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): July 30, 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 July 30, 2019, Aclaris Therapeutics, Inc. (the "***Company***") issued a press release announcing results from its Phase 2 clinical trial of ATI-501 (AUAT-201 Oral), an investigational oral Janus Kinase 1/3 inhibitor, in subjects with alopecia areata, 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 July 30, 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: July 30, 2019

Exhibit 99.1

Aclaris Therapeutics Announces Phase 2 Clinical Trial of ATI-501 Oral in Patients with Alopecia Areata Met Primary Endpoint

- ***ATI-501 achieved statistically significant improvement over placebo in several measures of hair growth, including the primary endpoint and certain secondary endpoints of the trial.***
- ***ATI-501 was generally well-tolerated at all doses. No serious adverse events or thromboembolic events were reported during the trial.***
- ***Patient population included moderate to severe Patchy Alopecia, Alopecia Universalis and Totalis***

Wayne, PA – July 30, 2019 (GLOBE NEWSWIRE) – Aclaris Therapeutics, Inc. (NASDAQ: ACRS), a physician-led biopharmaceutical company focused on immuno-inflammatory and dermatological diseases, today announced results from its Phase 2 clinical trial of ATI-501 (AUAT-201 Oral), an investigational oral Janus Kinase (JAK) 1/3 inhibitor, in subjects with alopecia areata (AA). Subjects treated with ATI-501 achieved statistically significant improvement over placebo in several measures of hair growth, including the primary endpoint and certain secondary endpoints of the trial.

AUAT-201 Oral, a Phase 2 randomized, double-blinded, parallel-group, placebo-controlled trial, evaluated the safety, efficacy, and dose response of three doses of ATI-501 on the regrowth of hair in 87 subjects with AA, including Patchy Alopecia, Alopecia Totalis and Alopecia Universalis. Subjects with 30% to 100% total scalp hair loss were randomized in a 1:1:1:1 ratio and received 24 weeks of treatment, twice daily, with either 400 mg, 600 mg or 800 mg of ATI-501 or a placebo oral suspension.

The primary endpoint of the trial was the mean percent change from baseline in the Severity of Alopecia Tool (SALT) score at week 24. Subjects in each of the three ATI-501 active dose groups (400 mg, 600 mg and 800 mg) had statistically significant improvements compared to placebo for the primary endpoint ($p=0.011$, $p=0.001$ and $p=0.010$, respectively).

Secondary endpoints for which subjects in all three active treatment arms of the trial also achieved statistically significant improvements at 24 weeks compared to placebo included the following:

- Absolute change in SALT scores from baseline: $p<0.05$ for all three ATI-501 doses;
- Alopecia Density and Extent (ALODEX) percent change from baseline: $p<0.05$ for all three ATI-501 doses; and
- ALODEX absolute change from baseline: $p<0.01$ for all three ATI-501 doses

Other exploratory secondary endpoints which were assessed were not statistically significant compared to placebo.

ATI-501 was observed to be generally well-tolerated at all doses. There were no serious adverse events reported. All adverse events (AEs) were mild or moderate in severity and rates of AEs were similar across all groups. No thromboembolic events were observed in the study. The most common AEs across all groups were: nasopharyngitis, influenza, upper respiratory tract infection, urinary tract infection, acne, blood creatine phosphokinase increased, and sinusitis. Two subjects in each of the placebo and 400 mg groups and one subject in the 600 mg group had AEs leading to discontinuation of study drug, with no such AEs in the 800 mg group.

“We are pleased with these results, and we thank the patients and the investigators who participated in this trial,” said Dr. David Gordon, the Chief Medical Officer of Aclaris.

Company to Host Conference Call

Management will conduct a conference call at 5:00 PM 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 2069789 prior to the start of the call.

About Alopecia Areata

Alopecia Areata (AA) is an autoimmune dermatologic condition typically characterized by patchy non-scarring hair loss on the scalp and body. More severe forms of AA include total scalp hair loss, known as alopecia totalis, and total hair loss on the scalp and body, known as alopecia universalis. The scalp is the most commonly affected area. Onset of AA may occur in childhood and most patients experience onset by age 40. The course of disease is unpredictable and may involve spontaneous hair regrowth and sudden hair loss. Over half of patients with AA experience poor health-related quality of life. The disease can be associated with serious psychological consequences, including anxiety and depression. AA affects up to 1.8% of people in the United States and 2.0% of people globally at some point during their lives.

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.

Aclaris Contact

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Corporate Strategy/Investor Relations
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EMPOWERING PATIENTS THROUGH
REVELATIONARY
SCIENCE

AUAT-201 Data

Phase 2 randomized, double-blinded, parallel-group, placebo-controlled trial, evaluated the safety, efficacy, and dose response of three doses of ATI-501 on the regrowth of hair in subjects with Alopecia Areata (AA).

JULY 2019

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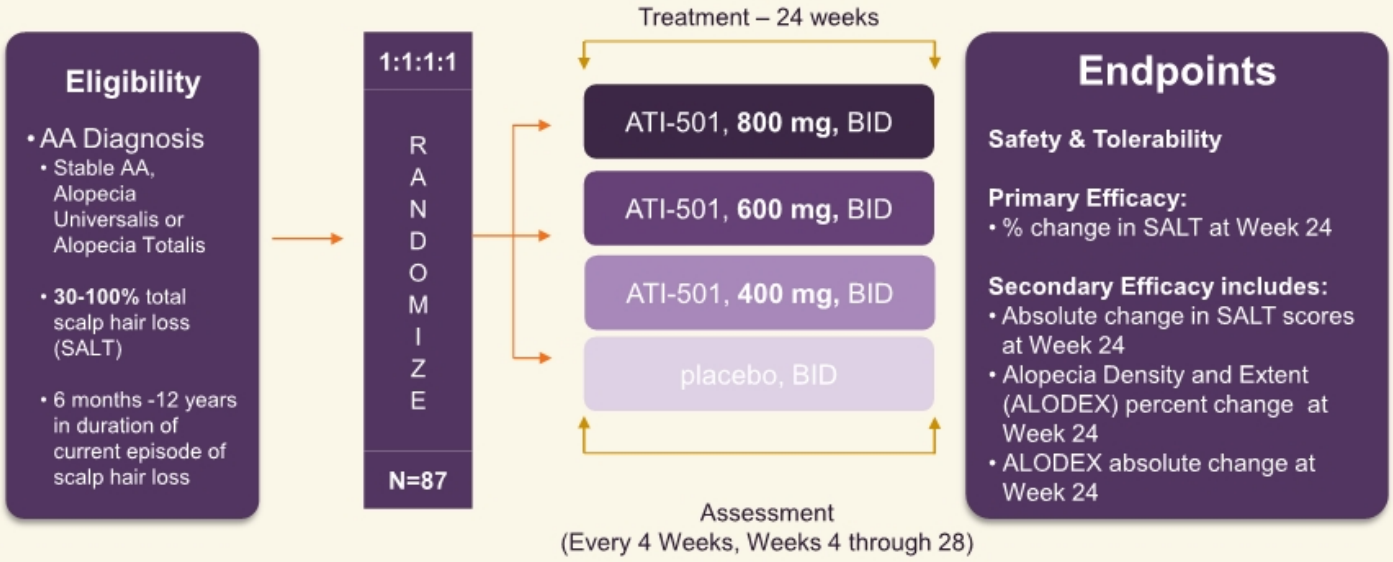
THERAPEUTICS

