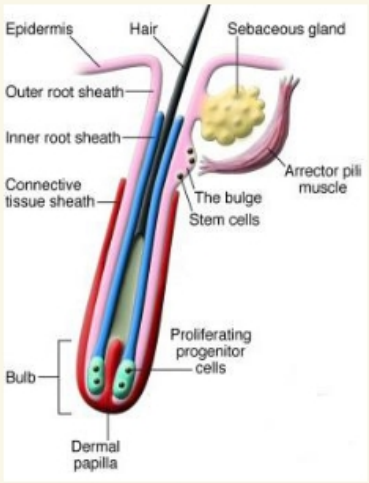
Androgenetic Alopecia (AGA): Male/Female pattern hair loss

- AGA is a genetic disorder and the most common cause of hair loss[1]
- Experienced by 70% of men and 40% of women at some point in their lives[1]; affects ~50 million men and ~30 million women in the US[2]
- Affected individuals highly motivated to seek treatment[1]
- 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, G. *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.

aclaris THERAPEUTICS

AGA – New Mechanism of Action Postulated

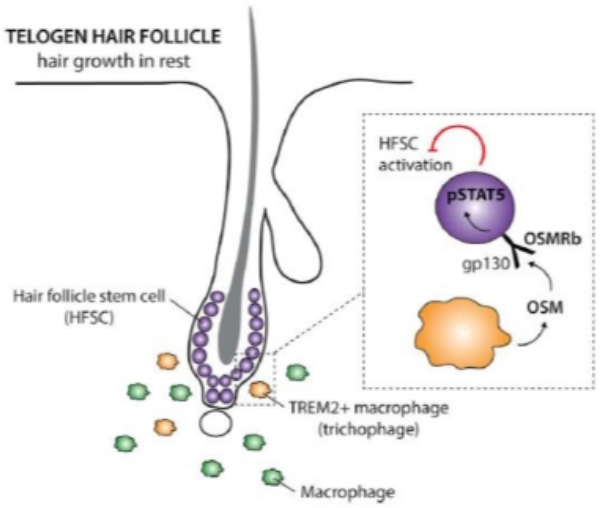


Figure 1. Role of TREM2+ Macrophages in Skin
Dermal TREM2+ macrophages, now termed "Trichophages," reside in close proximity to hair follicles. During telogen—the hair cycle phase when hair is not growing—trichophages produce the cytokine OSM that binds to OSM receptors on hair follicle stem cells (HFSCs). This triggers phosphorylation of STAT5 within HFSCs, impairing their activation, and therefore resulting in maintenance of telogen.

- Tissue-resident immune cells with potent sensing and effector functions are well-placed to fundamentally aid tissue homeostasis via crosstalk with stem cells.
- A dermis-resident TREM2+ macrophage subpopulation that promotes hair follicle stem cell quiescence via cytokine-mediated JAK-STAT signaling has been identified.
- pSTAT5 (the p indicates that STAT5 is in the ON position – ie: active, and then a red curved arrow blocks HFSC activation (this is telogen)
- The administration of a JAK inhibitor would turn the pSTAT5 to the OFF position, and then opens the red arrow and PROMOTES HFSC activation.

*Dalessandri, T and Kasper, M. TREMendous Macrophages Inhibit Hair Growth *Cell Stem Cell 24, 501-2* April 4, 2019 - 2019 Published by Elsevier Inc.
https://doi.org/10.1016/j.stem.2019.03.014

