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 8, 2021

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 8, 2021, Aclaris Therapeutics, Inc. (the "***Company***") will hold a conference call to discuss preliminary topline data for its Phase 2a clinical trial of ATI-1777, an investigational topical "soft" JAK 1/3 inhibitor, in subjects with moderate to severe atopic dermatitis (the "***Preliminary Topline Data***"), and related matters. A copy of the presentation that will accompany the conference call is furnished herewith 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 8.01 Other Events.

On June 8, 2021, the Company issued a press release announcing the Preliminary Topline Data and related matters. A copy of this press release is filed as Exhibit 99.2 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Company Presentation.
99.2	Press Release dated June 8, 2021.
104	The cover page from Aclaris Therapeutics, Inc.'s Form 8-K filed on June 8, 2021, formatted in Inline XBRL.

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 8, 2021

EMPOWERING PATIENTS THROUGH
KINOME INNOVATION

ATI-1777-AD-201
(Investigational Compound)

Preliminary Topline Data

June 8, 2021

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 ATI-1777 as a potential treatment for moderate to severe atopic dermatitis and the clinical development of ATI-1777. 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, risks and uncertainties associated with preliminary trial results varying from final results, Aclaris' reliance on third parties over which it may not always have full control, **the uncertainty regarding the COVID-19 pandemic including its impact on the timing of Aclaris’ regulatory and research and development activities**, 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, 2020 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” page of the “Investors” section 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. These data involve 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.

Atopic Dermatitis Opportunity

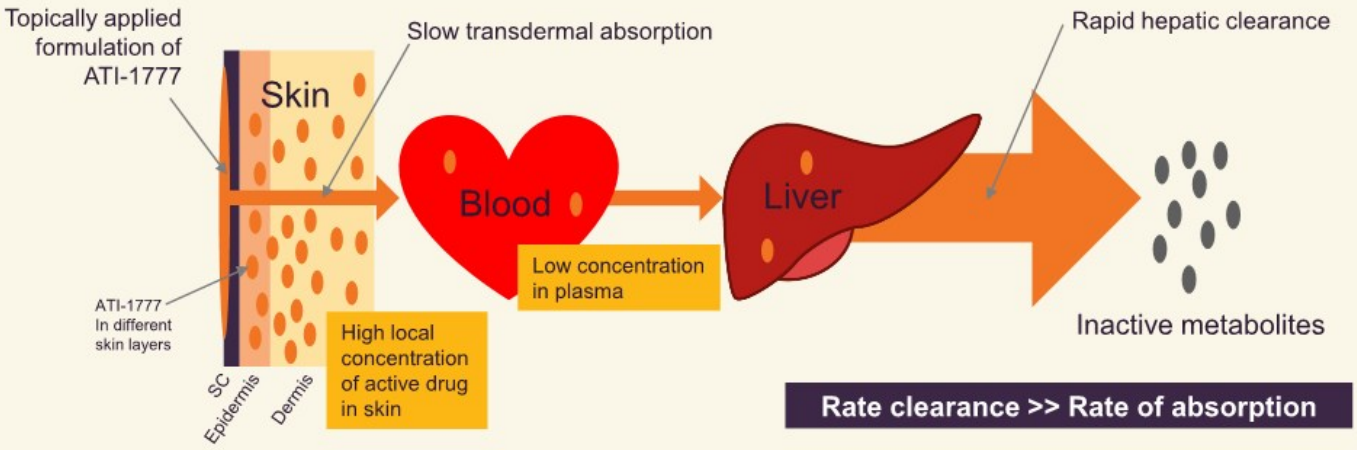
Atopic dermatitis (AD) is a chronic, pruritic inflammatory skin condition

- The U.S. prevalence of AD is reported to be 11.3–12.7% in children and 6.9–7.6% in adults[1]
- Market projected to be $8-12 billion at peak (moderate to severe AD)[2]
- Systemic and topical JAK inhibition has demonstrated promising results in AD clinical trials[3]

Goal	ATI-1777 (investigational compound)
• Comparable efficacy to other topical JAKs but a "soft" drug to minimize the potential for systemic toxicities • JAK1/3 selective to minimize JAK2 mediated hematopoietic effects • Patients with moderate to severe AD • Deliver in a patient-friendly formulation	• First-in-human Phase 2a trial in subjects with moderate to severe AD completed • 4-week trial in subjects with moderate to severe AD • Primary endpoint is percentage change from baseline in modified Eczema Area and Severity Index (mEASI)

