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 17, 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 17, 2019, Aclaris Therapeutics, Inc. (the "***Company***") issued a press release announcing 6-month results from its Phase 2 open-label clinical trial of ATI-502 (AGA-201), an investigational topical Janus Kinase 1/3 inhibitor, in patients with androgenetic alopecia, as well as information regarding a conference call to discuss these results and related matters. A copy of this press release is furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K. A copy of the presentation that will accompany the conference call is furnished herewith as Exhibit 99.2 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 Exhibits 99.1 and 99.2 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	Press Release dated June 17, 2019.
99.2	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 17, 2019

Exhibit 99.1

Aclaris Therapeutics Announces Positive 6-Month Results from a Phase 2 Open-Label Clinical Trial of ATI-502 Topical in Patients with Androgenetic Alopecia (Male/Female Pattern-Baldness)

WAYNE, Pa., June 17, 2019 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced positive results from a Phase 2 open-label clinical trial of ATI-502 (AGA-201), an investigational topical Janus Kinase (JAK) 1/3 inhibitor, in patients with androgenetic alopecia (AGA), a condition commonly known as male/female-pattern baldness.

The trial evaluated ATI-502 in women and men with AGA. Subjects aged 18-50 years (n=31) applied ATI-502 to their scalp twice daily for 26 weeks. Twenty-three subjects completed 6 months of treatment. Twenty subjects (14 male, 6 female) had evaluable hair counts, and twenty-two (15 male and 7 female) recorded investigator global assessment (IGA) and subject self-assessment (SSA) scores.

The primary endpoint was the mean change from baseline in non-vellus target area hair count (TAHC) at week 26. The overall change was an increase of 8.6 hairs/cm^2. TAHC increase was 15.3 hairs/cm^2 in female subjects and 5.6 hairs/cm^2 in male subjects.

The secondary endpoints included an IGA and SSA. Subjects who experienced increased hair growth were given a score of +1 or better on the IGA and SSA (+1 = slightly increased hair growth, +2 = moderately increased hair growth, and +3 = greatly increased hair growth). Based on these endpoints, investigators rated 73% of subjects (16/22) as experiencing increased hair growth, and 82% of subjects (18/22) rated themselves as experiencing increased hair growth. ATI-502 was well-tolerated. There were no treatment-related serious adverse events. There was one unrelated serious adverse event of breast cancer reported, and one patient withdrew for treatment-related alopecia in week one.

“The combination of the TAHC data, the investigator and subject assessments, and our own internal review of the formal photography, suggest topical JAK inhibition is a viable approach to treating AGA,” said Dr. Neal Walker, President and Chief Executive Officer of Aclaris. “This finding demonstrates that inhibiting a non-hormonal and inflammatory-mediated pathway may be an option for the treatment of AGA.”

“There has been no novel drug approved for the treatment of AGA for decades. These data are encouraging and suggest ATI-502 may be a potential treatment for patients with AGA – especially women,” said Dr. Janet Roberts of Northwest Dermatology Institute, Portland, Oregon, a Principal Investigator in the clinical trial.

Next Steps:

- The 12-month results from this trial are expected by year end 2019.
- Through recent formulation work, Aclaris can achieve significantly higher topical concentrations of ATI-502.
- As such, Aclaris believes the next step is initiating a double-blind, randomized, controlled Phase 2 dose-ranging clinical trial with higher concentrations of ATI-502, with potentially a female focus, in the first half of 2020.

Company to Host Conference Call

Management will conduct a conference call at 8:00 AM ET today to review these Phase 2 results and related matters. The conference call will be webcast live over the Internet and can be accessed by logging on to the “Investors” page of the Aclaris Therapeutics website, www.aclaristx.com, prior to the event. A replay of the webcast will be archived on the Aclaris Therapeutics website for 30 days following the call.

To participate on the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international), and reference conference ID 8887134 prior to the start of the call.

About Aclaris Therapeutics, Inc.

Aclaris Therapeutics, Inc. is a physician-led biopharmaceutical company committed to addressing the needs of people with immuno-inflammatory and dermatological diseases who lack satisfactory treatment options. The company's diverse and multi-stage portfolio includes two FDA-approved medicines, one late-stage investigational medicine, and a pipeline powered by a robust R&D engine exploring protein kinase regulation. Aclaris Therapeutics' active development programs focus on areas where significant treatment gaps exist, such as common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn or Twitter @aclaristx.

