UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): December 17, 2018

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))

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 December 17, 2018, Aclaris Therapeutics, Inc. (the "***Company***") issued a press release to provide updated data from three clinical trials for ATI-502, an investigational topical Janus kinase ("***JAK***") 1/3 inhibitor, an update on the expected release of topline data for one clinical trial for ATI-502, and an enrollment update for a clinical trial for ATI-501, an investigational oral JAK 1/3 inhibitor. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

Management of the Company will also host a conference call at 5:00 PM ET on December 17, 2018 to discuss these updates. A copy of the presentation that will accompany the call is furnished 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 December 17, 2018.
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: December 17, 2018

Exhibit 99.1

Aclaris Therapeutics Provides Update on Oral and Topical JAK 1/3 Inhibitor Clinical Trials

- Conference call to be held and accompanying slide deck with photos to be included with Current Report on Form 8-K

WAYNE, Pa., December 17, 2018 (GLOBE NEWSWIRE) -- Aclaris Therapeutics, Inc. (NASDAQ:ACRS), a dermatologist-led biopharmaceutical company committed to identifying, developing, and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology, today provided updated data from three clinical trials for ATI-502, an investigational topical Janus kinase (JAK) 1/3 inhibitor, an update on the expected release of topline data for one clinical trial for ATI-502, and an enrollment update for a clinical trial for ATI-501, an investigational oral JAK 1/3 inhibitor.

AA-202 Topical and AUATB-201 Topical are ongoing Phase 2 clinical trials of ATI-502 for the treatment of alopecia areata (AA) in the United States and Australia, respectively. In AA-202 Topical, 11 patients with the more severe forms of AA, alopecia universalis (AU) and alopecia totalis (AT), were treated with ATI-502 in an initial double-blind pharmacokinetic and pharmacodynamic study for 28 days before entering a 12-month open-label extension. In AUATB-201 Topical, an open-label clinical trial, 12 patients with eyebrow loss due to AA, including patients with AU or AT, had their eyebrows treated with ATI-502 for 6 months. VITI-201 Topical is an open-label pilot clinical trial of ATI-502 administered twice daily in 34 patients with non-segmental facial vitiligo.

As announced in November, Aclaris completed enrollment of AA-201 Topical, a randomized, double-blinded, parallel-group, placebo-controlled trial to evaluate the safety, efficacy and dose response of two concentrations of ATI-502 for the treatment of AA. This trial enrolled 129 patients with patchy AA, who were randomized to receive either ATI-502 or placebo. The primary efficacy endpoint is the mean change from baseline in the Severity of Alopecia Tool (SALT) score at Week 24. Topline data from the AA-201 Topical trial are now expected in the second quarter of 2019.

In addition, Aclaris announced today that it has completed enrollment of AUAT-201 Oral, a randomized, double-blinded, parallel-group, placebo-controlled trial to evaluate the safety, efficacy and dose response of three concentrations of ATI-501 oral suspension for the treatment of AA. This trial enrolled 87 patients with AA, including AT and AU, who were randomized to receive either ATI-501 or placebo. The primary efficacy endpoint is the mean change from baseline in the SALT score at Week 24. Topline data from the AUAT-201 Oral trial are now expected in the third quarter of 2019.

“AA can be a psychologically devastating disease for which many patients do not have adequate options for treatment. Inhibition of the JAK1 and JAK3 pathways is an emerging therapeutic

approach. We continue to advance our development programs for oral and topical formulations of JAK inhibitors with the goal of addressing the full spectrum of disease severity for patients living with AA," said Dr. David Gordon, Chief Medical Officer of Aclaris.

Aclaris to Host Conference Call

Management will conduct a conference call at 5:00 PM ET today to discuss these updates. The conference call will be webcast live over the Internet and can be accessed on the Events section of the Investors page of the Aclaris website at https://investor.aclaristx.com/events. A replay of the webcast will be archived on the Aclaris website for 30 days following the call. An accompanying slide deck with photos will be included as an exhibit to a Current Report on Form 8-K that Aclaris will furnish to the SEC today.

To participate on the live call, please dial (844) 776-7782 (domestic) or (661) 378-9535 (international), and reference **conference ID 3119988** prior to the start of the call.

About Alopecia Areata

Alopecia areata (AA) is an autoimmune disease characterized by partial or complete loss of hair on the scalp, face or body. 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 dermatologist-led biopharmaceutical company focused on identifying, developing, and commercializing innovative therapies to address significant unmet needs in dermatology, both aesthetic and medical, and immunology. Aclaris' focus on market segments with no FDA-approved medications or where treatment gaps exist has resulted in the first FDA-approved treatment for raised seborrheic keratoses and several clinical programs to develop medications for the potential treatment of common warts, alopecia areata, and vitiligo. For additional information, please visit www.aclaristx.com and follow Aclaris on LinkedIn.

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 Aclaris' clinical development of its drug candidates, including the timing for initiation and

completion of planned clinical trials and the availability of data from these 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 filed for the year ended December 31, 2017, Aclaris' Quarterly Report on Form 10-Q filed earlier for the quarter ended September 30, 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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Exhibit 99.2

R&D Update

ATI-502 Topical JAK 1/3 Inhibitor

Alopecia Areata

Vitiligo

ATI-501 Oral JAK 1/3 Inhibitor

Alopecia Areata

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December 17, 2018

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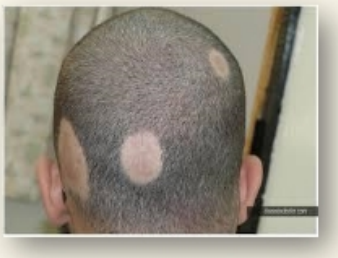
Important steps in defining the therapeutic regimen

- Positive proof of principle of the use of a topical JAK 1/3 to treat:
  - Alopecia areata (AA)
  - Vitiligo
- Provide insight into the emotional burden of AA and vitiligo
- Elucidate the potential role of topical therapy in patients with patchy AA, alopecia totalis (AT) and alopecia universalis (AU)
  - First step in defining the risk/benefit of the topical approach
  - PK/PD study in patients with severe AT/AU (mean duration of disease = 13.7 years)
  - Site specific (Eyebrow) study conducted in Australia to demonstrate efficacy with topical approach (mean duration of disease = 11.1 years)

Alopecia Areata – 1.8% of the US Population

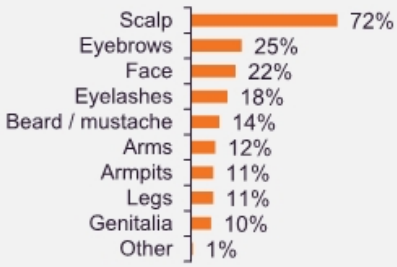
Alopecia Areata Cases in the US

5.8M

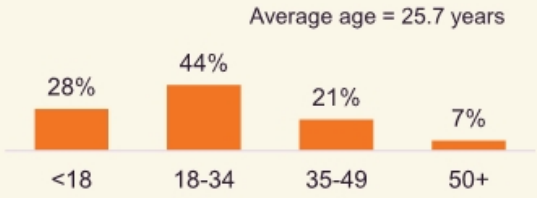


Highest frequency areas highlighted

COMMON BODY LOCATIONS



AGE & OTHER DEMOGRAPHICS



SYMPTOM FREQUENCY

Always	**32%**
At least once per month	**18%**
Every few months	**20%**
At least once per year	**12%**
Less than once per year	**6%**
First occurrence	**12%**