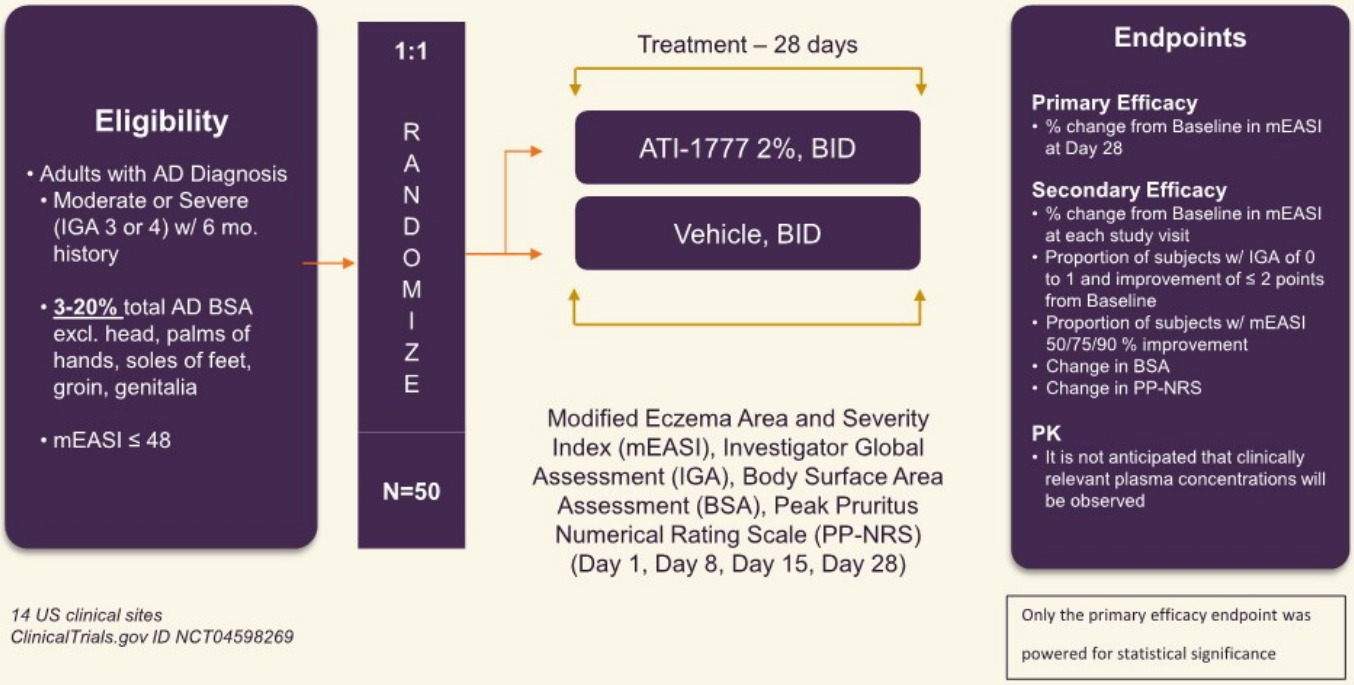
1. Silverberg J. *Dermatol Clin*. 2017;Jul;35(3):283-289.
2. Auster M, et al. Something Big Is Getting Bigger [research note]. *Credit Suisse Equity Research*; 2019.
3. Shreberk-Hassidim R, et al. *J Am Acad Dermatol*. 2017;Apr;76(4):745-753.

Soft Design: Multiple Metabolic Sites to Limit Systemic Exposure



ATI-1777-AD-201: Trial Design

Phase 2a, Multicenter, Randomized, Double-blind, Vehicle-controlled, Parallel-group Trial



14 US clinical sites
ClinicalTrials.gov ID NCT04598269

Only the primary efficacy endpoint was powered for statistical significance

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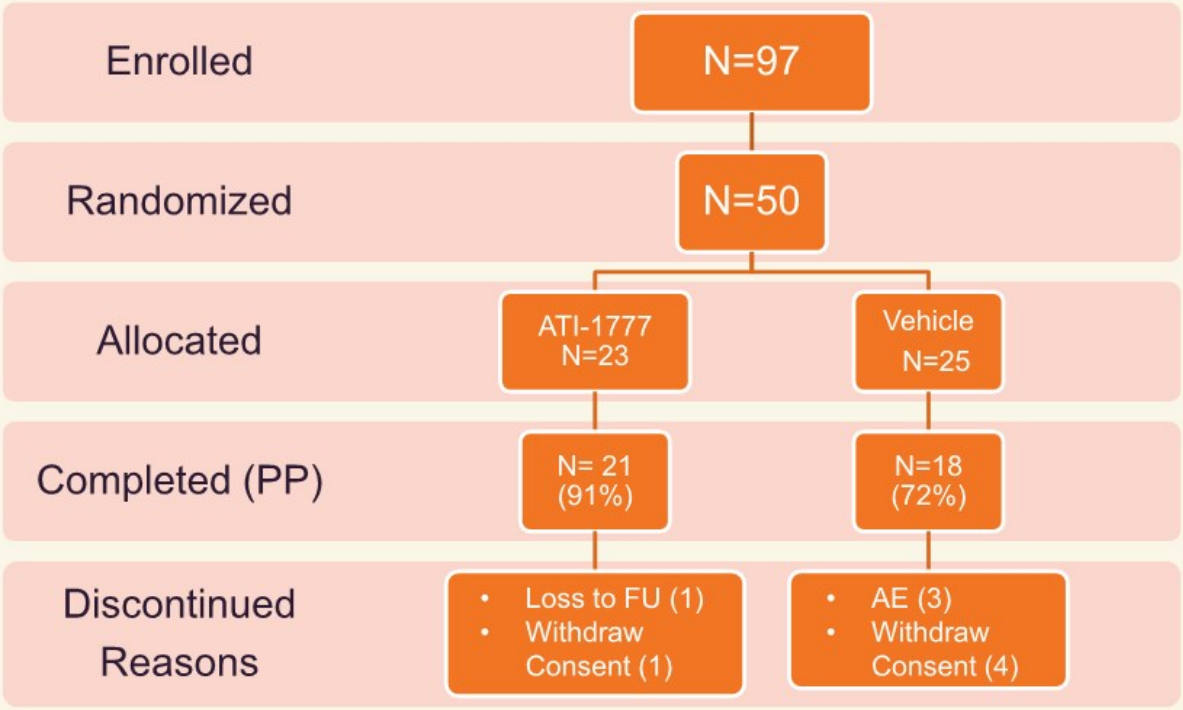
Subject Disposition



2 subjects (012-0016 and 013-0005) randomized into the ATI-1777 arm did not have verified treatment and discontinued after day 1. These subjects were not included in the Full Analysis Set (FAS).