Core Intellectual Property: JAK inhibitor

- US & Global JAK IP estate consisting of >150 patents/applications (issued and/or pending)
- Exclusive license with Rigel Pharmaceuticals for ATI-501 & ATI-502 (COM) in dermatology
  - US Natural expiry dates 2030-2034 + potential applicable PTE for the treatment of AA
  - Corresponding patents & applications in 18 additional jurisdictions (EU, AU, CA, IN, JP, others) - Natural expiry dates 2030 + potential applicable PTE
- Exclusive license under Columbia University
  - Covers the use of certain JAK inhibitors for the treatment of AA, AGA, and other hair loss disorders and biomarkers to identify potential responders
  - This portfolio includes 6 issued U.S. patents and 1 pending application directed to methods of treating AA, AGA or hair loss disorders by administering ruxolitinib, deuterated ruxolitinib, baricitinib, decernotinib, topical tofacitinib or monotherapy tofacitinib.
  - This portfolio also includes an issued patent in Europe for tofacitinib or decernotinib for use in treating hair loss disorders and a pending European application for ruxolitinib or baricitinib to treat hair loss disorders, 3 issued patents in Japan to ruxolitinib, baricitnib, tofacitinib (topically or as monotherapy) and a pending Japanese application, and 1 issued patent in South Korea to methods of treating hair loss disorders using JAK 1 and/or JAK 2 inhibitors and 2 pending applications in South Korea to methods of treating hair loss disorders using JAK3 inhibitors.
  - Natural expiry in US 2031; naturally expiry in EU, JP, KR 2031-2033

ATI-450 (MK2 Inhibitor)

(Investigational Drug Candidate)