Source: Phoenix Market Research, November 2018

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AUATB-201 Topical

Australian Eyebrow Study

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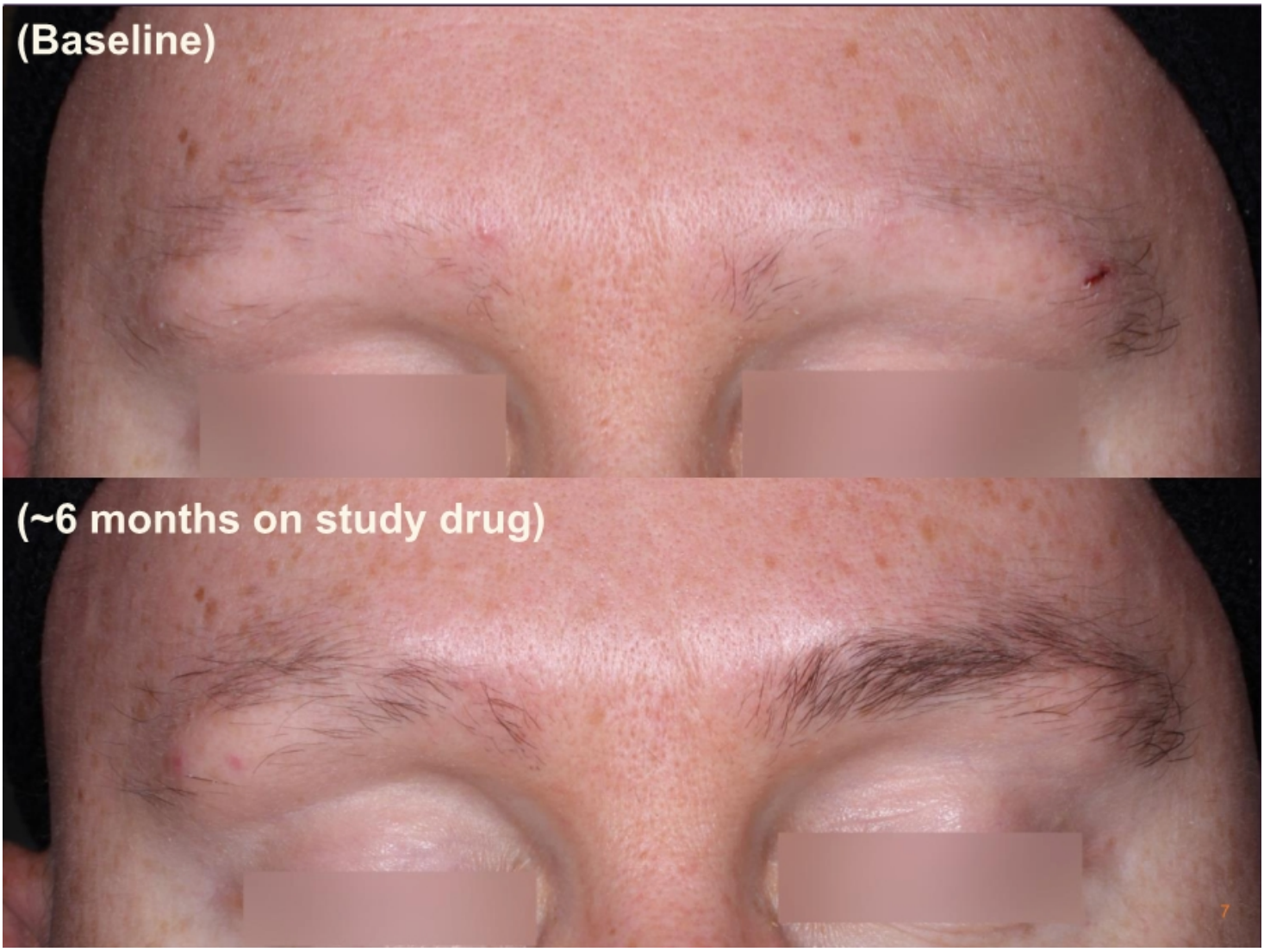
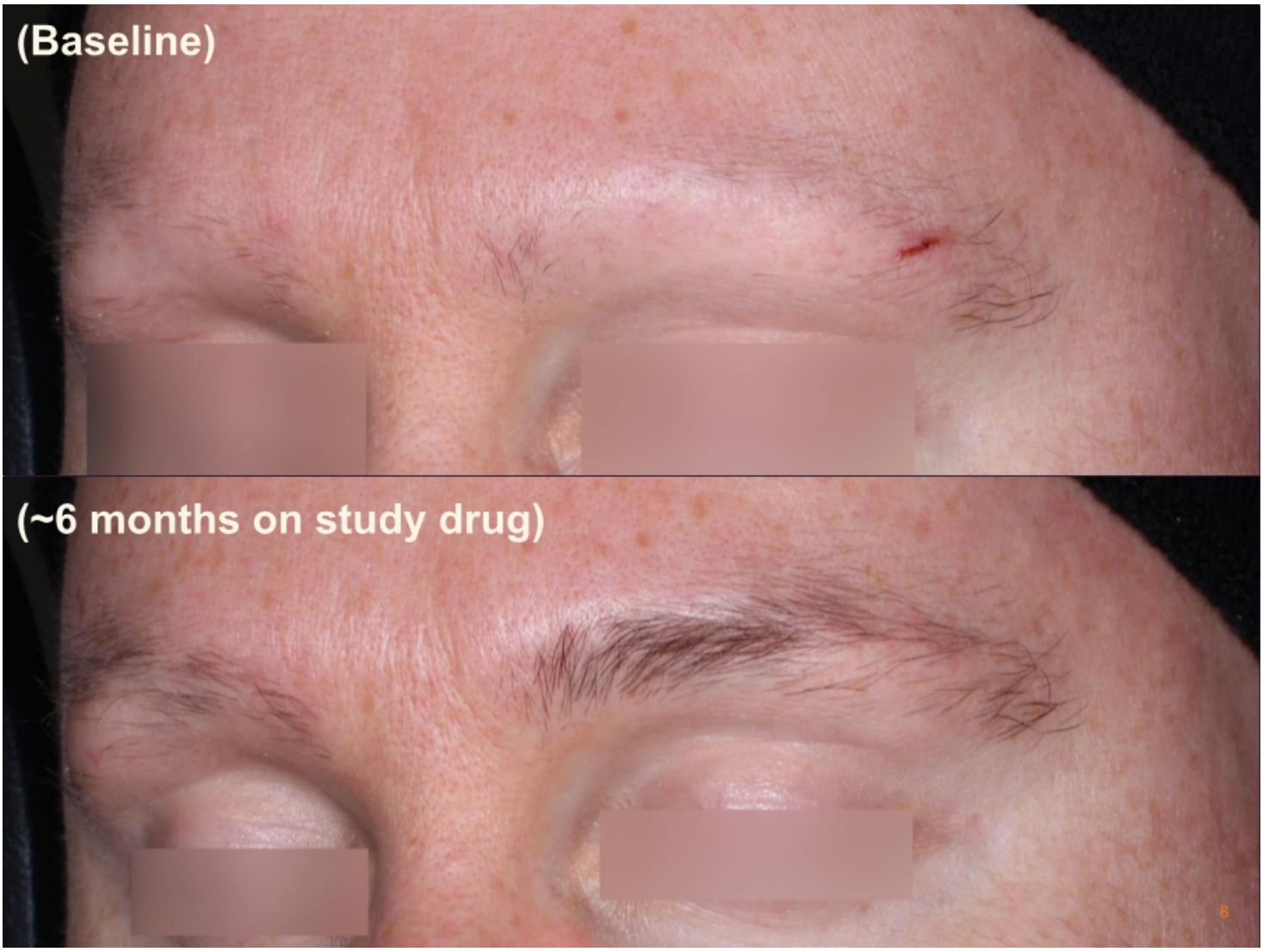
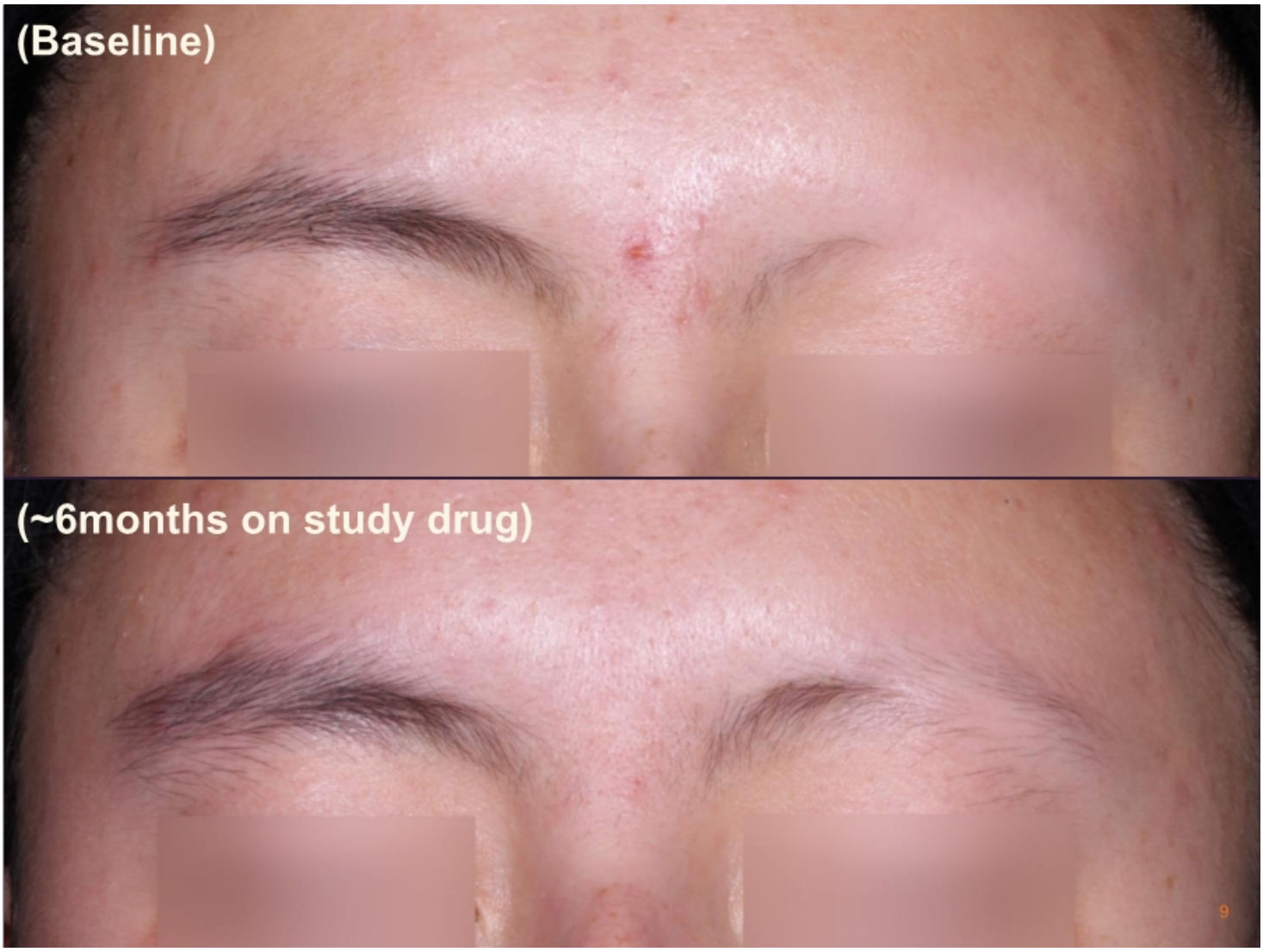
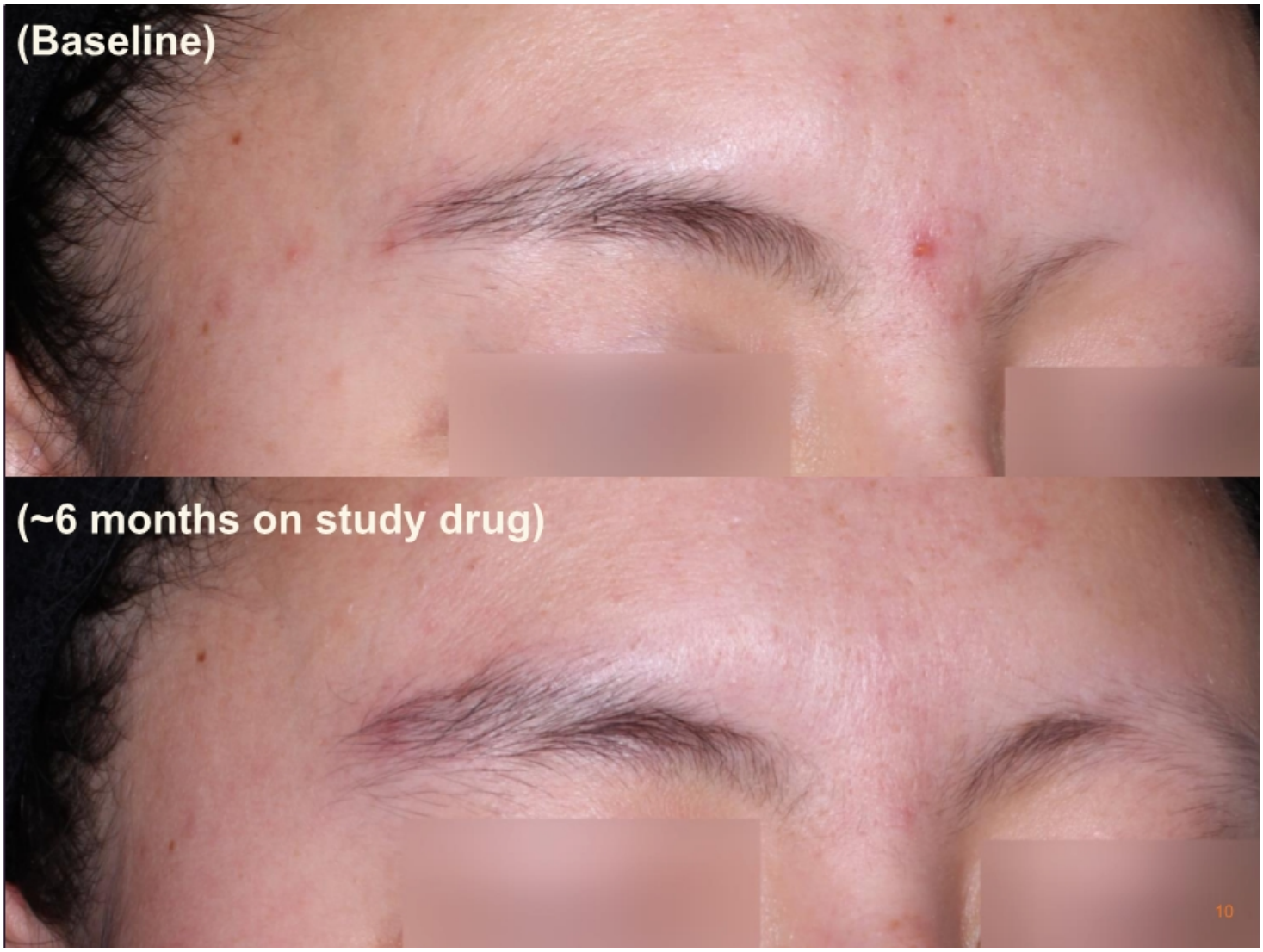
AUATB-201 Topical