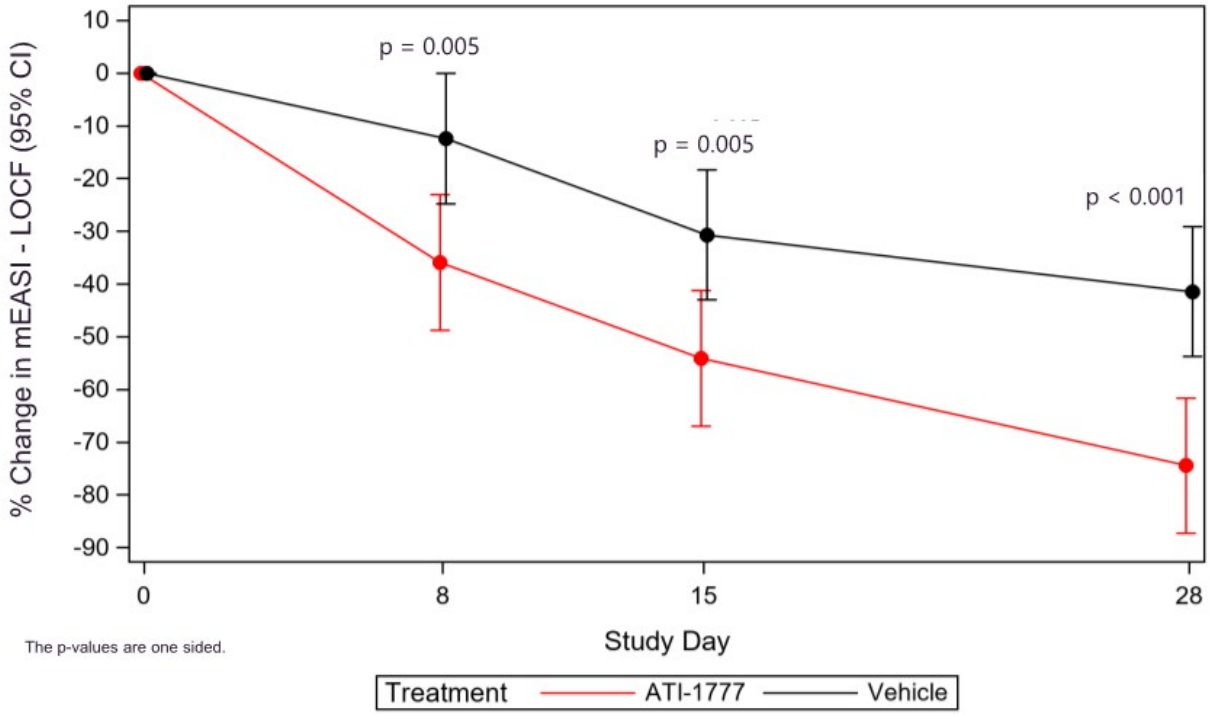
Data on file

Demographics & Baseline Characteristics (FAS)

	ATI-1777 N=23	Vehicle N=25
Age Mean (SD)	43.1 (13.99)	41.4 (14.31)
Sex Male N(%)	7 (30.4)	5 (20.0)
Sex Female N(%)	16 (69.6)	20 (80.0)
Race		
White	15 (65.2)	12 (48.0)
African American	7 (30.4)	10 (40.0)
Other	1 (4.3)	3 (12.0)
Disease Severity		
Moderate	22 (95.7)	24 (96.0)
Severe	1 (4.3)	1 (4.0)
Mean Baseline BSA (SD)	9.61 (5.433)	6.96 (4.286)
Mean Baseline mEASI (SD)	8.63 (3.823)	7.68 (3.730)