aclaris THERAPEUTICS

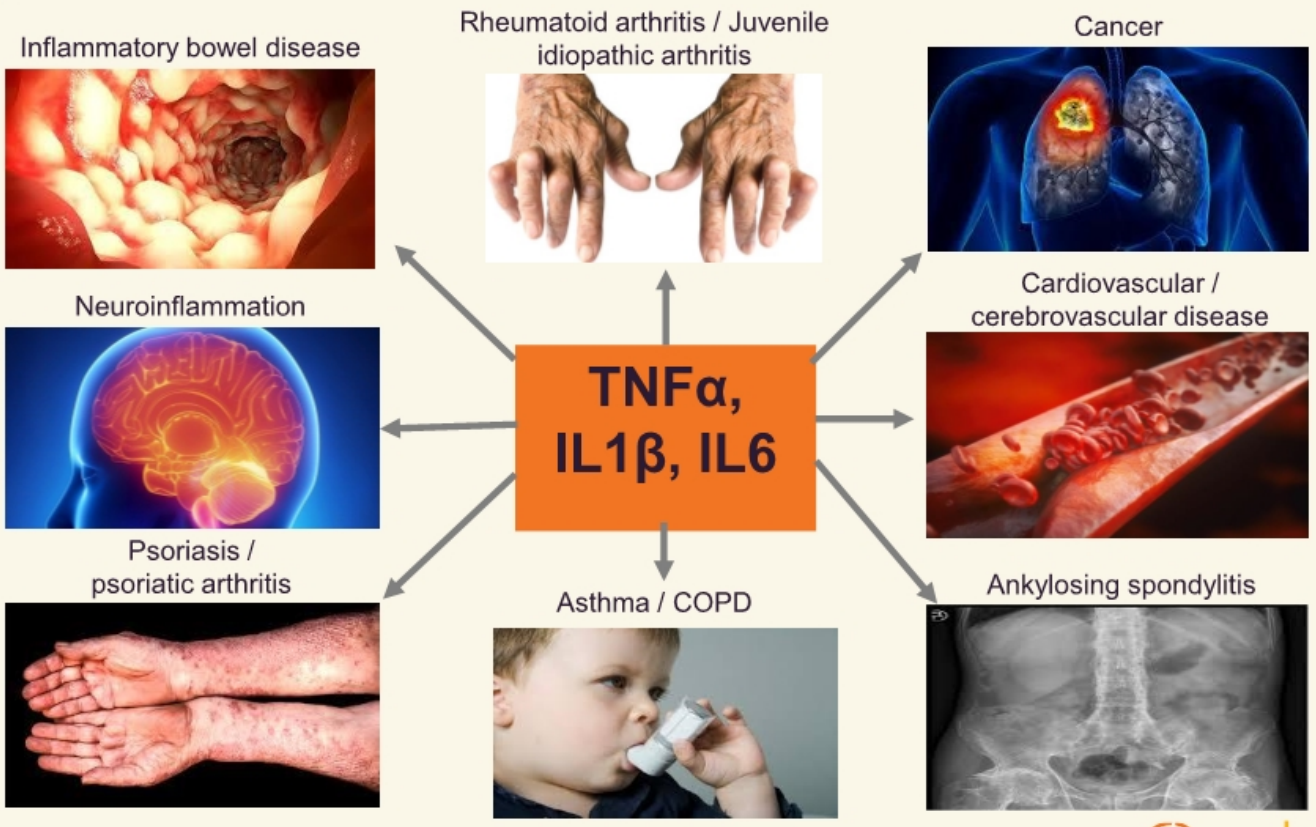
MK2 Pathway Inhibitor (MK2 PI) ATI-450

- IND for treatment of RA allowed in May 2019
- Plan to initiate a Single Ascending Dose / Multiple Ascending Dose Phase 1 trial in approximately 80 patients in the second half of 2019
- If the Phase 1 trial is successful, plan to advance ATI-450 into Phase 2 trials in patients with RA and an additional inflammatory indication
- Pharmacologically unique MOA
- MK2 pathway inhibitors target the production and activity of key inflammatory cytokines including TNFα, IL-1α, IL-1β 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