About Androgenetic Alopecia

Androgenetic alopecia (AGA), also known as male pattern baldness or female pattern hair loss, is the most common form of hair loss, affecting approximately 50 million men and 30 million women in the U.S.[1,3] The condition may affect up to 70% of men and 40% of women, beginning at some point in their adult lives.[2] Male pattern baldness usually involves hairline recession and balding of the highest point of the head, while female pattern hair loss tends to manifest as thinning hair over the top of the scalp.[1,2] Susceptibility to AGA is largely determined by genetics, though environmental factors may play a minor role.[2] While AGA is widespread, negative image perceptions make individuals with AGA highly motivated to seek diagnosis and treatment.[2] Currently available treatment procedures can be invasive and costly and are not optimal for some patients for various reasons, such as adverse reactions and contraindications.

1 Ghanaat M. Types of Hair Loss and Treatment Options. *South Med J*. 2010;103(9):917-921.

2 McElwee, K. J., & Shapiro, J. Promising Therapies for Treating and/or Preventing Androgenic Alopecia. https://www.skintherapyletter.com/alopecia/promising-therapies/. Published June 1, 2012. Accessed May 13, 2019.

3 National Institutes of Health. Androgenetic alopecia. https://ghr.nlm.nih.gov/condition/androgenetic-alopecia. Accessed May 13, 2019.

Cautionary Note Regarding Forward-Looking Statements

Any statements contained in this press release 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 the clinical development of its JAK inhibitor candidates, including the availability of data from its ongoing clinical trials, and timing for initiation of planned clinical trials. 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 and in commercialization of products, 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 press release and are based on information available to Aclaris as of the date of this release, 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.

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AGA-201 Data

Phase 2 open-label clinical trial evaluating the safety and efficacy of ATI-502, an investigational topical JAK1/3 inhibitor, on the regrowth of hair in patients with androgenetic alopecia (AGA), also known as male/female pattern hair loss.

June 2019

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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 the clinical development of its JAK inhibitor candidates, including the availability of data from its ongoing clinical trials, and timing for initiation of planned clinical trials. 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.

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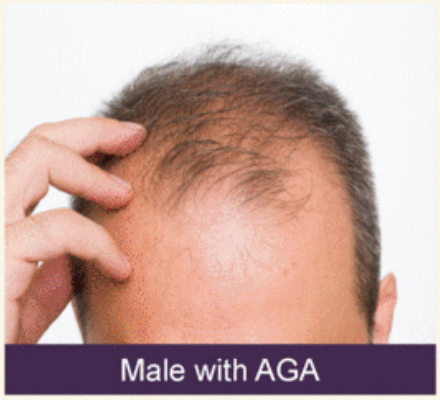
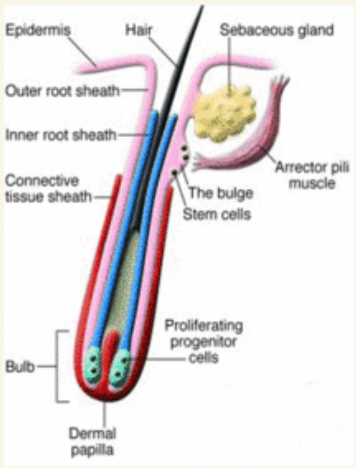
Androgenetic Alopecia (AGA): Male/Female pattern hair loss

- 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 for women with AGA



Male with AGA

Female with AGA



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

[1] McElwee, K. J., & Shapiro, J. Promising Therapies for Treating and/or Preventing Androgenic Alopecia. https://www.skintherapyletter.com/alopecia/promising-therapies/. Published June 1, 2012. Accessed May 13, 2019.
[2] National Institutes of Health. Androgenetic alopecia. https://ghr.nlm.nih.gov/condition/androgenetic-alopecia#statistics. Accessed March 30, 2019.