Data on file

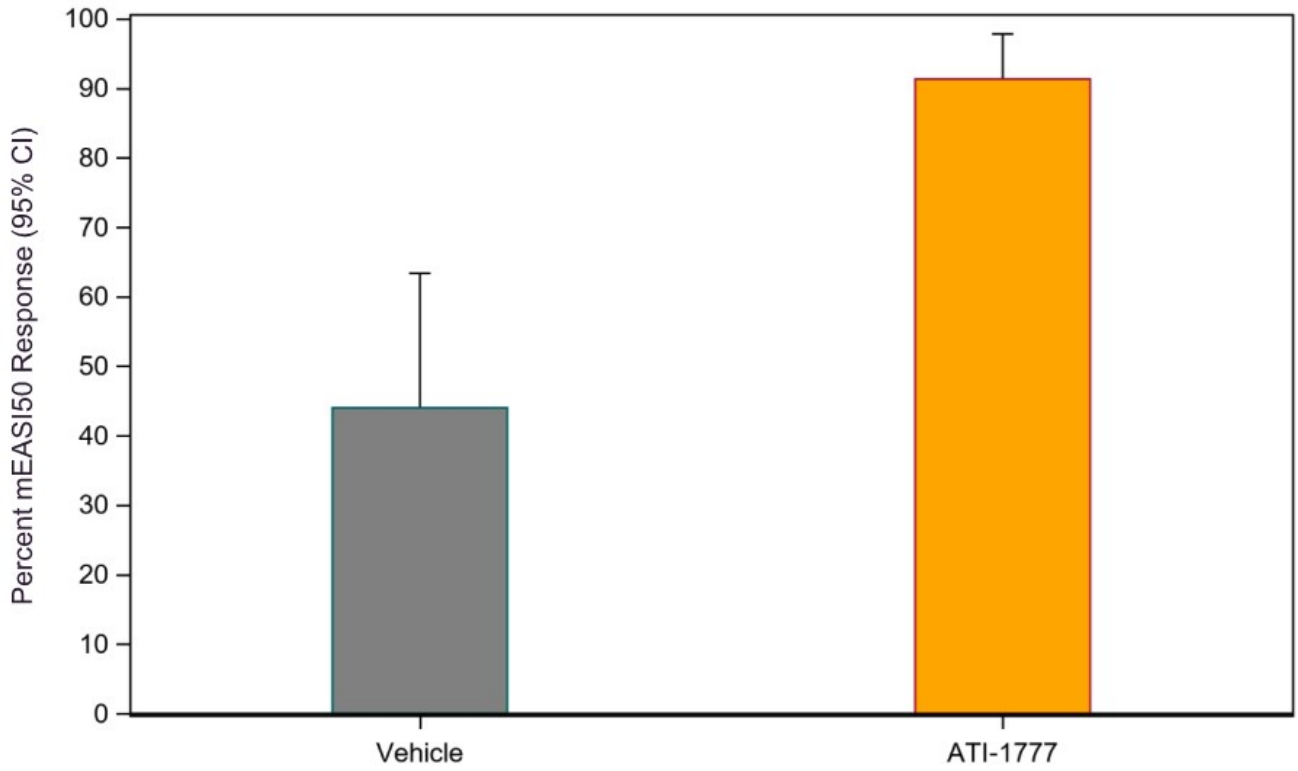
Primary Efficacy Endpoint: % Change in mEASI – LOCF (FAS)



A sensitivity analysis conducted adding baseline EASI for 012-0016 and 013-0005 and using Last Observation Carried Forward (LOCF) showed the statistical superiority of ATI-1777 to Vehicle at all post-baseline timepoints.

Data on file

Secondary Efficacy Endpoint: mEASI 50 at Day 28 (FAS)



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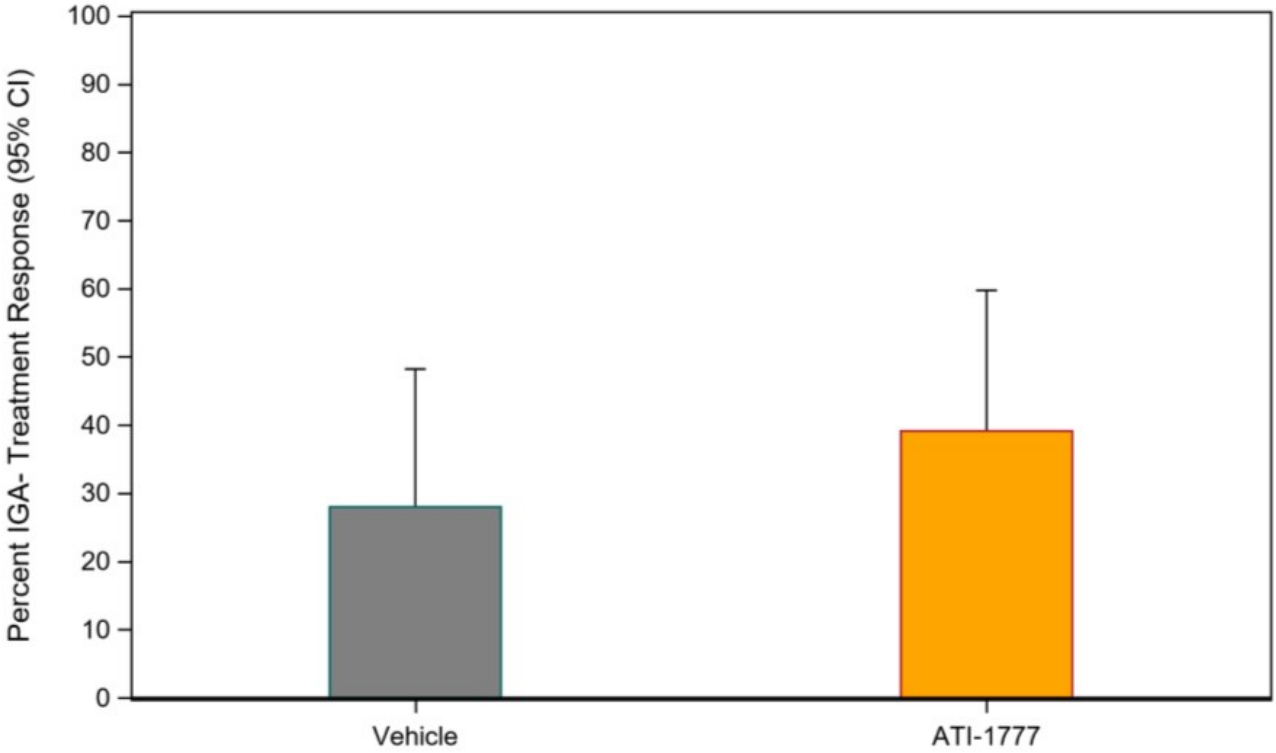
Secondary Efficacy Endpoint: IGA score of 0 or 1 with ≥2 Point Improvement at Day 28 (FAS)