- An ongoing Phase 2 open-label clinical trial of ATI-502, a topical JAK 1/3 inhibitor, for the treatment of AA in Australia.
- In this trial, Aclaris is evaluating the safety and efficacy of ATI-502 on the regrowth of eyebrows in patients with AA, including patients with AT and AU.
  - 12 patients enrolled
  - Average duration of disease = 11.1 years
  - 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])
  - 4 patients withdrew after receiving ≤ 3 months of drug
- Safety results - generally well-tolerated; no treatment-related serious adverse events reported to date.


(Baseline)
(~6 months on study drug)


(Baseline)
(~6 months on study drug)


(Baseline)
(~6months on study drug)
9


(Baseline)
(~6 months on study drug)
10

AA-202 Topical

28 Day PK/PD Study with 12-Month Open Label Extension

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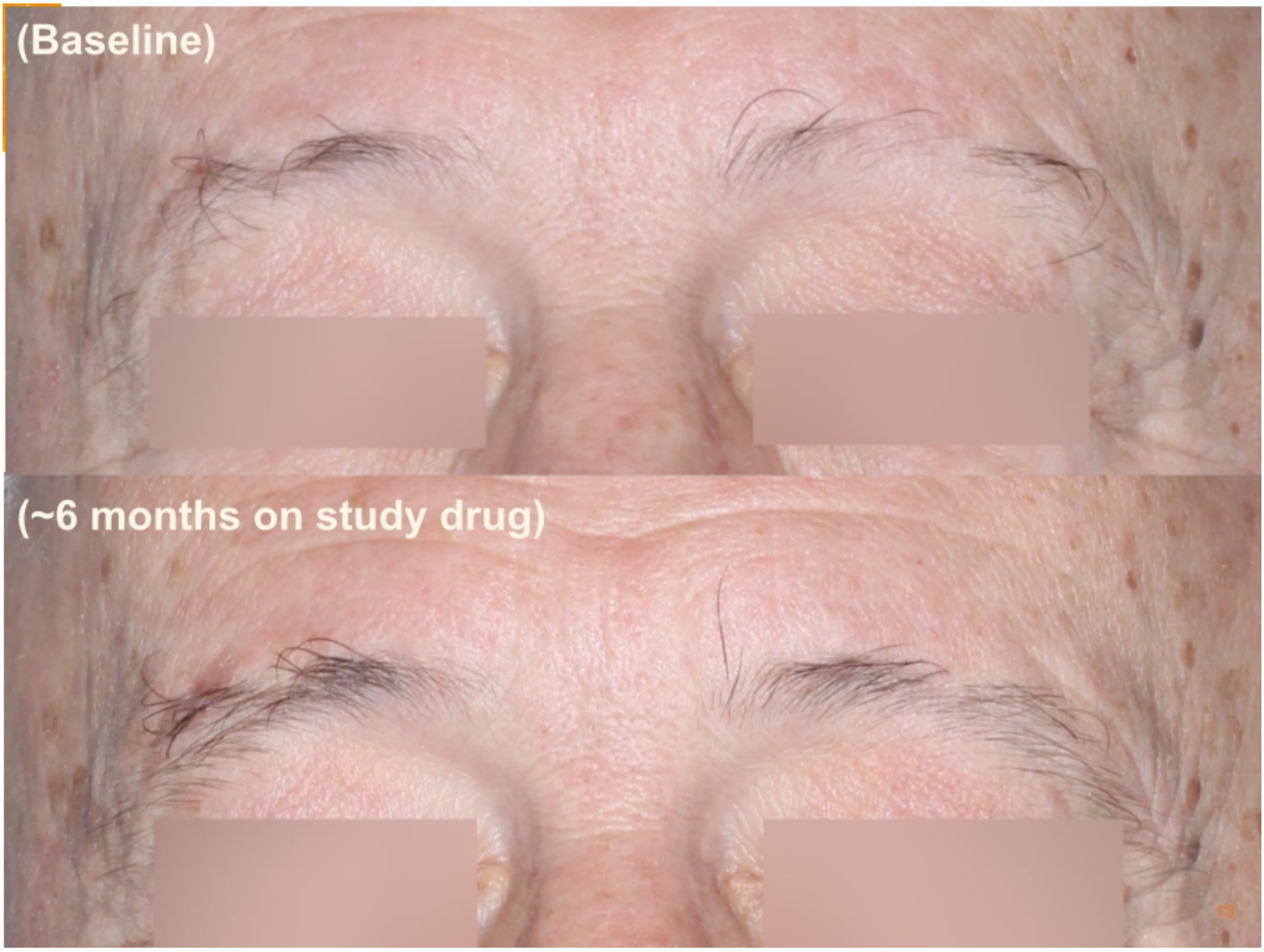
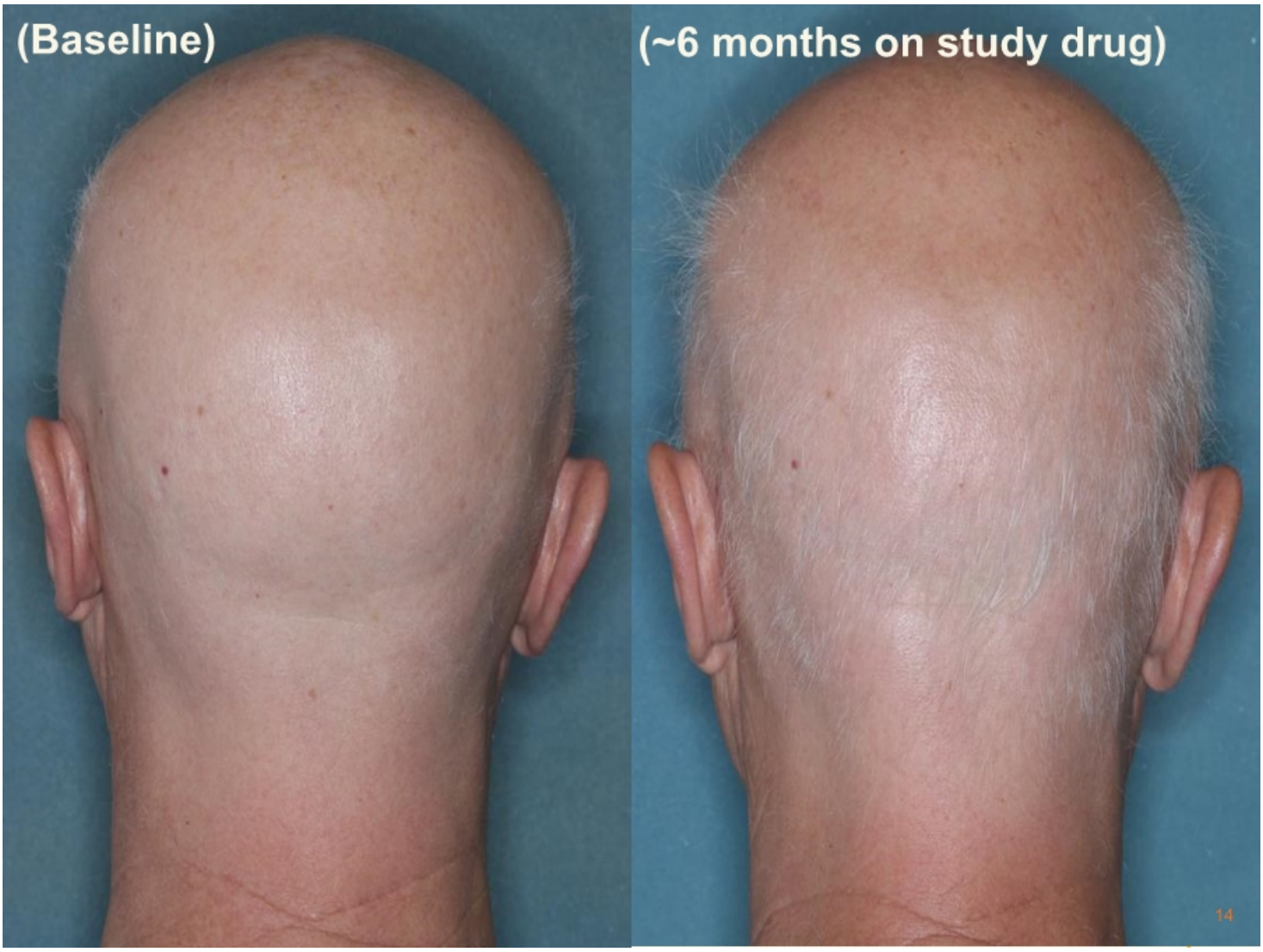
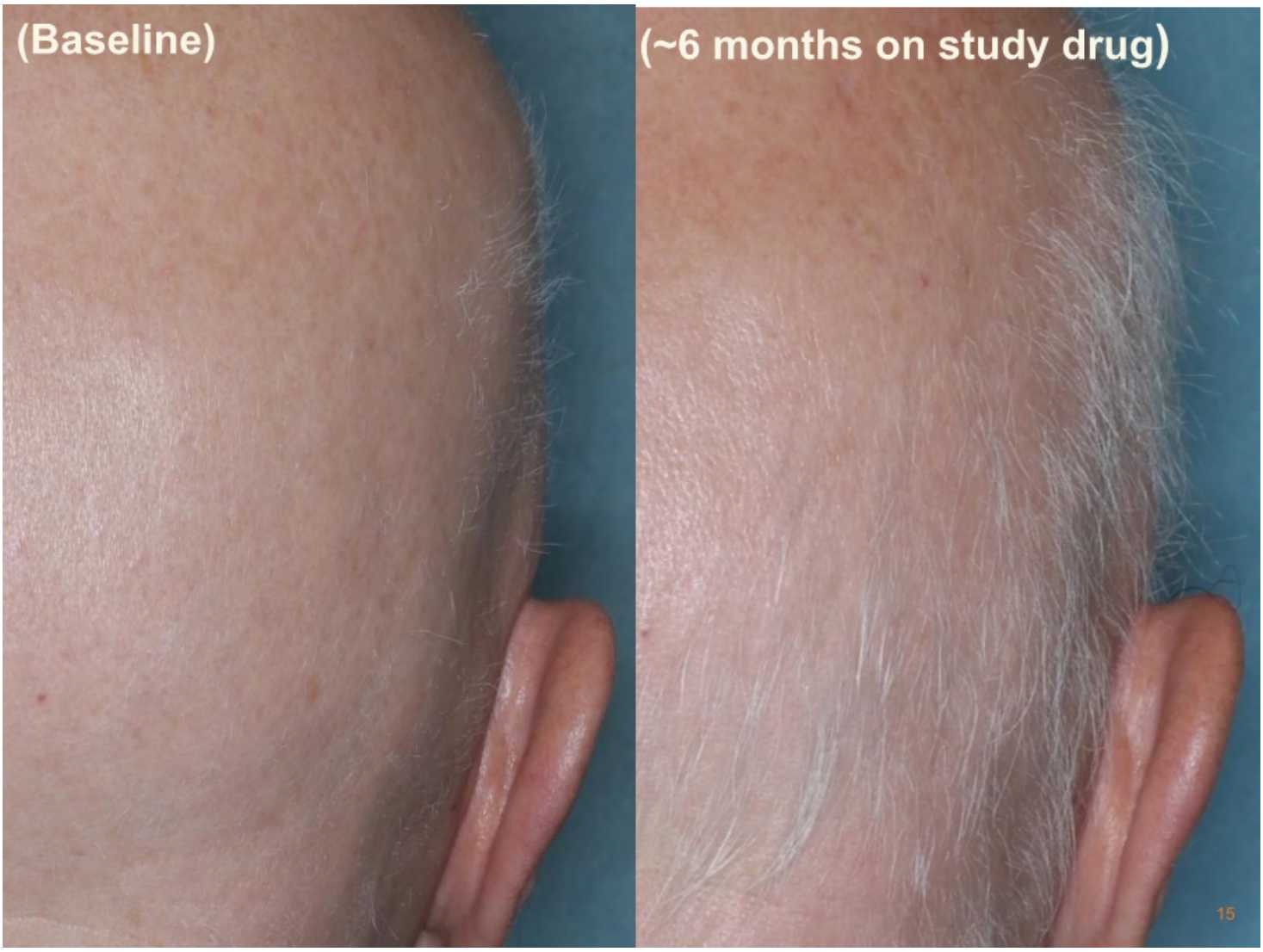
AA-202 Topical – PK/PD study