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AGA – New Mechanism of Action Postulated

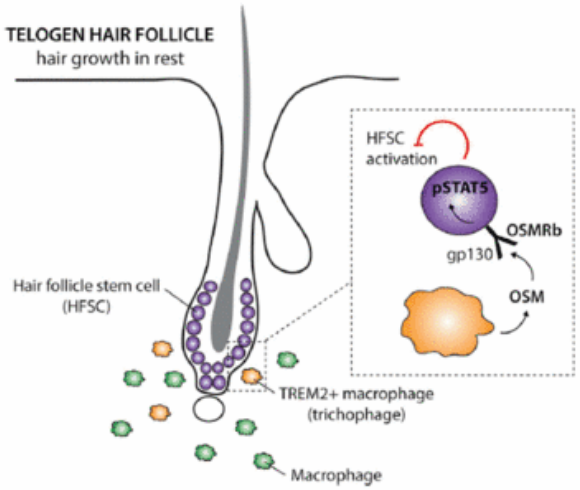

Figure 1. Role of TREM2+ Macrophages in Skin
Dermal TREM2+ macrophages, now termed "Trichophages," reside in close proximity to hair follicles. During telogen—the hair cycle phase when hair is not growing—trichophages produce the cytokine OSM that binds to OSM receptors on hair follicle stem cells (HFSCs). 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 (HFSC) 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
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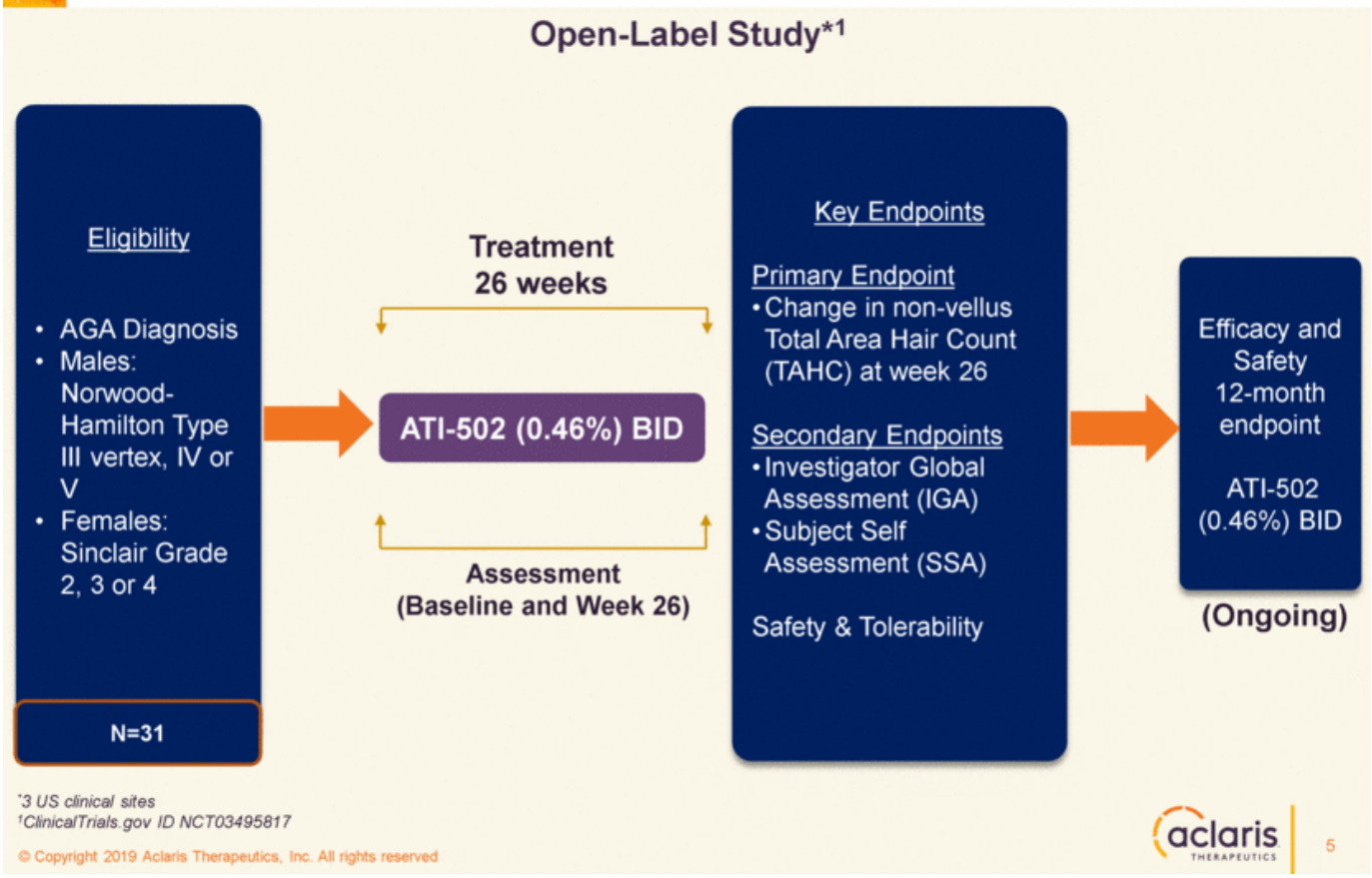
AGA-201: Male and Female Subjects With Androgenetic Alopecia (AGA) Treated With ATI-502