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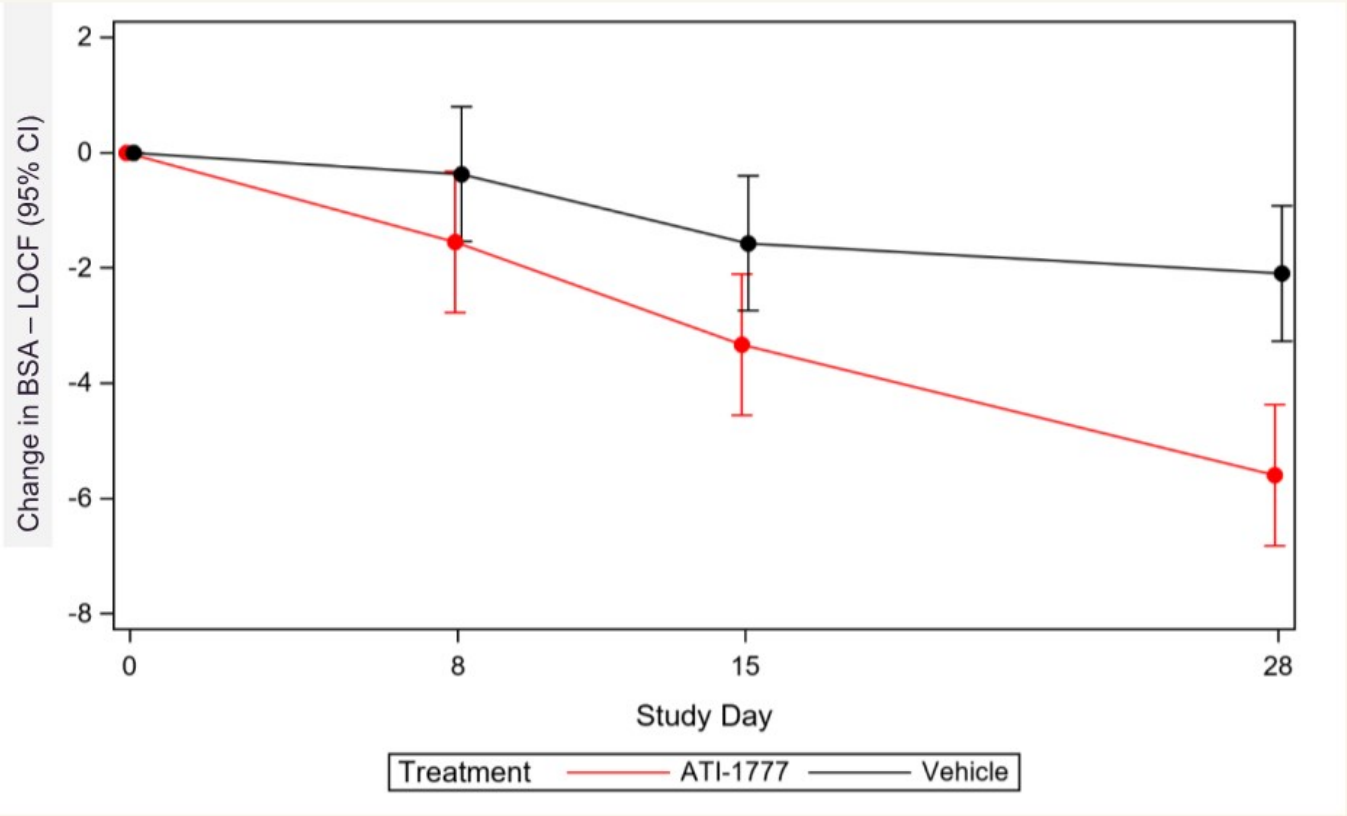
Secondary Efficacy Endpoint: Change in BSA (FAS)