- An ongoing Phase 2 clinical trial of ATI-502, a topical JAK 1/3 inhibitor, for the treatment of AT/AU.
- After completing the 28-day portion of the trial, patients entered a -month open-label extension during which all continuing patients received drug.
  - 11 patients enrolled with the most severe phenotype of AT/AU
  - Average duration of disease = 13.7 years
  - Of the 9 patients who received at least 6 months of drug, 3 had evidence of hair regrowth
  - 2 patients withdrew after receiving ≤ 2 months of drug
- PK/PD
  - Systemic exposure as indicated by plasma drug levels were below the limits of quantification (1ng/ml) in all patients at day 28.
  - To assess skin penetration, punch biopsies were obtained at baseline and day 28 which demonstrated topical ATI-502 absorption consistent with pre-clinical skin models.
    - Mean of 5710 nanograms/gram at day 28
- Safety results - generally well-tolerated; no treatment related serious adverse events reported to date.


(Baseline)
(~6 months on study drug)


(Baseline)
(~6 months on study drug)
14


(Baseline)
(~6 months on study drug)
15

Phenotypic Spectrum

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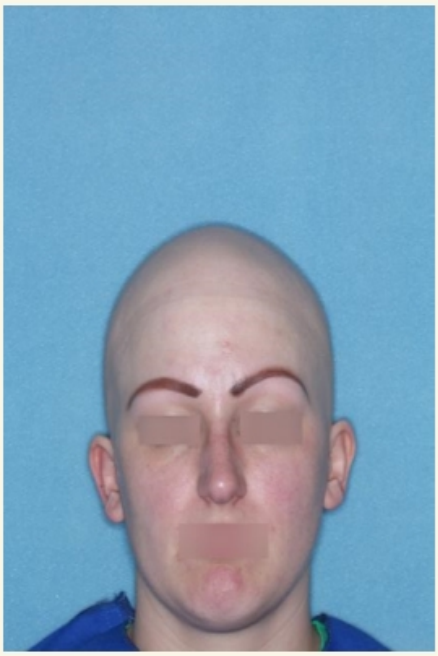
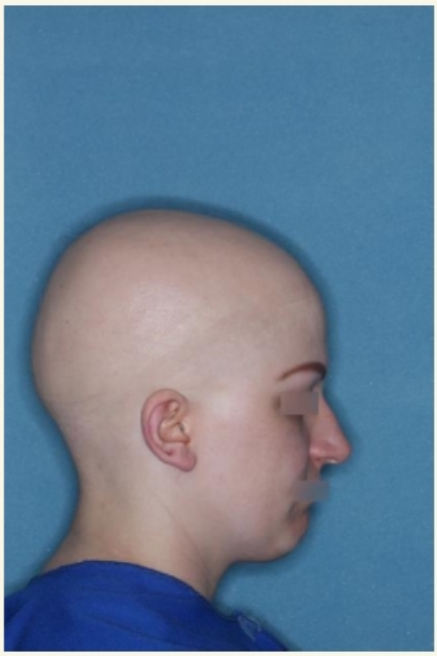
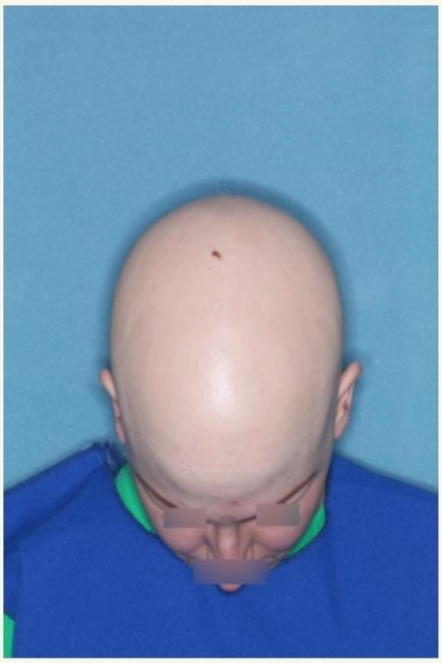
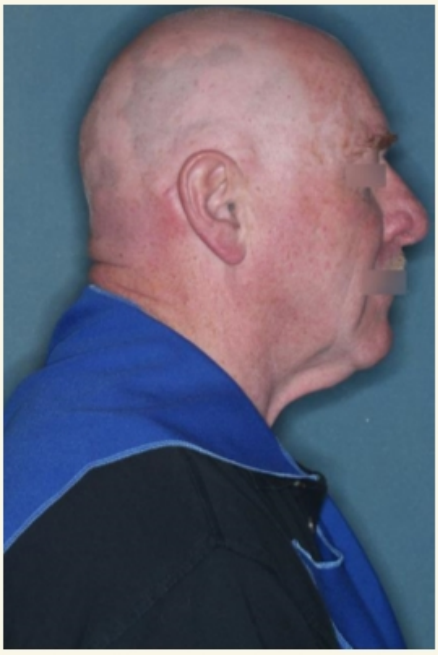
Baseline SALT 100%