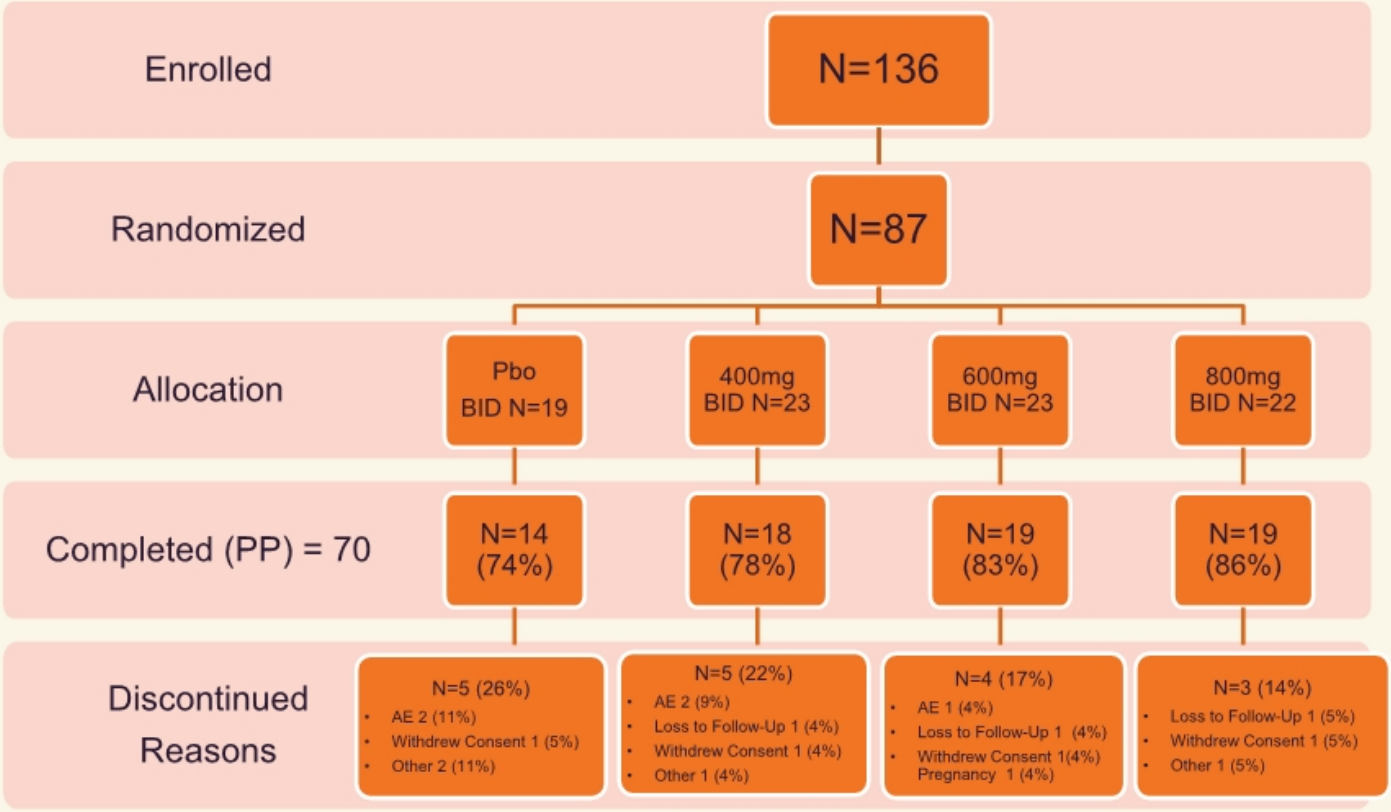
AUAT-201: Study Design

Randomized, Double-blind, Placebo-controlled Multicenter Study



25 US clinical sites
ClinicalTrials.gov ID NCT03594227

Subject Disposition



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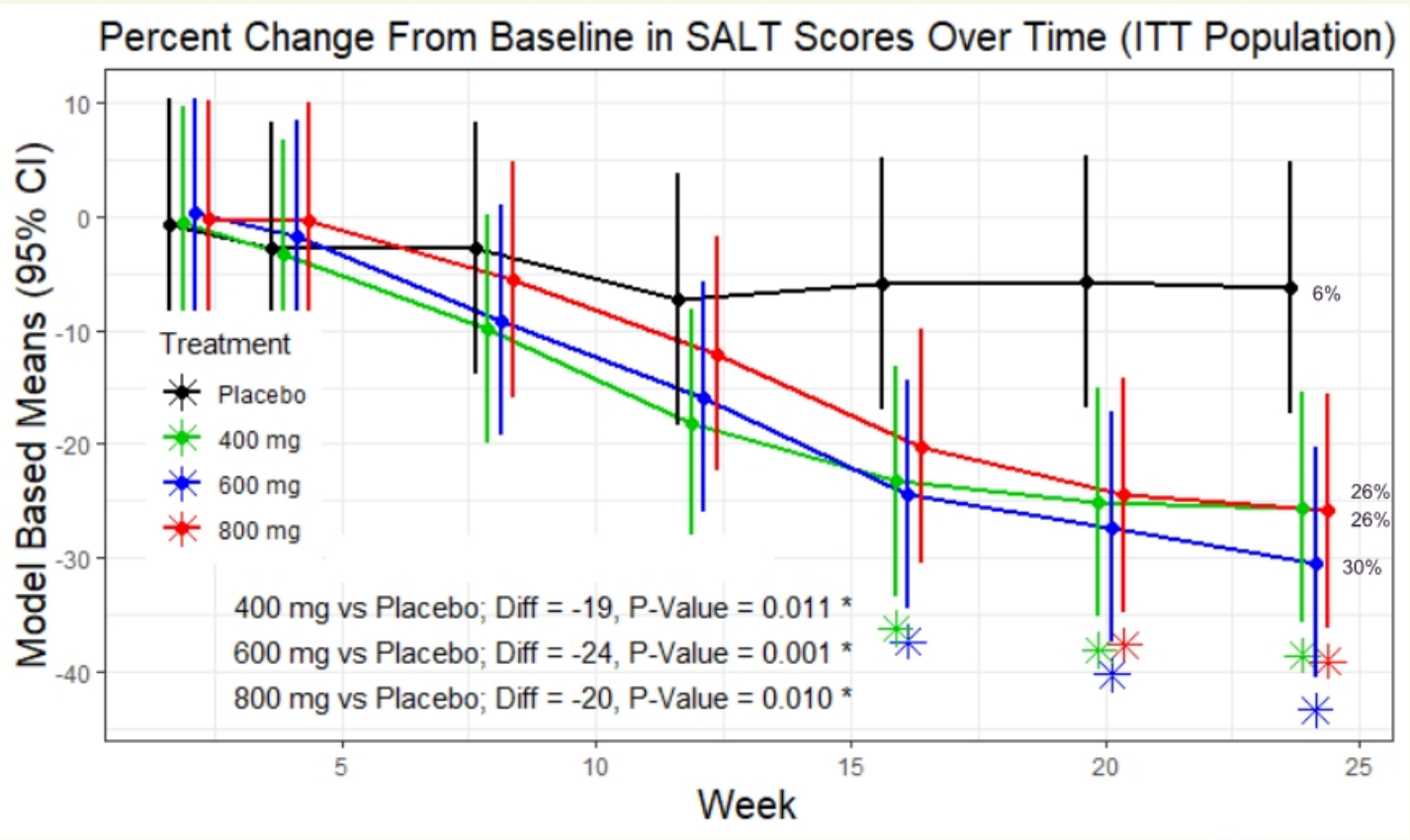
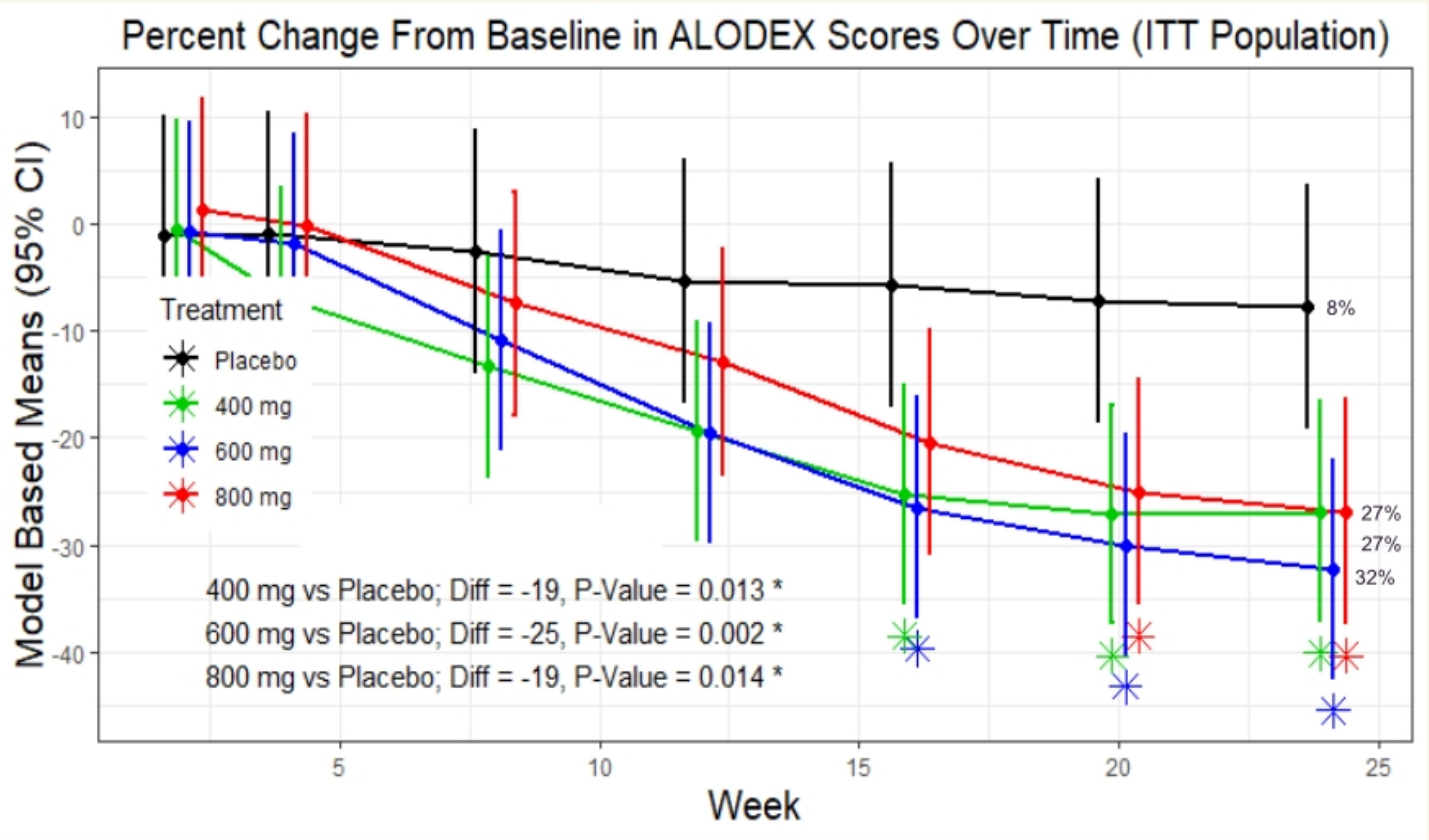
Demographics & Baseline Characteristics

	Pbo, BID N=19	400 mg, BID N=23	600 mg, BID N=23	800 mg, BID N=22
Age Mean (SD)	41.8 (16.01)	38.7 (12.99)	40.4 (13.56)	40.5 (12.44)
Sex Male N(%)	5 (26.3%)	6 (26.1%)	11 (47.8%)	9 (40.9%)
Sex Female N(%)	14 (73.7%)	17 (73.9%)	12 (52.2%)	13 (59.1%)
Race				
White	15 (78.9%)	17 (73.9%)	17 (73.9%)	14 (63.6%)
African American	3 (15.8%)	6 (26.1%)	3 (13.0%)	5 (22.7%)
Other	1 (5.3%)	0	3 (13.0%)	3 (13.6%)
Diagnosis				
Areata	9 (47.4%)	11 (47.8%)	14 (60.9%)	9 (40.9%)
Universalis	5 (26.3%)	4 (17.4%)	5 (21.7%)	7 (31.8%)
Totalis	5 (26.3%)	8 (34.8%)	4 (17.4%)	6 (27.3%)
Mean Duration of Alopecia (yrs, SD)	11.3 (12.04)	13.7 (11.01)	9.5 (9.78)	10.7 (11.36)
Mean Duration of Current Alopecia episode (yrs, SD)	4.9 (2.94)	4.3 (3.54)	3.6 (2.84)	3.4 (3.11)
Mean Baseline SALT (SD)	85 (24.9)	78 (26.7)	76 (23.4)	81 (25.8)