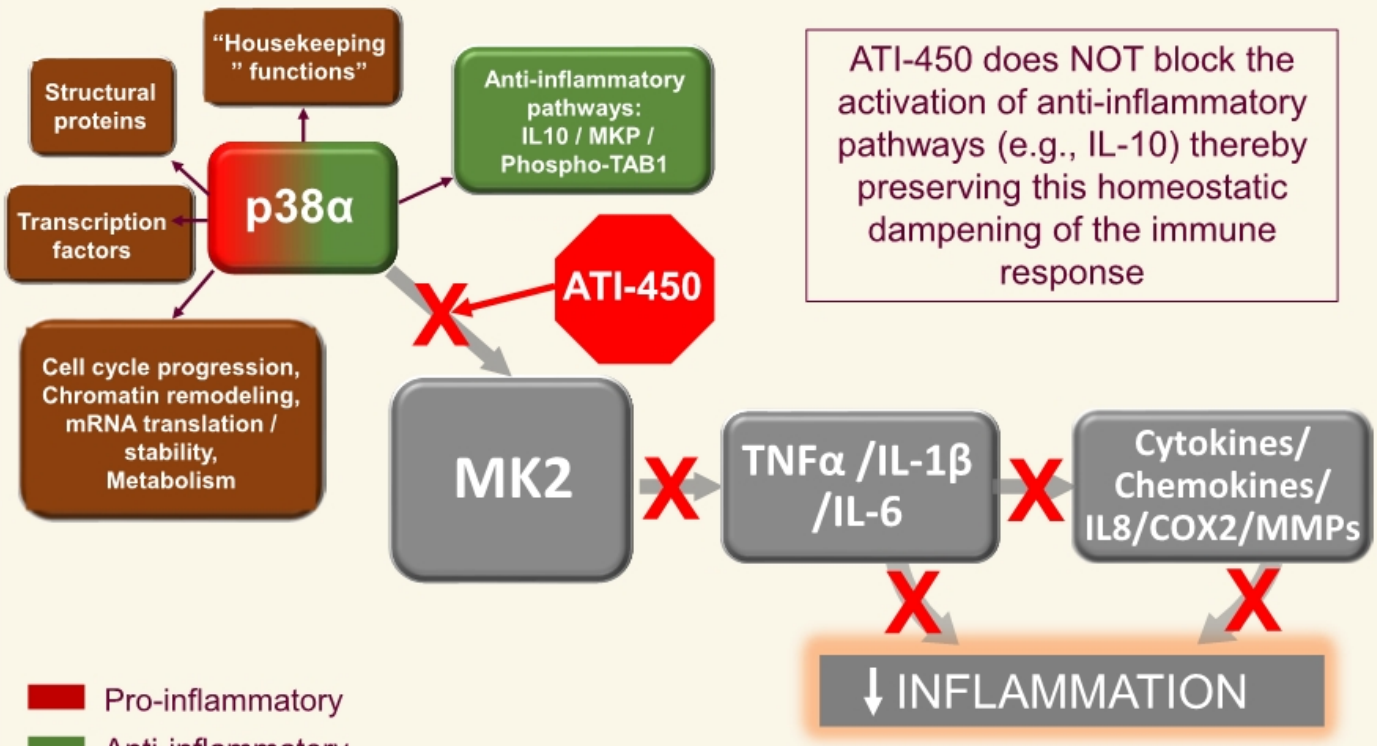
aclaris THERAPEUTICS

MK2-driven cytokines are central to many diseases



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

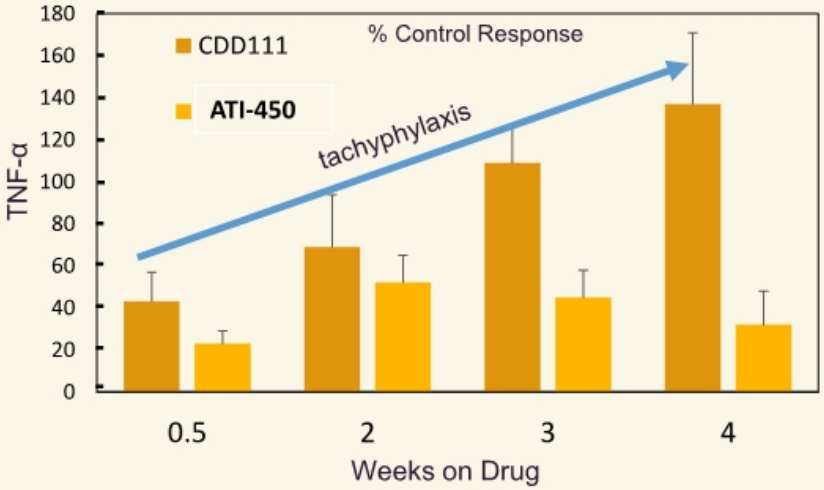
ATI-450 Inhibits the Expression of Key Inflammatory Cytokines: TNFα, IL-1β and IL-6



Mouse LPS-Induced TNFα 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 mouse model (no tachyphylaxis)**

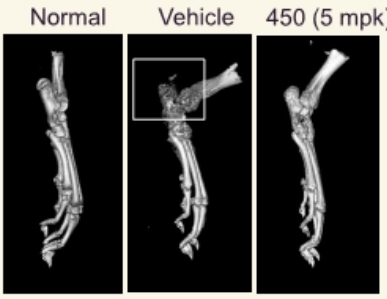


- Conventional p38 (CDD-111) and MK2PI (ATI-450) administered to mice in feed starting day 1 and continuing through day 28
- At the time point indicated, mice were LPS challenged and blood TNFα levels determined

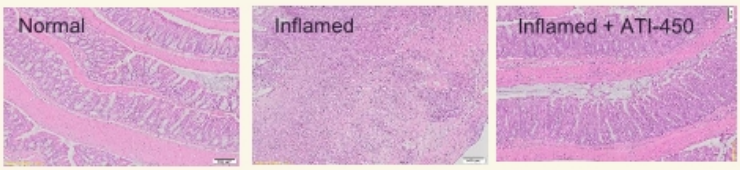
aclaris THERAPEUTICS

In vivo Results of MK2 Pathway Inhibitor ATI-450

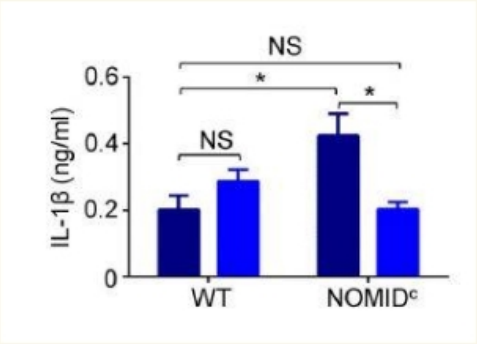
Joint Protection in Rat Arthritis Model[1]



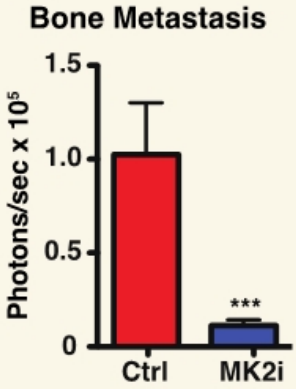
Blockade of Gut Inflammatory Infiltrate in Murine Adoptive Transfer Ulcerative Colitis Model[3]