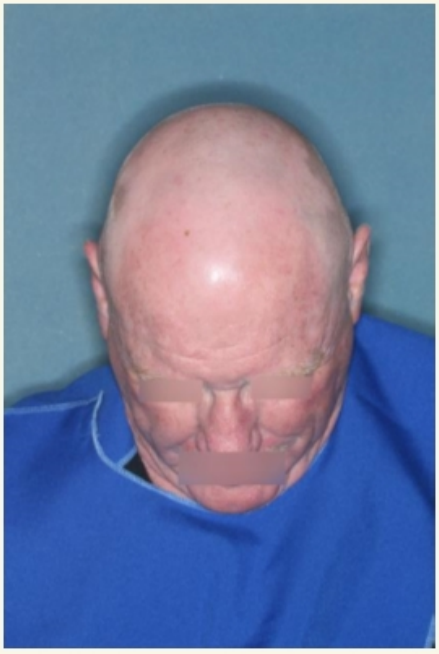


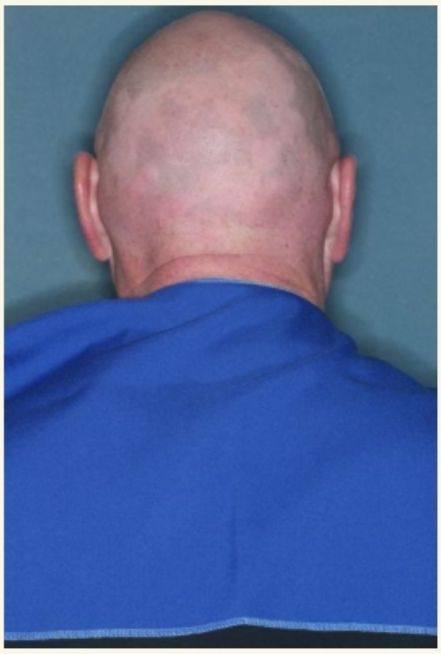




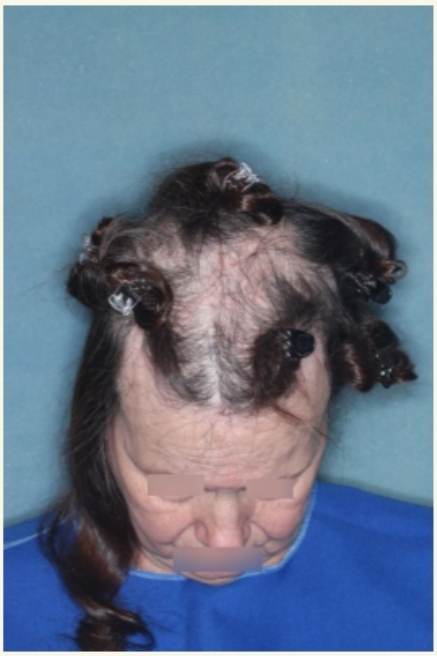
Baseline SALT 51%

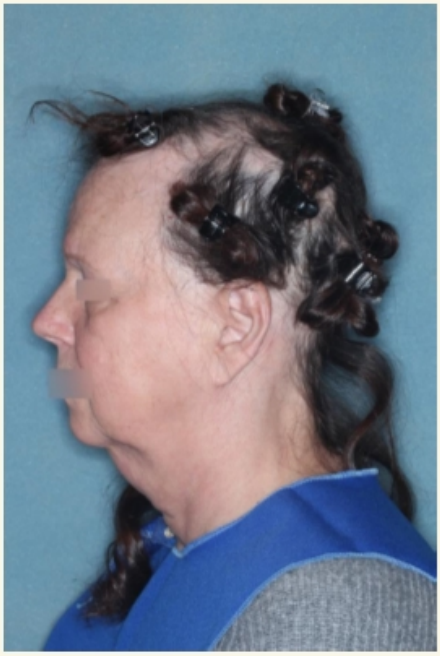




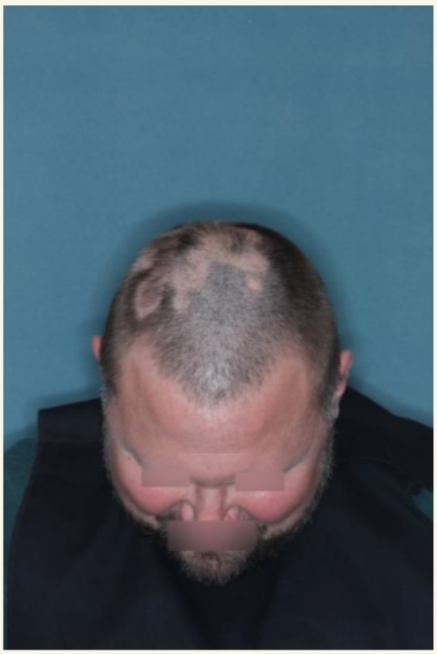


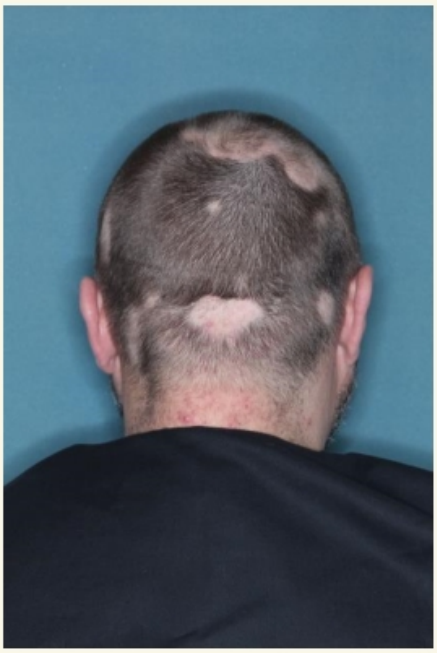
Baseline SALT 43%

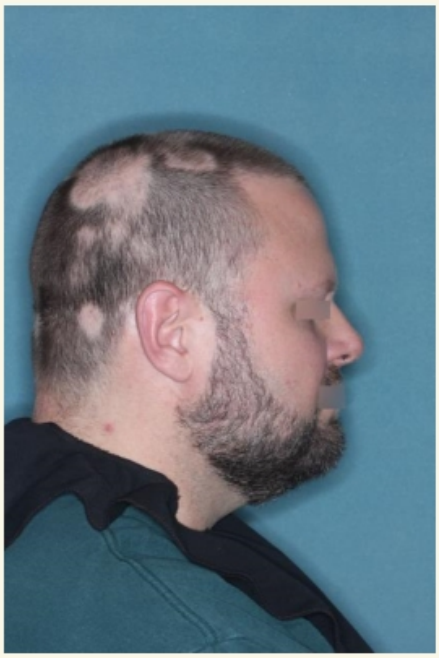