*3 US clinical sites
[1]ClinicalTrials.gov ID NCT03495817

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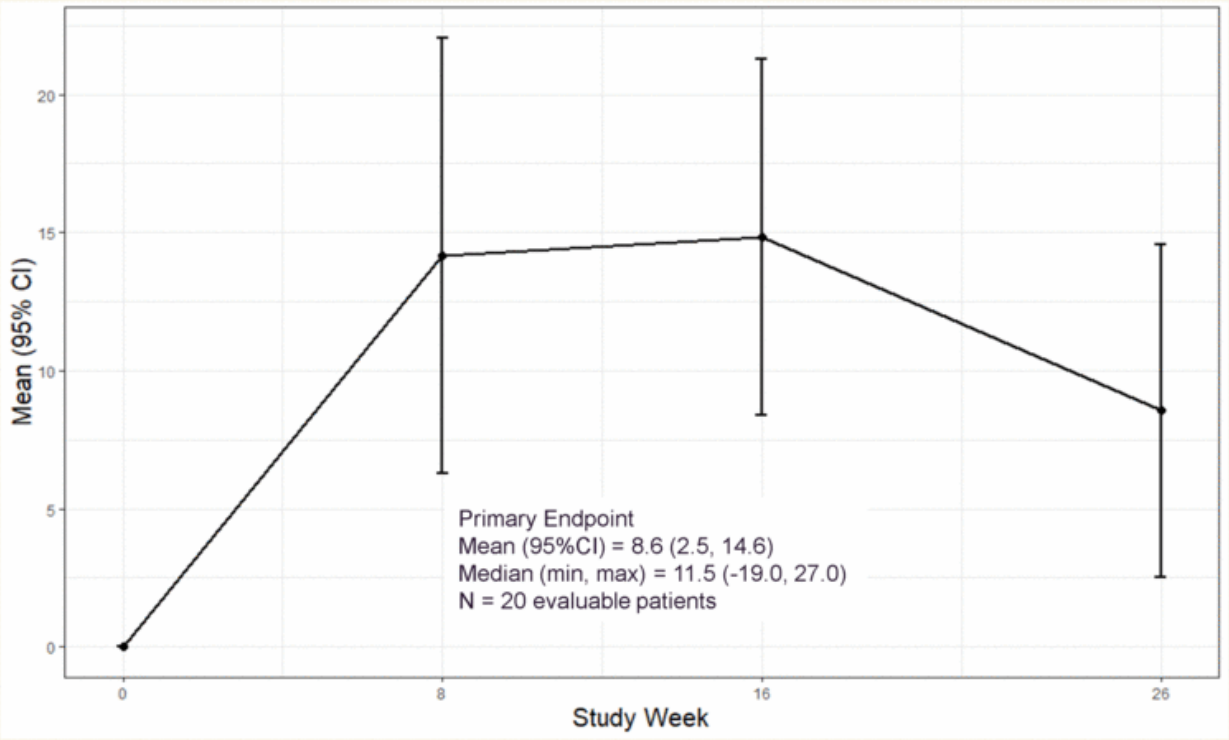
AGA-201: Primary Endpoint - Mean Change from Baseline in Non-Vellus Target Area Hair Count (TAHC) at Week 26