Primary Endpoint



Secondary Endpoint



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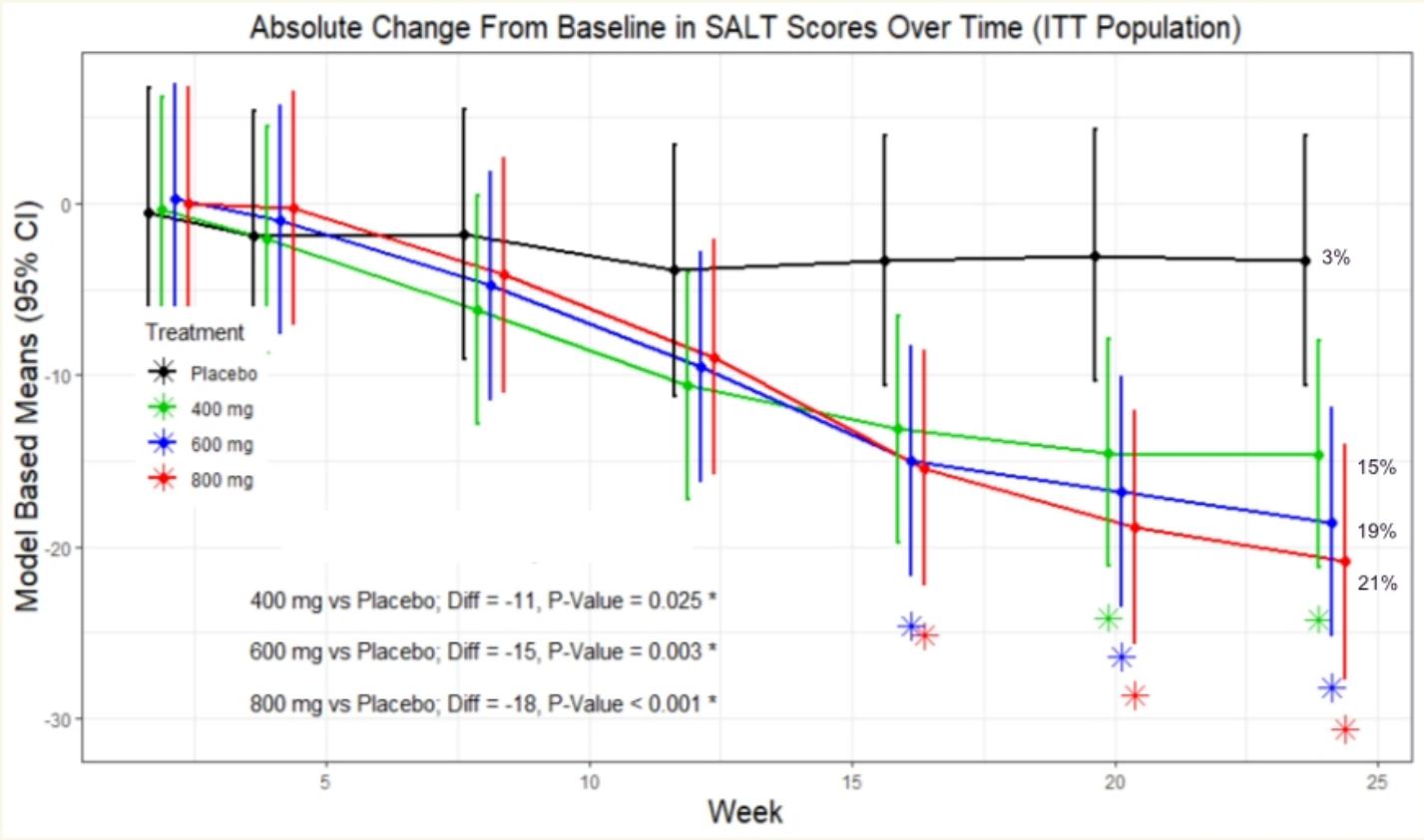
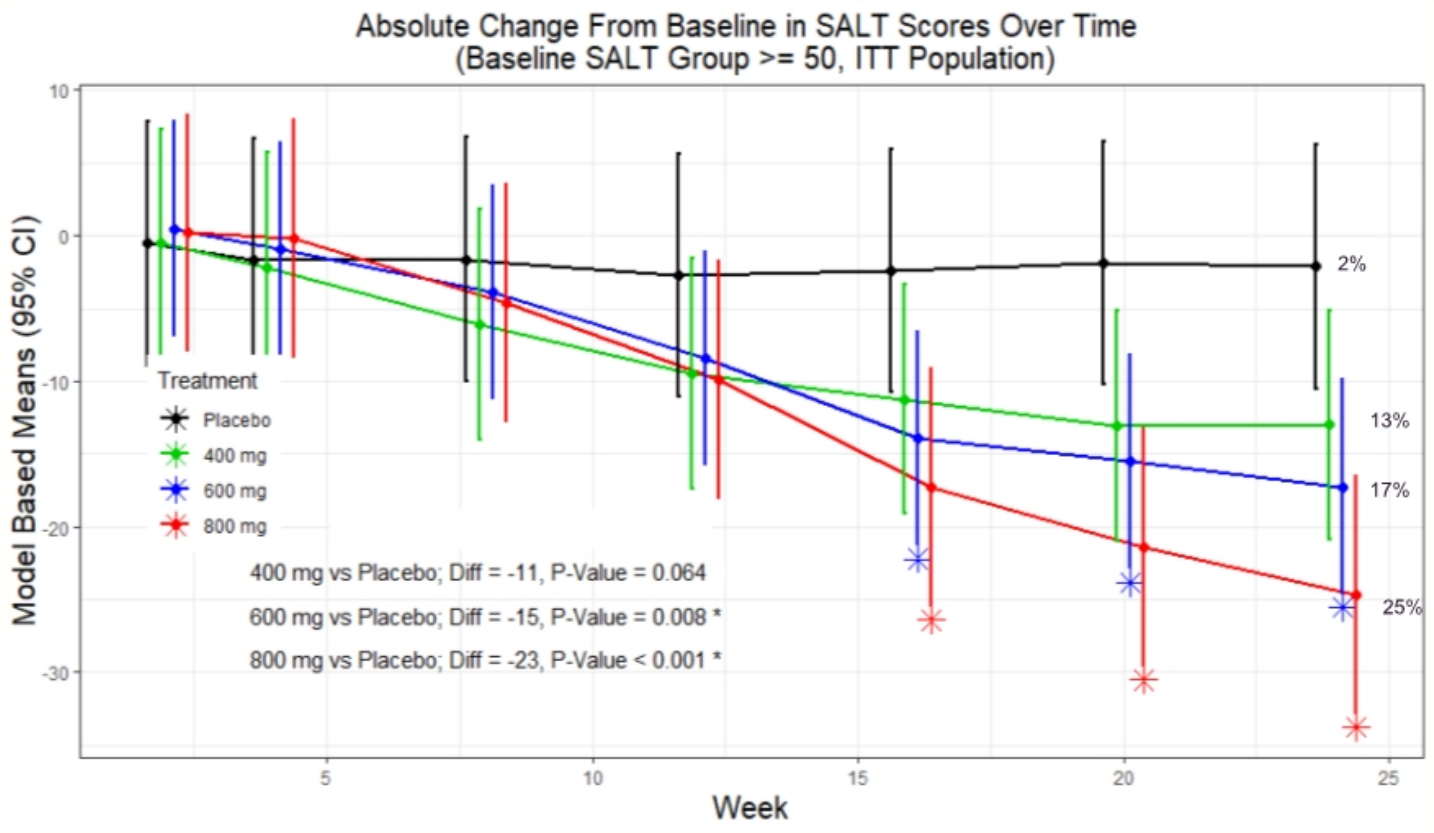
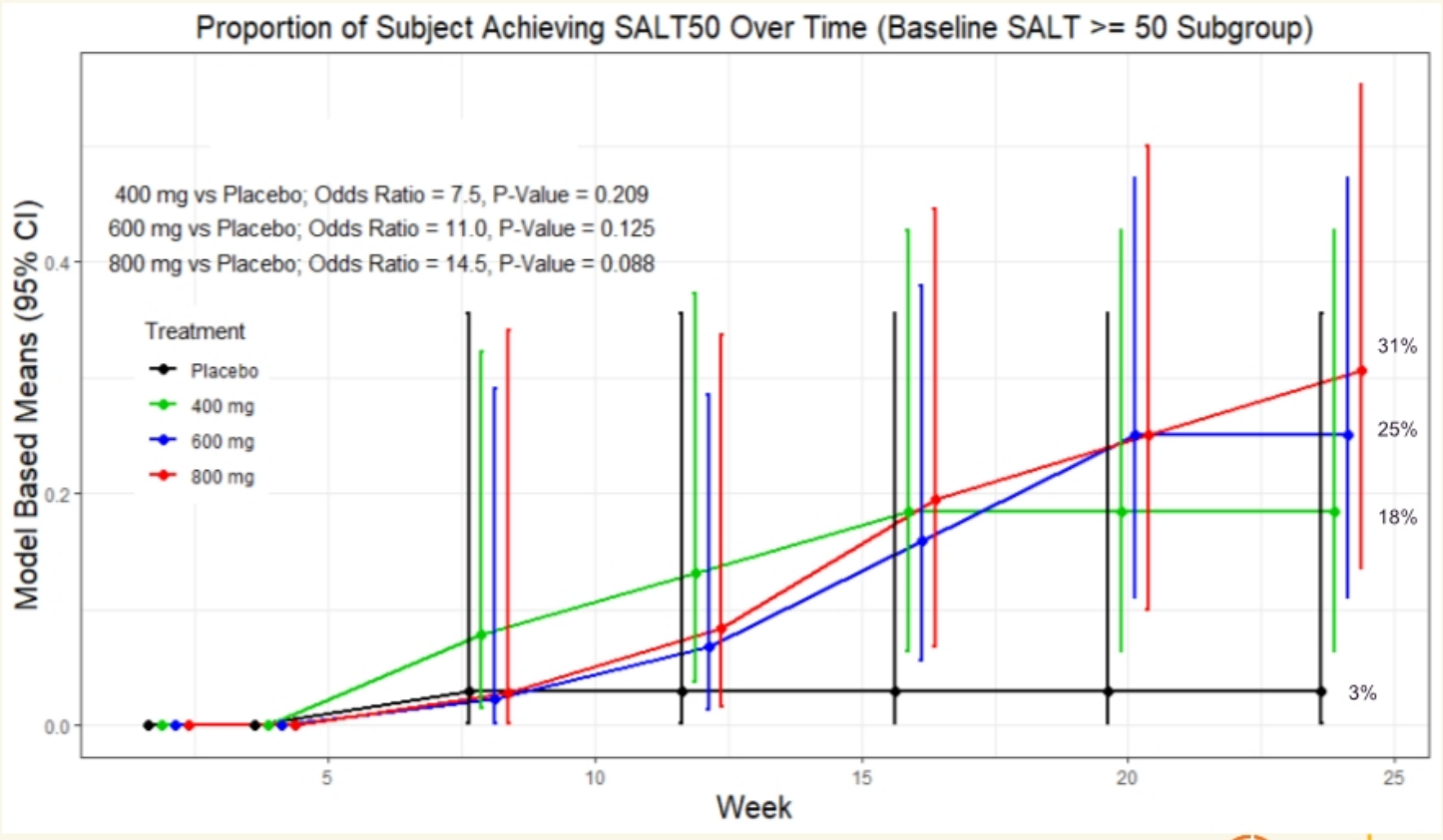