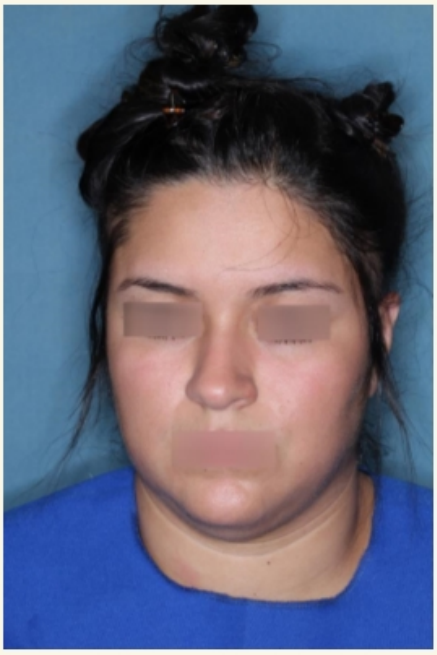
Baseline SALT 34%

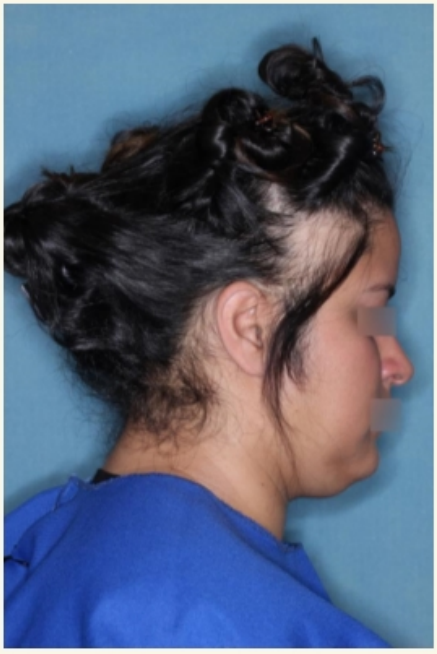




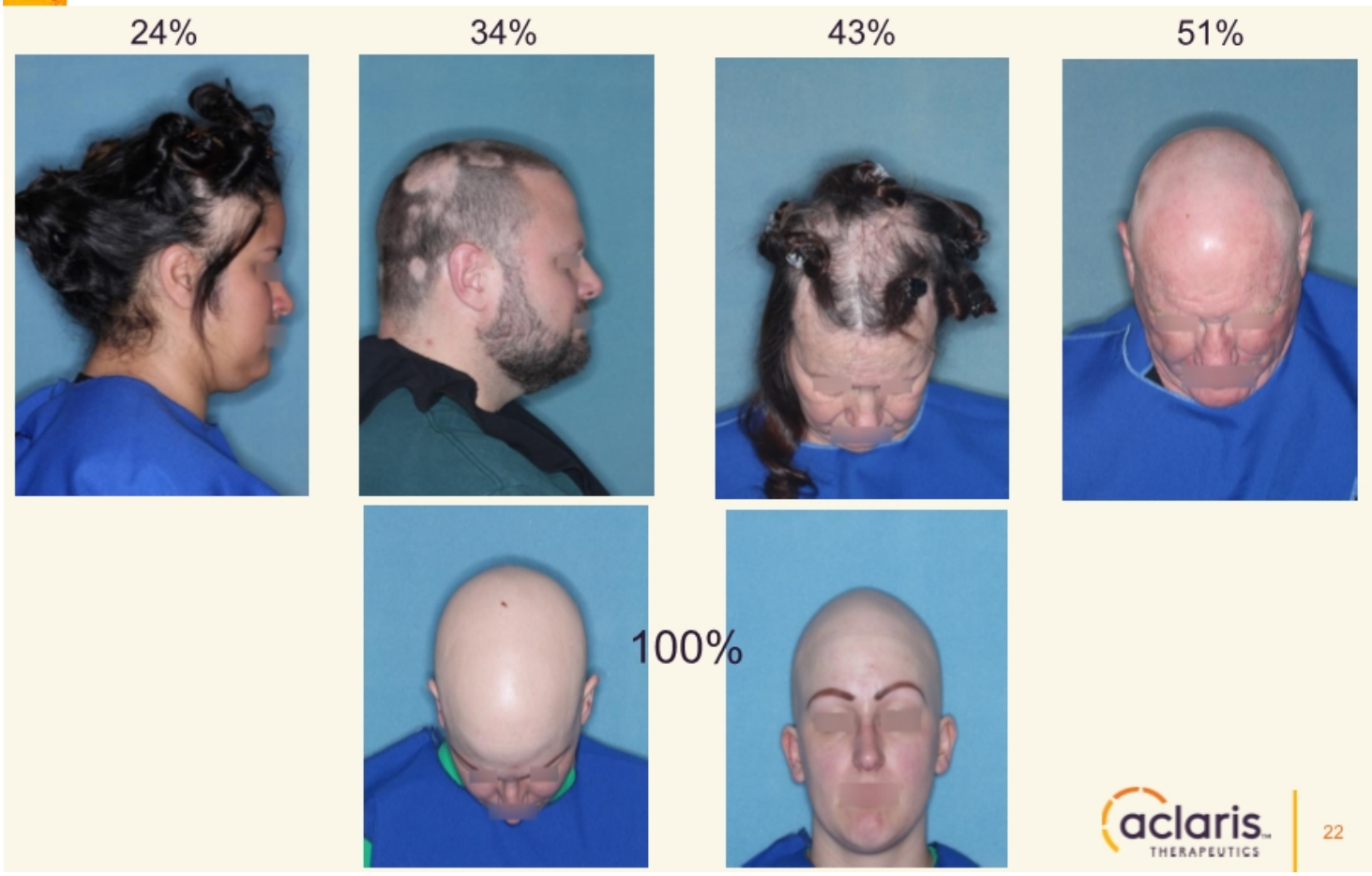


Baseline SALT 24%





Spectrum of Hair Loss



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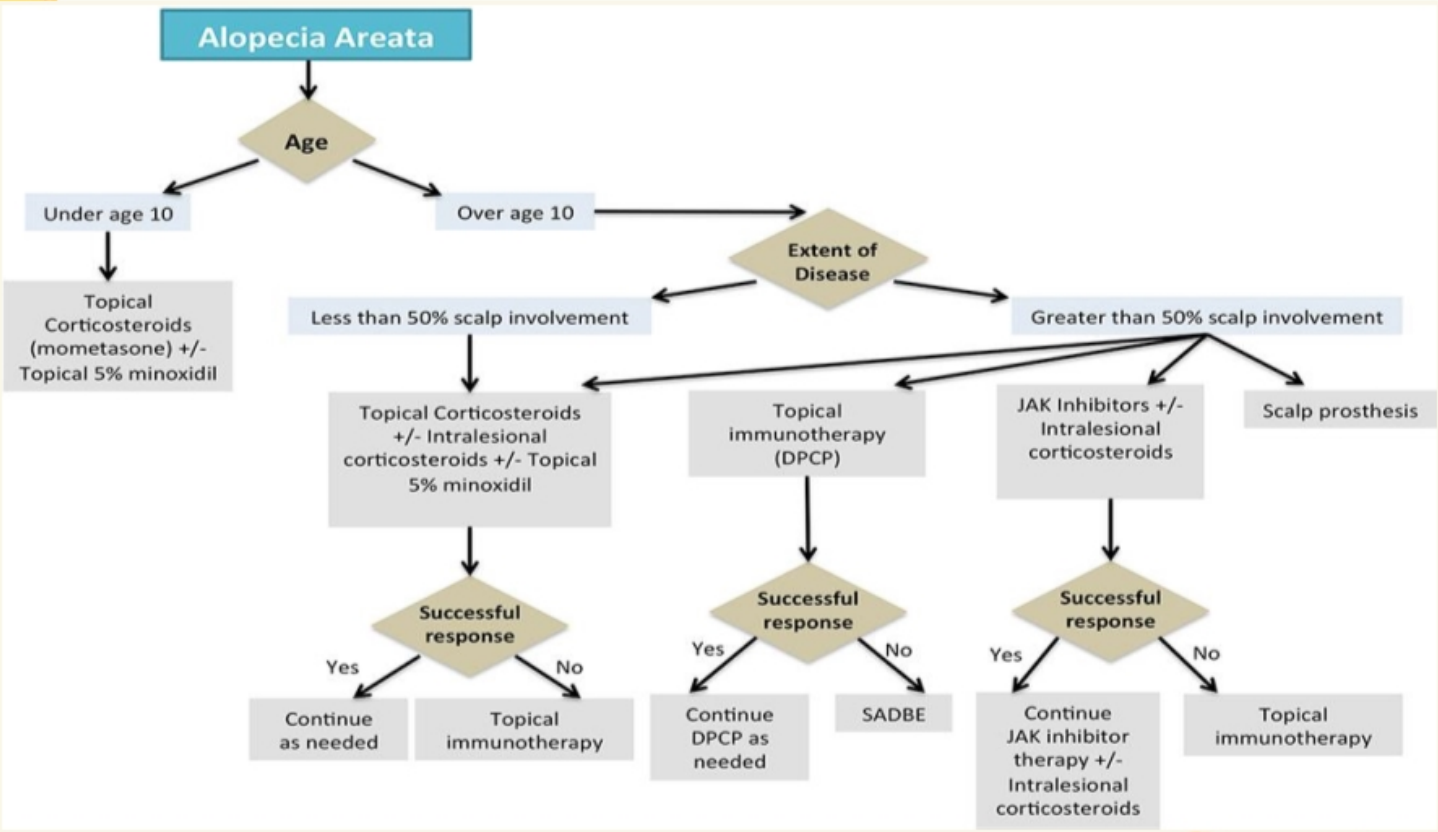
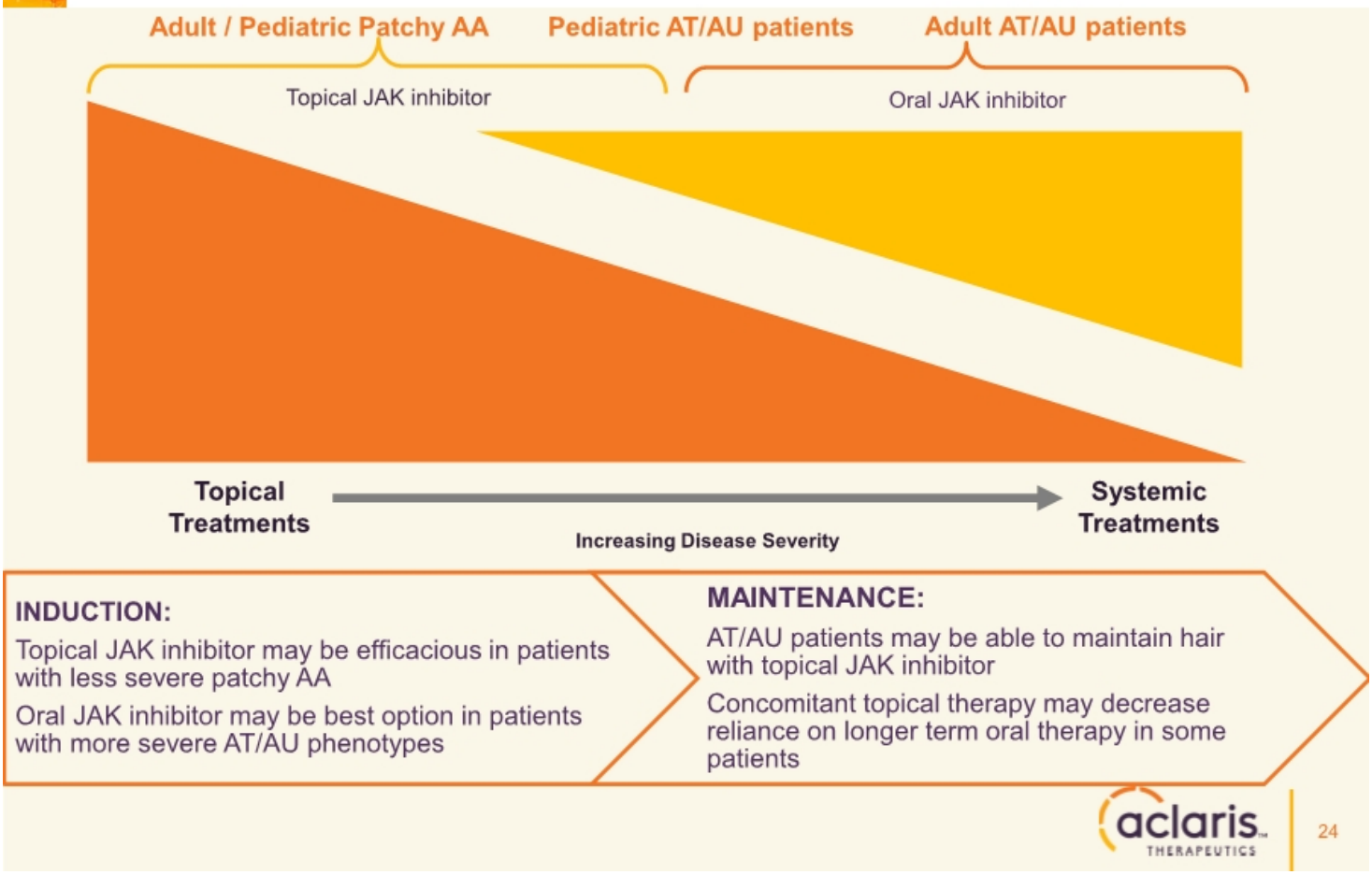
Current treatment paradigm