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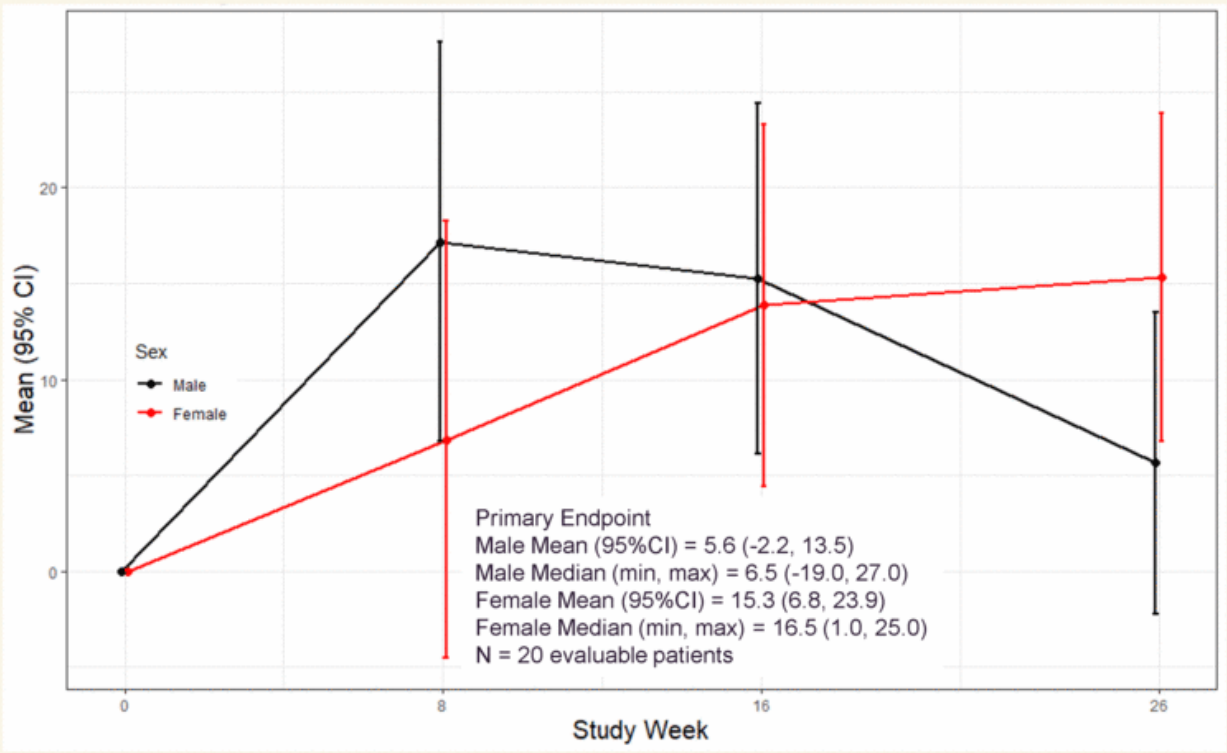
AGA-201: Primary Endpoint - Mean Change from Baseline in Non-Vellus Target Area Hair Count (TAHC) at Week 26 By Gender



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AGA-201: Secondary Endpoints - Investigator Global Assessment (IGA) and Subject Self-Assessment (SSA)

Response Rates for IGA and SSA

Sex (N)	Week	IGA N (%)	SSA N (%)
Male (15)	26	12/15 (80.0)	13/15 (86.7)
Female (7)	26	4/7 (57.1)	5/7 (71.4)
Total (22)	**26**	**16/22 (72.7)**	**18/22 (81.8)**

Grade	Description
-3	Greatly decreased hair growth
-2	Moderately decreased hair growth
-1	Slightly decreased hair growth
0	No change
+1	Slightly increased hair growth
+2	Moderately increased hair growth
+3	Greatly increased hair growth