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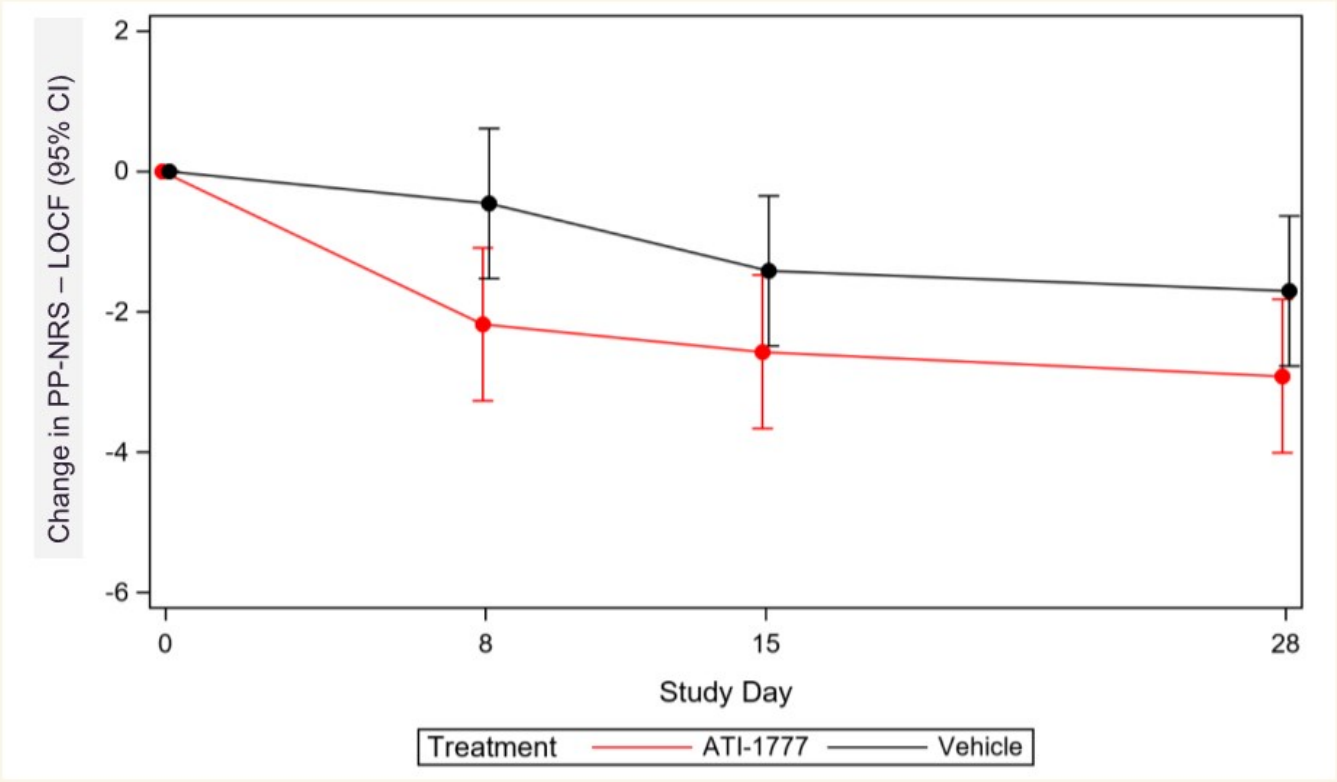
Secondary Efficacy Endpoint: Peak Pruritus-NRS (FAS)



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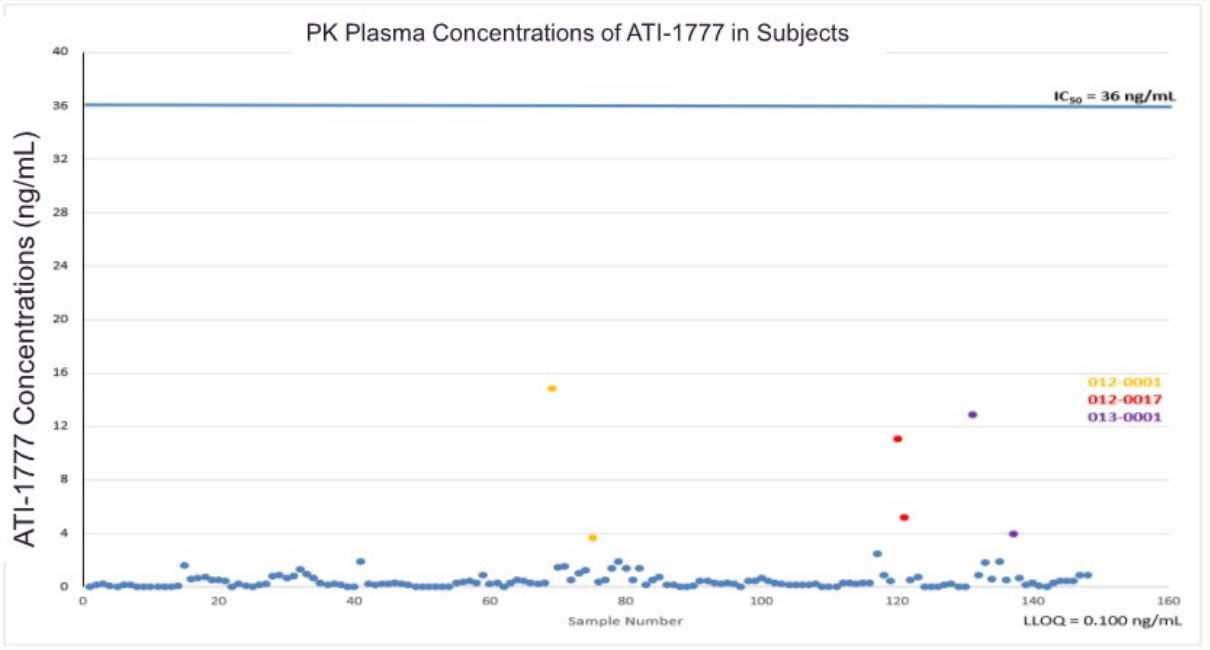
Plasma Levels of ATI-1777 Following Topical Application