Secondary Endpoint

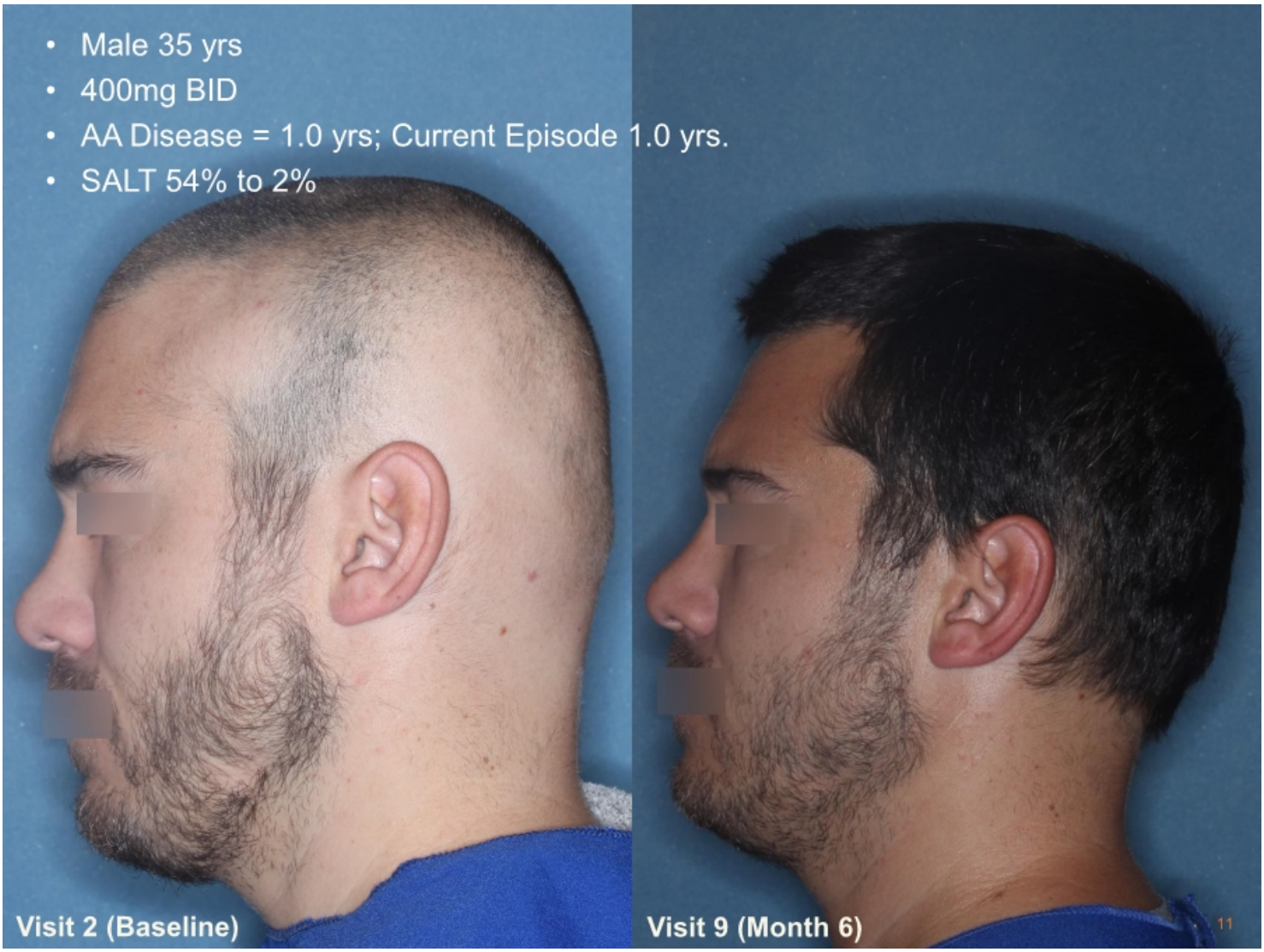


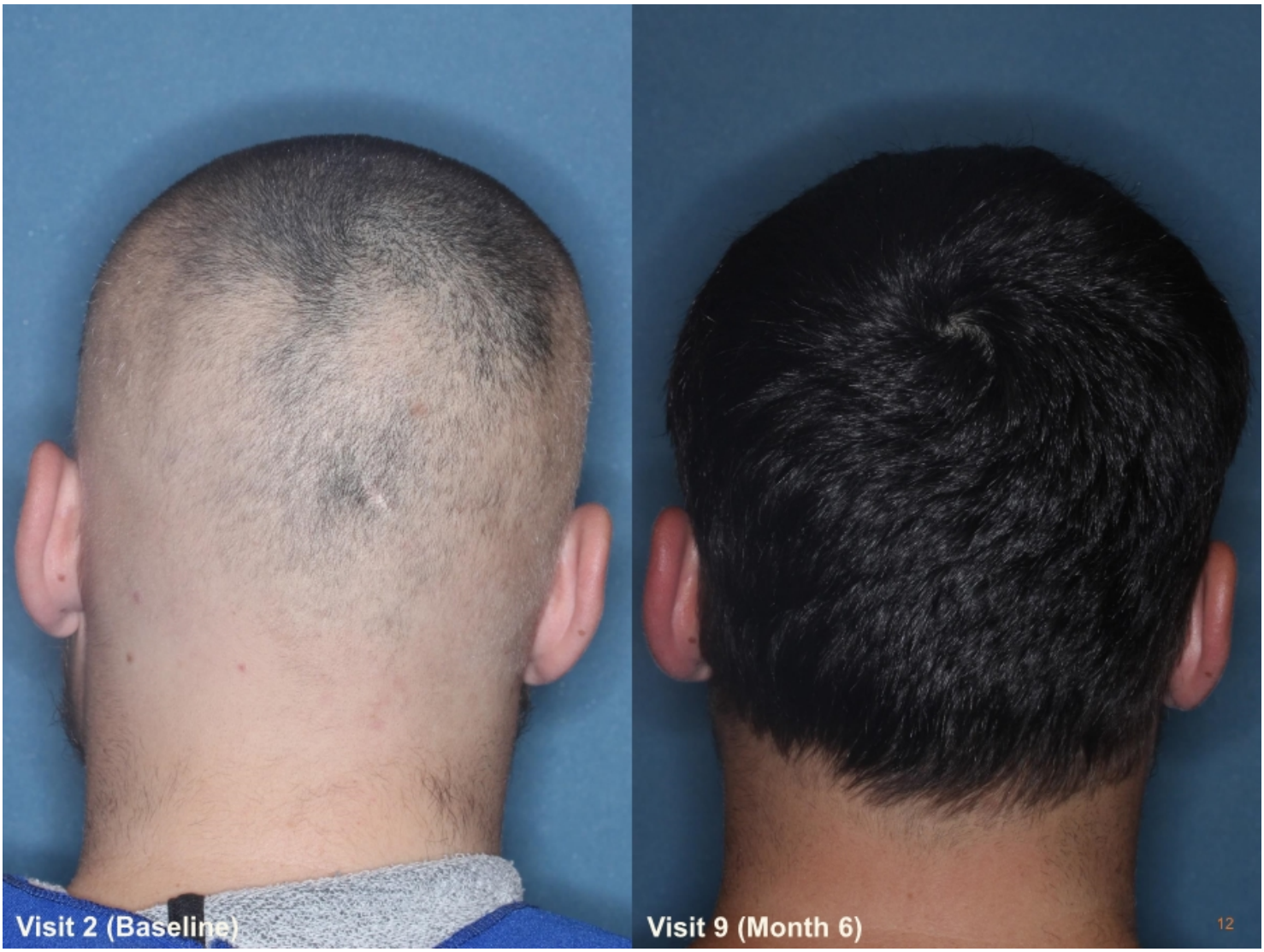
Secondary Endpoint



Overall Summary of Adverse Events (AEs)

	Placebo oral suspension (N=19)	ATI-501 oral suspension 400 mg BID (N=23)	ATI-501 oral suspension 600 mg BID (N=23)	ATI-501 oral suspension 800 mg BID (N=22)	All ATI-501 subjects (N=68)	All subjects (N=87)
Subjects with at least one AE	14 (73.7%)	16 (69.6%)	16 (69.6%)	15 (68.2%)	47 (69.1%)	61 (70.1%)
Subjects with at least one SAE	0	0	0	0	0	0
Subjects with at least one severe AE	0	0	0	0	0	0
Subjects with at least one related AE	3 (15.8%)	5 (21.7%)	2 (8.7%)	3 (13.6%)	10 (14.7%)	13 (14.9%)
Subjects with at least one AE leading to discontinuation of study drug	2 (10.5%)	2 (8.7%)	1 (4.3%)	0	3 (4.4%)	5 (5.7%)
Subjects with at least one related AE leading to discontinuation of study drug	1 (5.3%)	1 (4.3%)	0	0	1 (1.5%)	2 (2.3%)