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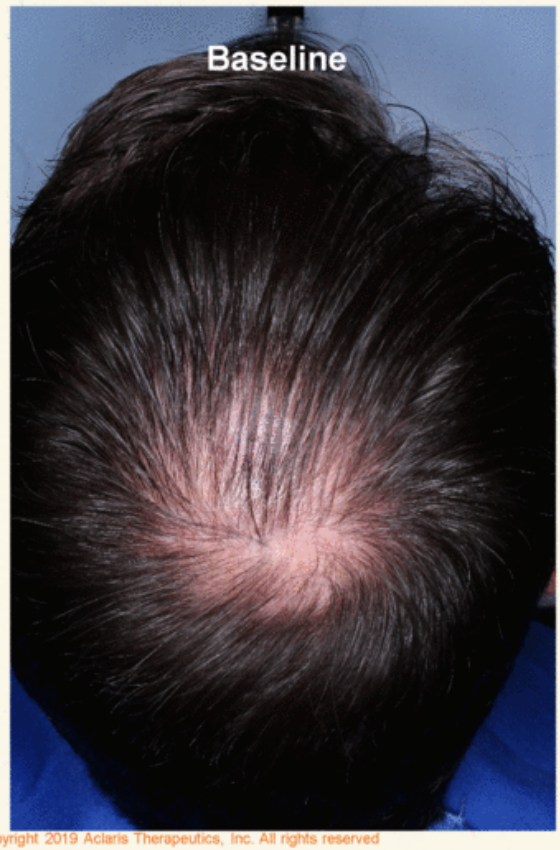
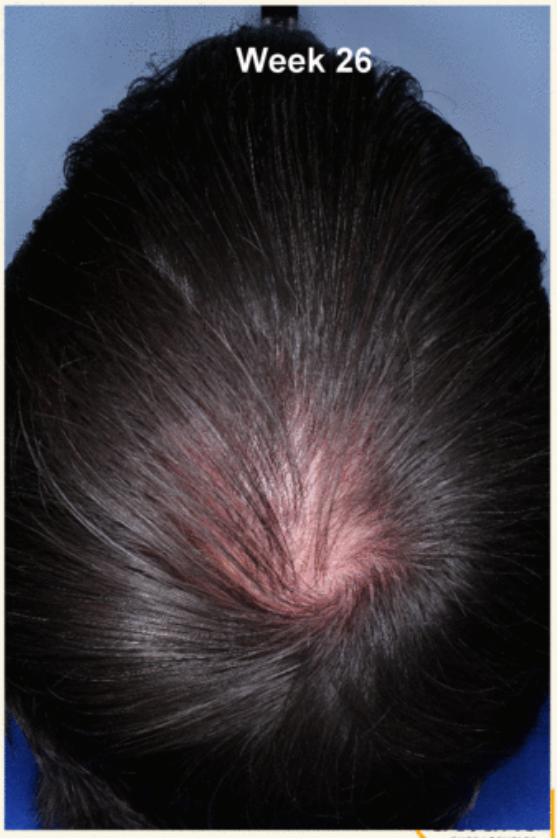
Subject 01-012 – 48 y/o Male

IGA	SSA	TAHC Δ
+3	+3	+11





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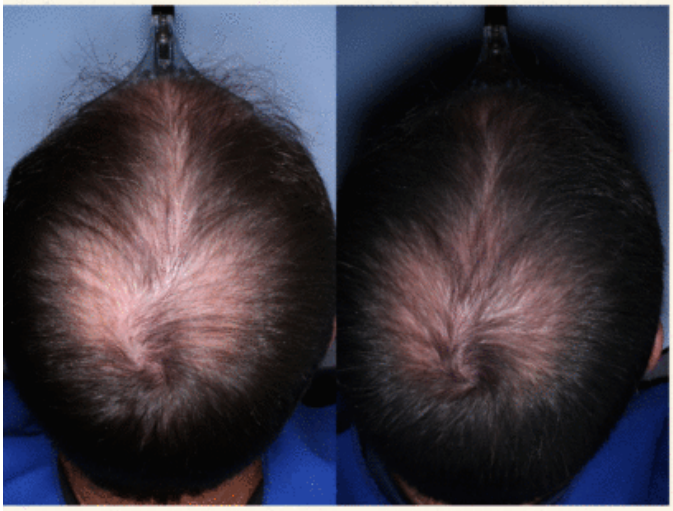
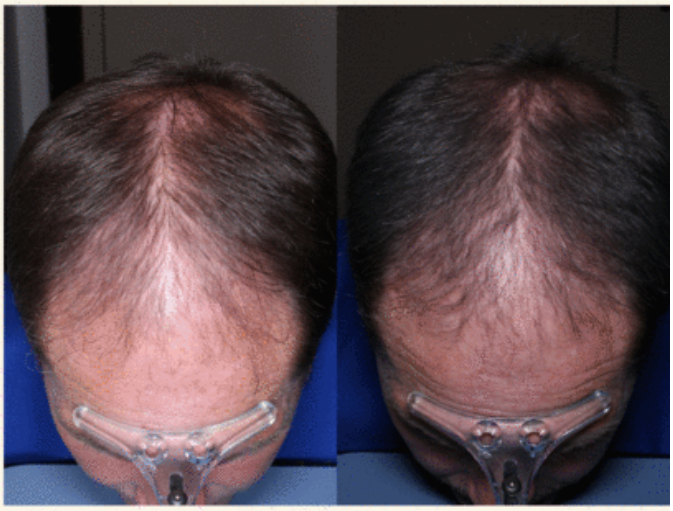
Subject 03-005 – 42 y/o Male