Cytokine Modulation in Orphan Autoinflammatory Disease (CAPS)[1]

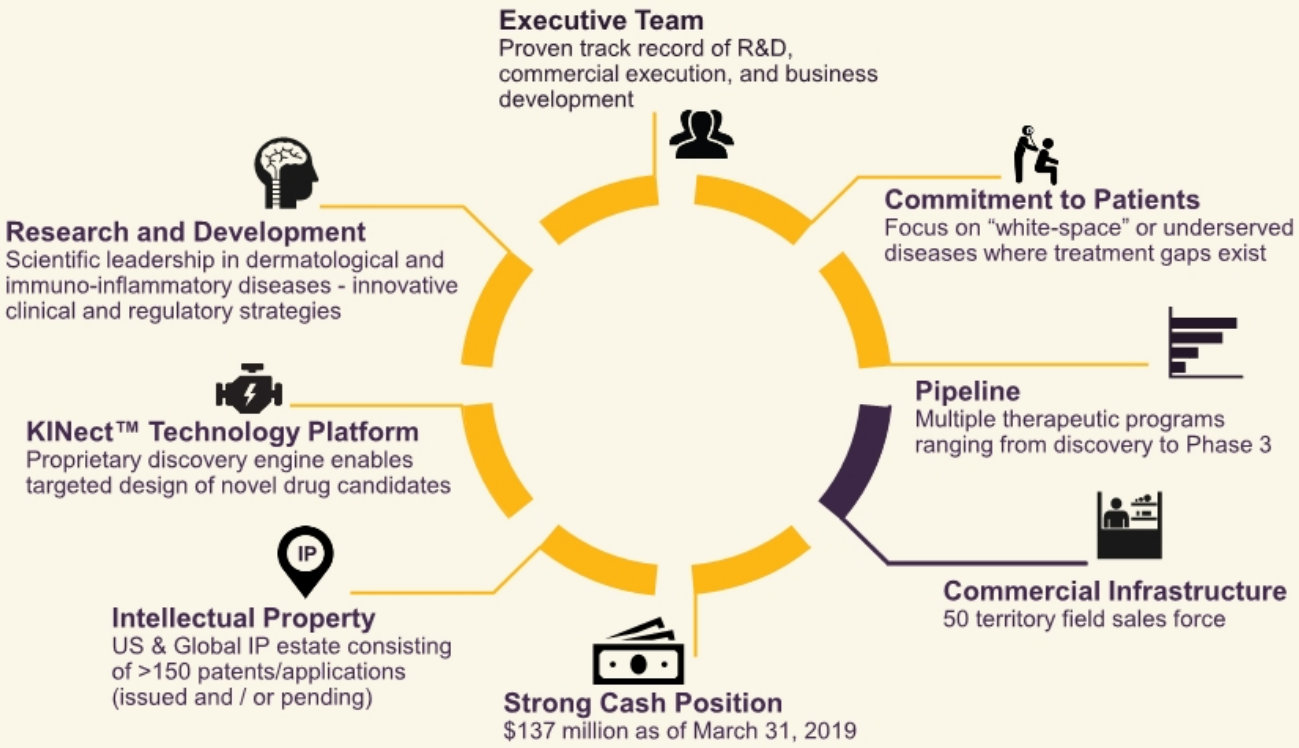


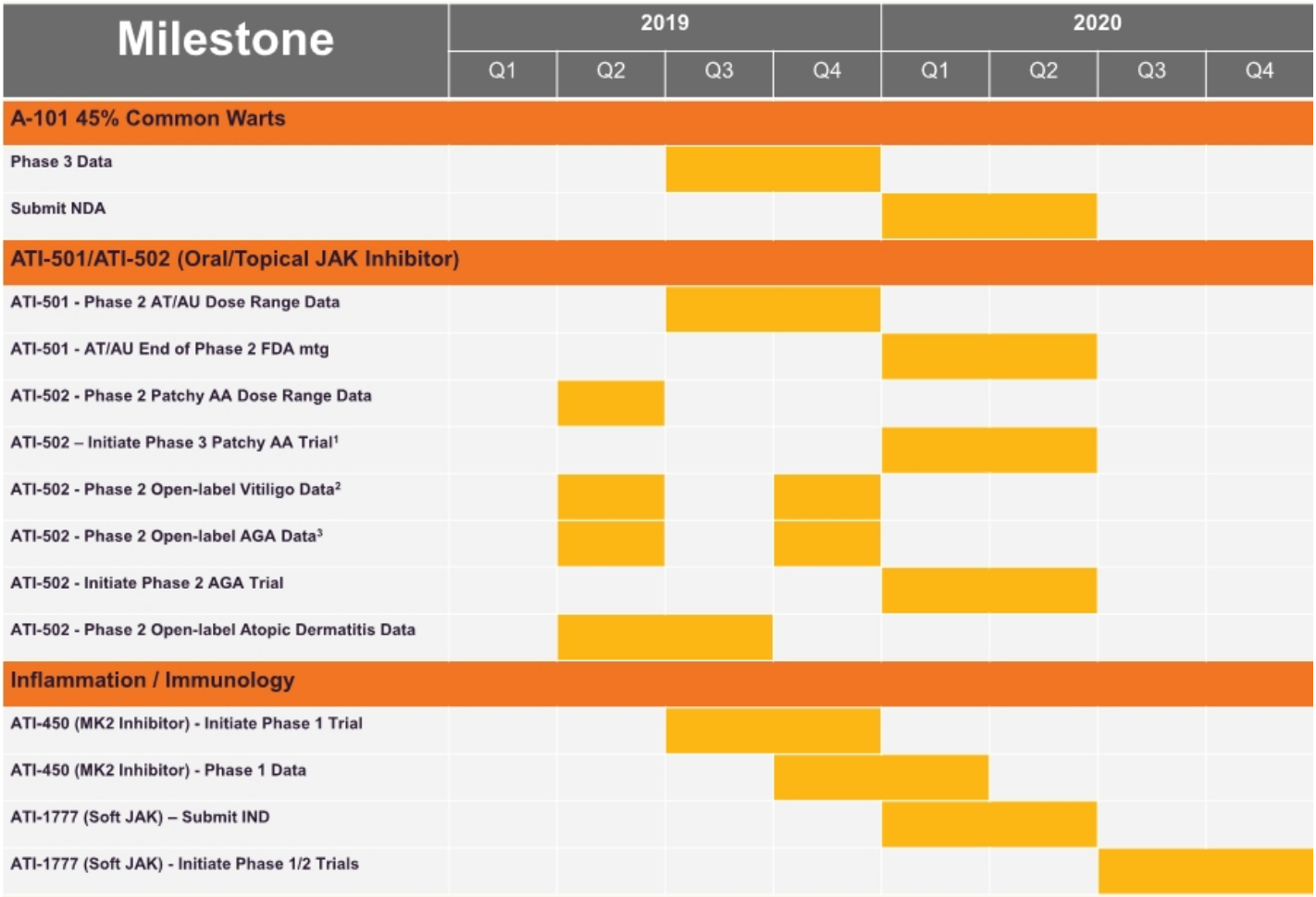
Reduction in Breast Cancer Bone Metastasis in Mice[2]



[1] Wang C, et al. *J Exp Med*. 2019;215(5):1315-1325.
[2] Murali B, et al. *Cancer Res*. 2019;78(19)5618-5630.
[3] Data on File. Aclaris Therapeutics, Inc.

Fully Integrated Biopharmaceutical Company





[1] If the results from the AA-201 trial are positive, our next steps may include holding an end of Phase 2 meeting with the FDA, and initiating a Phase 3 trial of ATI-502 as a topical treatment for AA in the first half of 2020.
[2] VITI-201: 6-month data interim expected mid-2019; 12-month data expected fourth quarter of 2019
[3] AGA-201: 6-month data expected second quarter of 2019; 12-month data expected fourth quarter of 2019

aclaris THERAPEUTICS

THANK YOU

aclaris THERAPEUTICS