- All concentrations < ½ IC_{50} (IC_{50} = 36 ng/mL for JAK1/3)
- >86% of samples tested following ATI-1777 administration exhibited blood levels <1ng/mlL
- Average concentration in subjects receiving ATI-1777 solution was never >5% the IC_{50}
- Only 3 subjects (6 out of 148 total samples) with concentrations > 1/10th the IC_{50}

Data on file

Summary of AEs (FAS)

	ATI-1777 N=23 Subjects (%) events	Vehicle N=25 Subjects (%) events	Total N=48 Subjects (%) events
Subjects with at least one **AE**	9 (39.1%) 16	9 (36.0%) 10	18 (37.5%) 26
Subjects with at least one **SAE**	0	0	0
Subjects with at least one **severe** AE	2 (8.7%) 2	0	2 (4.2%) 2
Subjects with at least one **related** AE*	1 (4.3%) 1	1 (4.0%) 1	2 (4.2%) 2
Subjects with at least one AE **leading to discontinuation of study drug**	0	3 (12.0%) 3	3 (6.3%) 3

*One treatment related AE in each of the ATI-1777 and vehicle arms - application site pruritus in the ATI-1777 arm and application site irritation in the vehicle arm.

Data on file

Adverse Events: Subjects with at Least One Event (FAS)

Preferred Term	ATI-1777 BID (N = 23)			Vehicle (N = 25)		
	Mild	Moderate	Severe	Mild	Moderate	Severe
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
Acrochordon	1 (4.3)	0	0	0	0	0
Amylase increased	1 (4.3)	0	0	0	0	0
Application site irritation	0	0	0	0	1 (4.0)	0
Application site pruritus	1 (4.3)	0	0	0	0	0
Atrial fibrillation	0	0	1 (4.3)	0	0	0
Blood creatine phosphokinase increased	1 (4.3)	0	1 (4.3)	0	0	0
Candida infection	0	1 (4.3)	0	0	0	0
COVID-19	0	0	0	0	1 (4.0)	0
Dizziness	1 (4.3)	0	0	0	0	0
Food poisoning	1 (4.3)	0	0	0	0	0
Folliculitis	1 (4.3)	0	0	0	0	0
Headache	2 (8.7)	0	0	0	0	0
Lipase increased	1 (4.3)	0	0	0	0	0
Oropharyngeal pain	0	0	0	1 (4.0)	0	0
Pharyngitis streptococcal	0	0	0	1 (4.0)	0	0
Rash	0	0	0	1 (4.0)	0	0
SARS-CoV-2 test positive	0	0	0	1 (4.0)	0	0
Sinus congestion	0	0	0	0	1 (4.0)	0
Skin fragility	0	0	0	0	1 (4.0)	0
Somnolence	0	0	0	1 (4.0)	0	0
Tinea infection	0	1 (4.3)	0	0	0	0
Transaminases increased	1 (4.3)	0	0	0	0	0
Urinary tract infection	0	1 (4.3)	0	0	1 (4.0)	0

- No Serious Adverse Events
- No subjects in ATI-1777 group W/D due to AE
- 3 subjects in vehicle group W/D for COVID-19, SARS-CoV-2, & Application site irritation

Data on file

Conclusions

- Positive Proof of Concept First in Human Study
  - ✓ Moderate to Severe Atopic Dermatitis
    - Traditionally the domain of systemic therapy
  - ✓ Rapid and continuing improvement over 4 weeks
  - ✓ PK supports tissue specific approach
  - ✓ Generally well tolerated
- Potential positioning in moderate to severe atopic dermatitis
  - ✓ Monotherapy
  - ✓ Combination therapy with biologics to potentially drive improved efficacy[1]

1. Reich, Teixeira, Bruin-Weller, Bieber, *Lancet* 397, Issue 10290, P2169-2181, June 5, 2021

Data on file

Aclaris Therapeutics Announces Positive Preliminary Topline Data from Phase 2a Trial of ATI-1777 for Moderate to Severe Atopic Dermatitis

- ***ATI-1777 Achieved Statistically Significant Result in the Primary Efficacy Endpoint at Week 4***
- ***Minimal Systemic Exposure Supports "Soft" Topical JAK Inhibitor Approach***
- ***ATI-1777 was Generally Well Tolerated***
- ***Data Support Progression to Phase 2b***
- ***Management to Host Conference Call at 8:00 AM ET Today***

WAYNE, Pa., June 8, 2021 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a clinical-stage biopharmaceutical company focused on developing novel drug candidates for immuno-inflammatory diseases, today announced positive preliminary topline results from its first in human Phase 2a, multicenter, randomized, double-blind, vehicle-controlled, parallel-group clinical trial to evaluate the efficacy, safety, tolerability and pharmacokinetics of ATI-1777, an investigational topical "soft" JAK 1/3 inhibitor, in 50 subjects with moderate to severe atopic dermatitis (AD) (ATI-1777-AD-201). ATI-1777 is the second compound generated from Aclaris' proprietary KINect® drug discovery platform to demonstrate positive proof of concept in clinical trials.

"We are very pleased that we achieved positive results in this trial of ATI-1777 in subjects with moderate to severe AD with minimal systemic exposure to drug," said Dr. David Gordon, Chief Medical Officer at Aclaris. "Our approach to treating patients with moderate to severe atopic dermatitis is particularly relevant in light of some of the potential safety concerns with oral therapies. We look forward to advancing ATI-1777 into the next phase of clinical development."