IGA	SSA	TAHC Δ
+1	+2	+24



Baseline Week 26



Baseline Week 26

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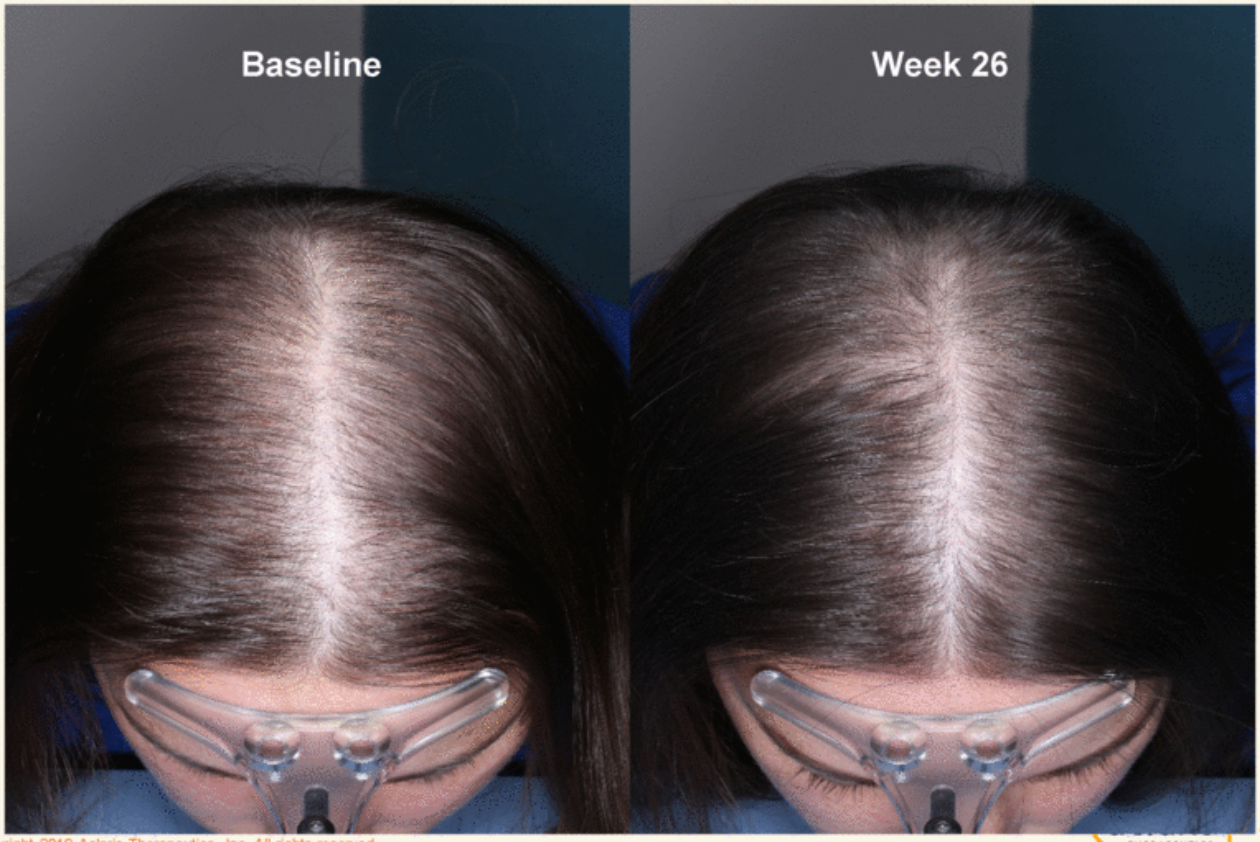
Subject 01-029 – 31 y/o Female