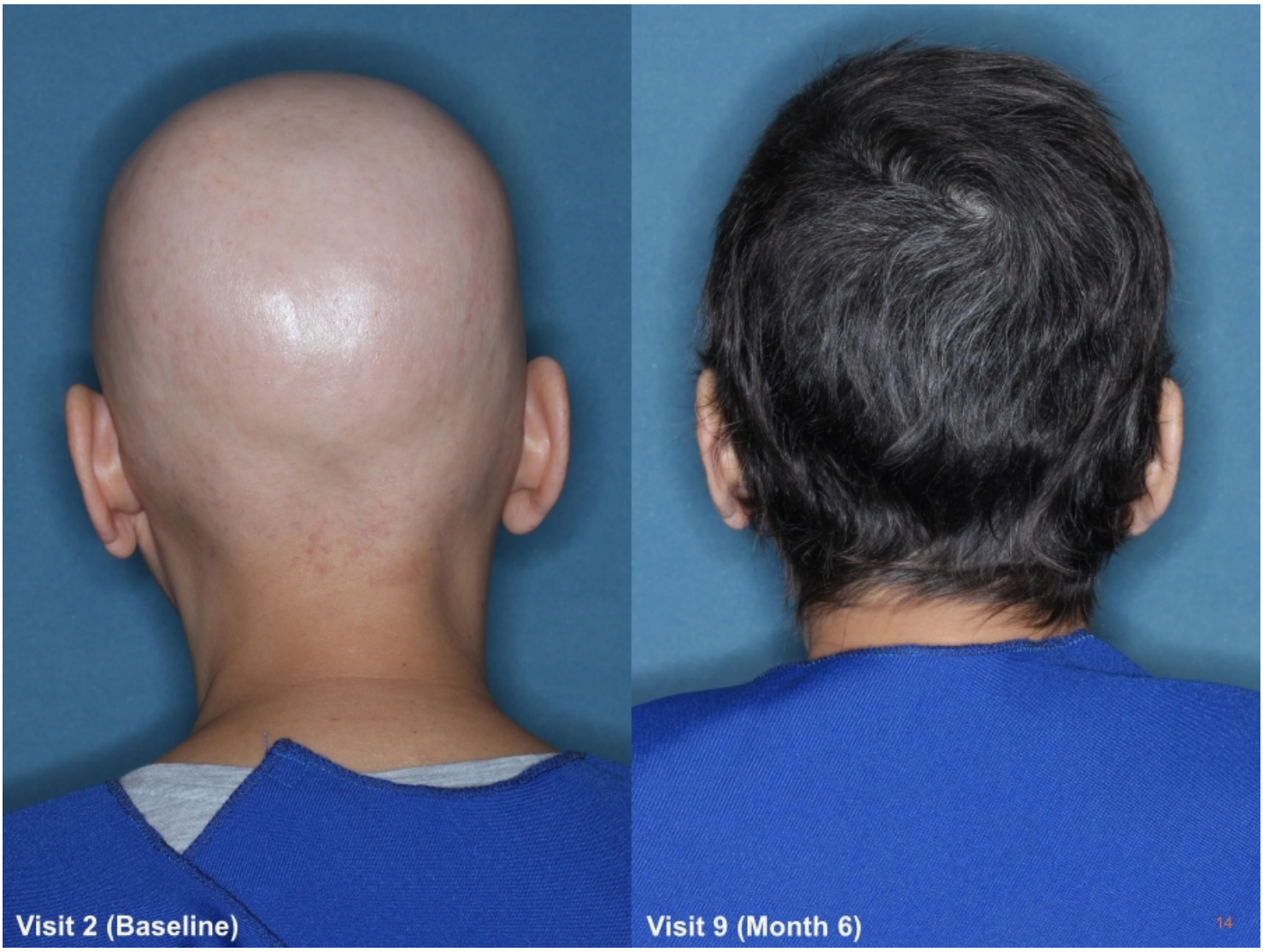

• Male 35 yrs
• 400mg BID
• AA Disease = 1.0 yrs; Current Episode 1.0 yrs.
• SALT 54% to 2%
Visit 2 (Baseline)
Visit 9 (Month 6)
11