In the trial, which consisted of a 4-week treatment period and a 2-week follow-up period during which no treatment was given, 50 subjects with moderate to severe AD were randomized in a 1:1 ratio into one of two arms: ATI-1777 topical solution 2.0% w/w or vehicle applied twice daily. One of the key objectives of this first in human trial was to assess the "soft" aspect of this topical JAK inhibitor compound in subjects with moderate to severe atopic dermatitis. A preliminary analysis of pharmacokinetic plasma samples in the ATI-1777 arm showed greater than 86% of the plasma samples had concentrations below 1 ng/ml and mean drug levels in the ATI-1777 arm (as a group) were not greater than 5% of the IC50 of ATI-1777.

The primary efficacy endpoint of this trial was the percent change from baseline in the modified Eczema Area and Severity Index (mEASI) score at week 4. The mEASI is a modified measure of EASI which excludes evaluation of the body areas that were not treated in the trial (i.e., the head, palms of hands, soles of feet, groin, or genitalia). Only the primary efficacy endpoint was powered to detect a statistically significant outcome.

The Full Analysis Set (FAS), which was comprised of subjects randomized and documented to have received at least one dose of trial medication, was used for the primary endpoint. Two subjects in the ATI-1777 arm were excluded from the FAS analysis on the basis that they were lost to follow up after the baseline visit and did not have a formal record of having received at least one dose of trial medication. Key secondary efficacy endpoints, which were not powered for statistical significance, included the proportion of subjects who achieved 50% improvement in mEASI score (mEASI-50) within 4 weeks of the start of treatment, the change from baseline in the Investigator's Global Assessment (IGA) score at each trial visit, IGA responder analysis,

change from baseline in Body Surface Area (BSA) affected by AD at each trial visit, and change from baseline in peak pruritus numerical rating scale (PP-NRS) score over time.

The FAS was comprised of 23 and 25 subjects in the ATI-1777 and vehicle arms, respectively. The trial achieved its primary endpoint with a high degree of statistical significance ($p<0.001$) (one-sided p-value), which corresponded to a 74.4% reduction in mEASI score from baseline at week 4 in subjects applying ATI-1777 compared to a 41.4% reduction in subjects applying vehicle. In addition, a post-hoc analysis which included the two randomized subjects not in the FAS, using their baseline mEASI score carried forward to day 28, was statistically significant ($p=0.002$) (one-sided p-value).

In addition, positive trends in favor of ATI-1777 were observed in key secondary efficacy endpoints, such as improvement in itch, percent of mEASI-50 responders, IGA responder analysis, and reduction in BSA impacted by disease.

ATI-1777 was generally well tolerated. Nine subjects in each arm reported treatment-emergent adverse events (9/23 and 9/25 in the ATI-1777 and vehicle arm, respectively). No serious adverse events were reported. One treatment-related adverse event (AE), application site pruritus, was reported in one subject in the ATI-1777 arm. The most common AEs (reported in ≥2 subjects in the trial) were increased blood creatinine phosphokinase and headache in subjects in the ATI-1777 arm and urinary tract infection (one each in the ATI-1777 and the vehicle arm); none of these AEs in the ATI-1777 arm were determined by the clinical trial investigators to be related to ATI-1777. There were no reports of thrombosis in the trial. In the FAS analysis, two subjects from the ATI-1777 arm withdrew from the trial (one lost to follow up, one withdrew consent), while seven subjects withdrew from the vehicle arm (three due to AEs and four withdrew consent).

Final trial results will be submitted for publication in a peer-reviewed scientific journal.

Conference Call and Webcast

Management will host a conference call and webcast with an accompanying slide presentation at 8:00 AM ET today to review these preliminary topline Phase 2a data and related matters. To participate in the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international) and reference conference ID 8990539. To access the live webcast of the call and the accompanying slide presentation, please visit the “Events” page of the “Investors” section of Aclaris’ website, www.aclaristx.com. The webcast will be archived for at least 30 days on the Aclaris website.

About Atopic Dermatitis

Atopic dermatitis (AD) is a chronic skin disease, affecting 11.3 to 12.7% of children and 6.9 to 7.6% of adults in the United States and is characterized by inflammation and intense itch. Signs and symptoms of AD include irritated and itchy skin that can cause red lesions that may ooze and crust.

About ATI-1777

ATI-1777 is an investigational topical “soft” Janus kinase (JAK) 1/3 inhibitor. “Soft” JAK inhibitors are designed to provide JAK inhibition at the site of application and be rapidly metabolized in systemic circulation. Aclaris plans to develop ATI-1777 as an emollient-containing spray formulation. Aclaris is developing ATI-1777 as a potential treatment for moderate to severe atopic dermatitis. ATI-1777 is currently in clinical development and its safety and efficacy has not been evaluated by regulatory authorities.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a clinical-stage biopharmaceutical company developing a pipeline of novel drug candidates to address the needs of patients with immuno-inflammatory diseases who lack satisfactory treatment options. The company has a multi-stage portfolio of drug candidates powered by a robust R&D engine exploring protein kinase regulation. For additional information, please visit www.aclaristx.com.

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Aclaris Contact

investors@aclaristx.com