IGA	SSA	TAHC Δ
+1	+2	+15



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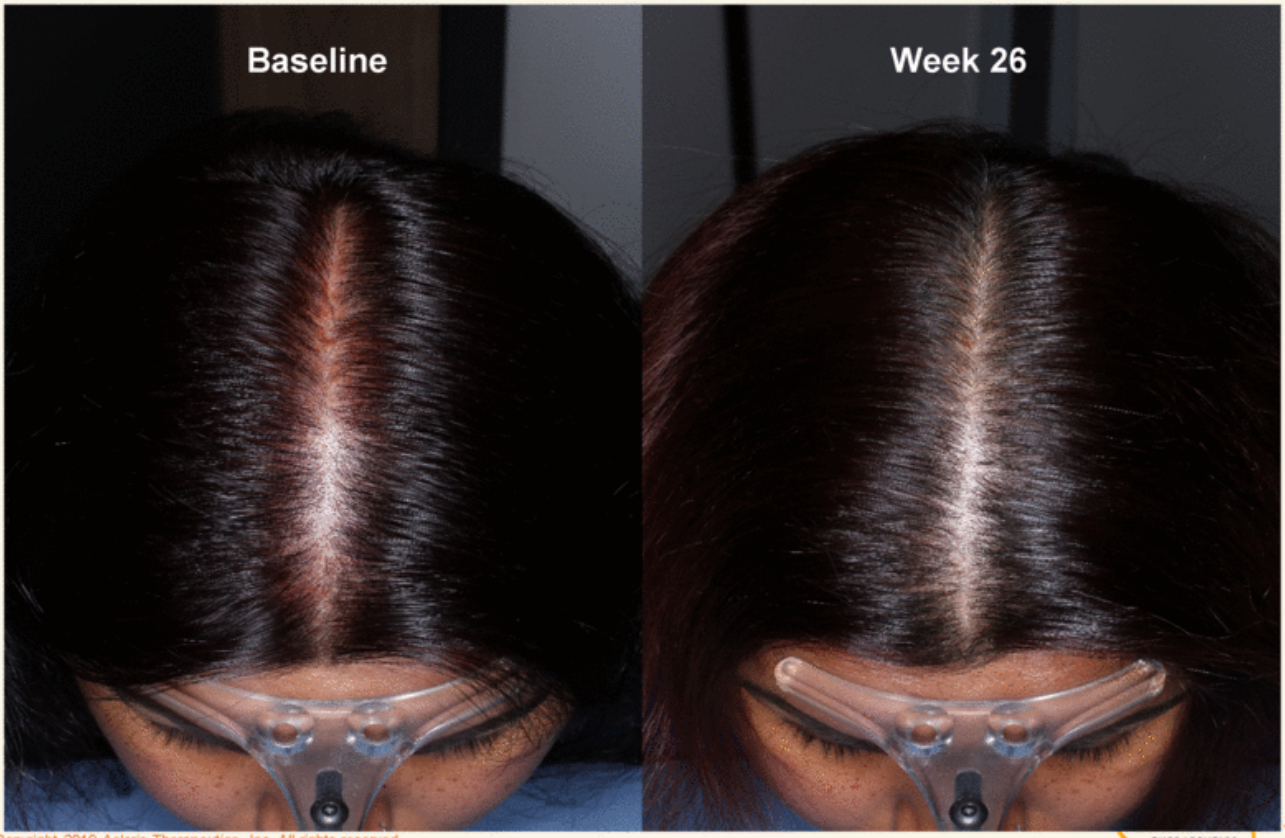
Subject 02-002 – 41 y/o Female

IGA	SSA	TAHC Δ
+2	+1	+18



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Safety Summary

- ATI-502 (0.46% concentration) was generally well-tolerated.
- No treatment-related serious adverse events (SAEs) reported in this study.
  - ✓ One subject had an unrelated SAE of breast cancer which led to withdrawal of study medication.
- Three additional subjects had adverse events (AEs) leading to discontinuation:
  - ✓ Alopecia assessed by the investigator as related to study medication
  - ✓ Unrelated event of herpes zoster,
  - ✓ Unrelated events of acne, constipation, amnesia, and photopsia.
- Two subjects experienced treatment-related AEs, one with folliculitis and one with pruritus.
- AEs occurring in > 1 subject were vertigo, upper respiratory infection, neck pain, and alopecia.

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Next Steps

- Design next clinical trial
  - ✓ Positive advisory board meeting with leading hair loss KOLs reinforced plan for definitive Phase 2 study
  - ✓ Double-blind, randomized, controlled Phase 2 clinical study with potentially female focus
  - ✓ Dose range with higher concentrations of ATI-502
- Market Research - assessment underway

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