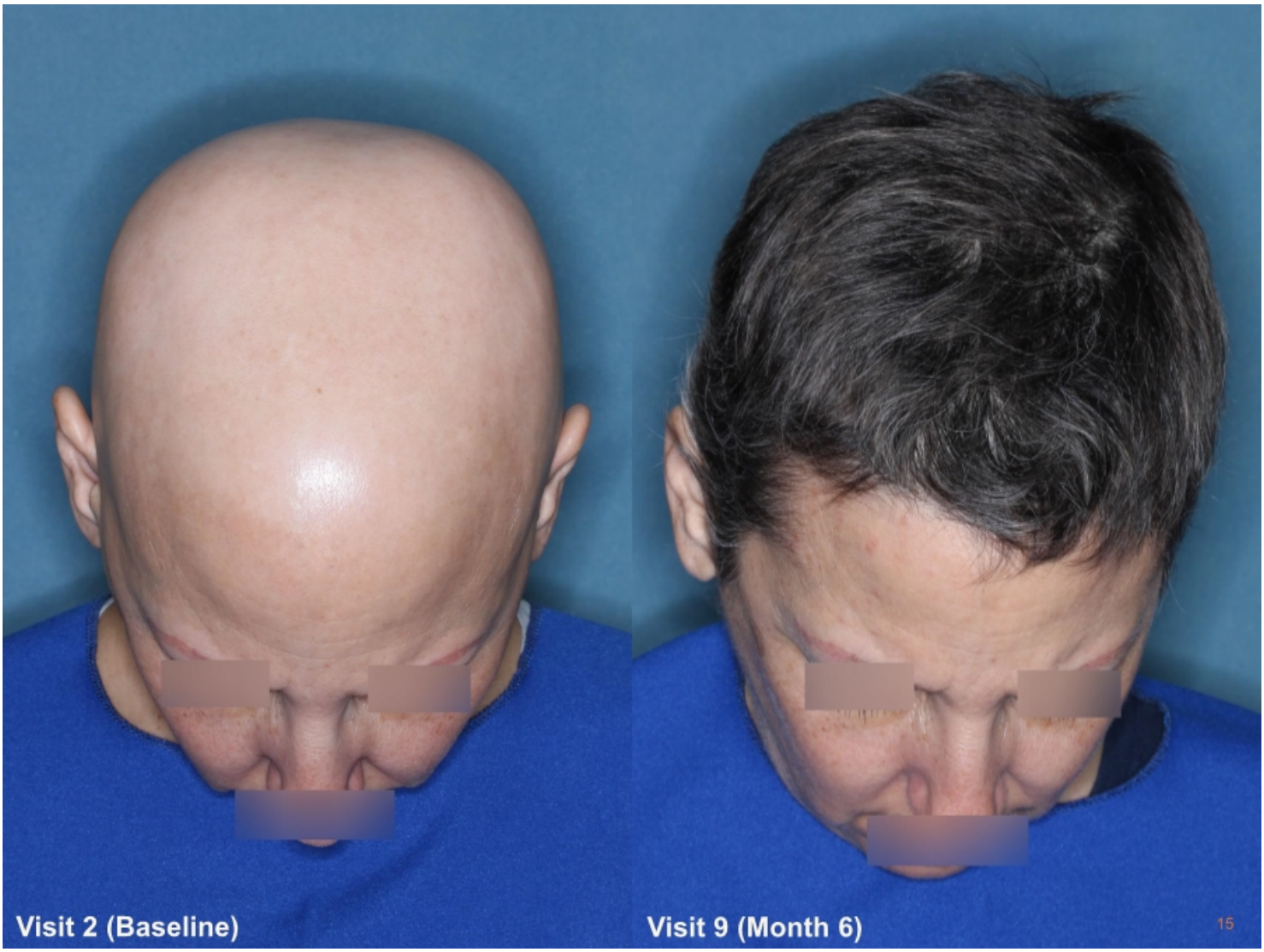

Visit 2 (Baseline)
Visit 9 (Month 6)

- Female 48 yrs
- 600mg BID
- AA Disease = 38.7 yrs; Current Episode 1.1 yrs
- SALT 100% to 0%.

Visit 2 (Baseline)

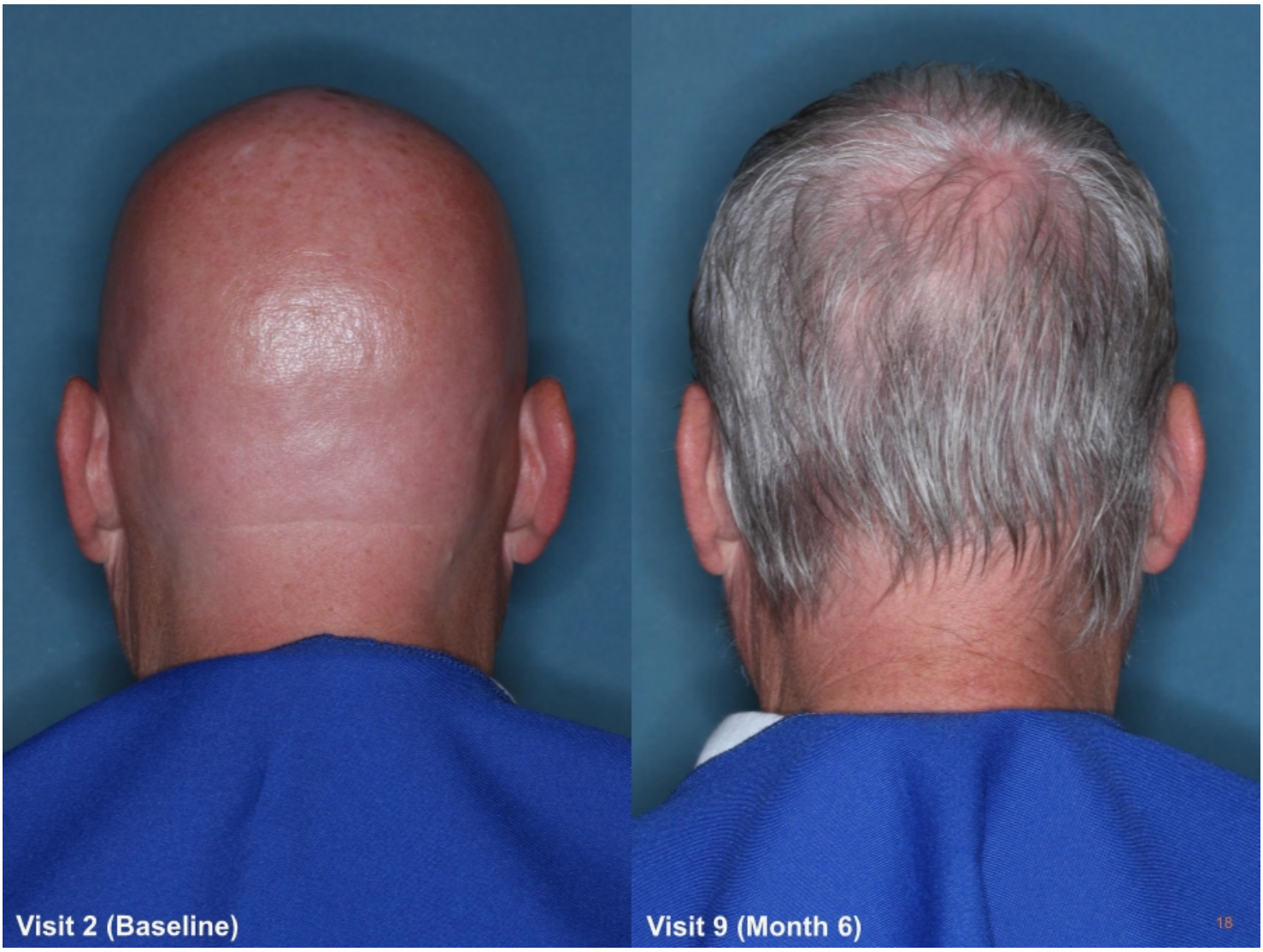
Visit 9 (Month 6)


Visit 2 (Baseline)
Visit 9 (Month 6)


Visit 2 (Baseline)
Visit 9 (Month 6)


• Male 53 yrs
• 800mg BID
• AA Disease = 23.6 yrs; Current Episode 4.6 yrs.
• SALT 100% to 17%.
Visit 2 (Baseline)
Visit 9 (Month 6)
16


Visit 2 (Baseline)
Visit 9 (Month 6)


Visit 2 (Baseline)
Visit 9 (Month 6)

Summary

- Subjects in each of the three ATI-501 active dose groups (400 mg, 600 mg and 800 mg) had statistically significant improvements compared to placebo for the primary endpoint (p=0.011, p=0.001 and p=0.010, respectively).

- ATI-501 was generally well-tolerated at all doses.
  - ✓ There were no serious adverse events
  - ✓ All adverse events AEs) were mild or moderate in severity
  - ✓ No thromboembolic events observed
  - ✓ The most common AEs across all groups were: nasopharyngitis, influenza, upper respiratory tract infection, urinary tract infection, acne, blood creatine phosphokinase increased, and sinusitis

THANK YOU

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