https://www.naaf.org/alopecia-areata/alopecia-areata-treatments - Last accessed 12-14-18

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

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VITI-201 Topical

6-month Open Label Study in Subjects with Non-Segmental Facial Vitiligo

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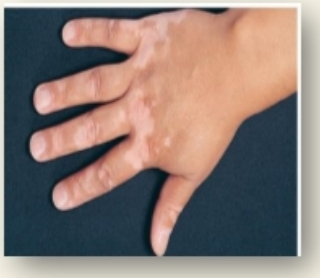
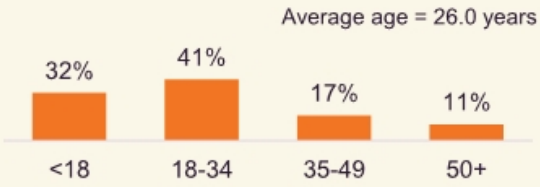
Vitiligo - 3.3% of US Population

Vitiligo Cases in the US

10.9M

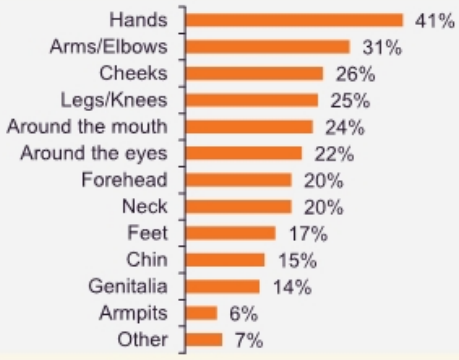


AGE & OTHER DEMOGRAPHICS



- Slightly higher incidence in the West (26%)
- Greater proportion with HH incomes of $35K to under $100K (53%)
- Above-average percentage of Afro-Americans with condition (32%) and fewer White, Non-Hispanic (43%)

COMMON BODY LOCATIONS

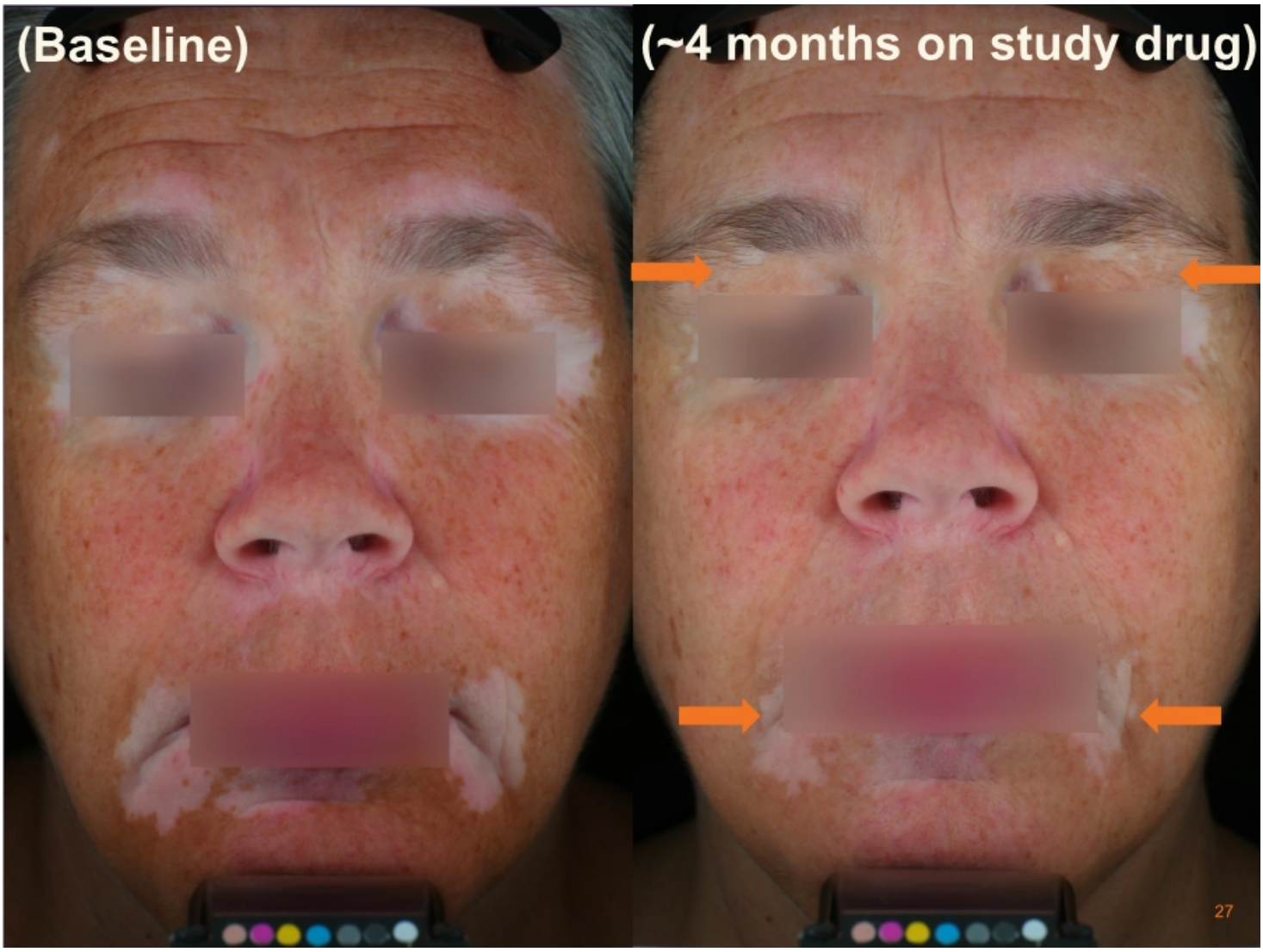


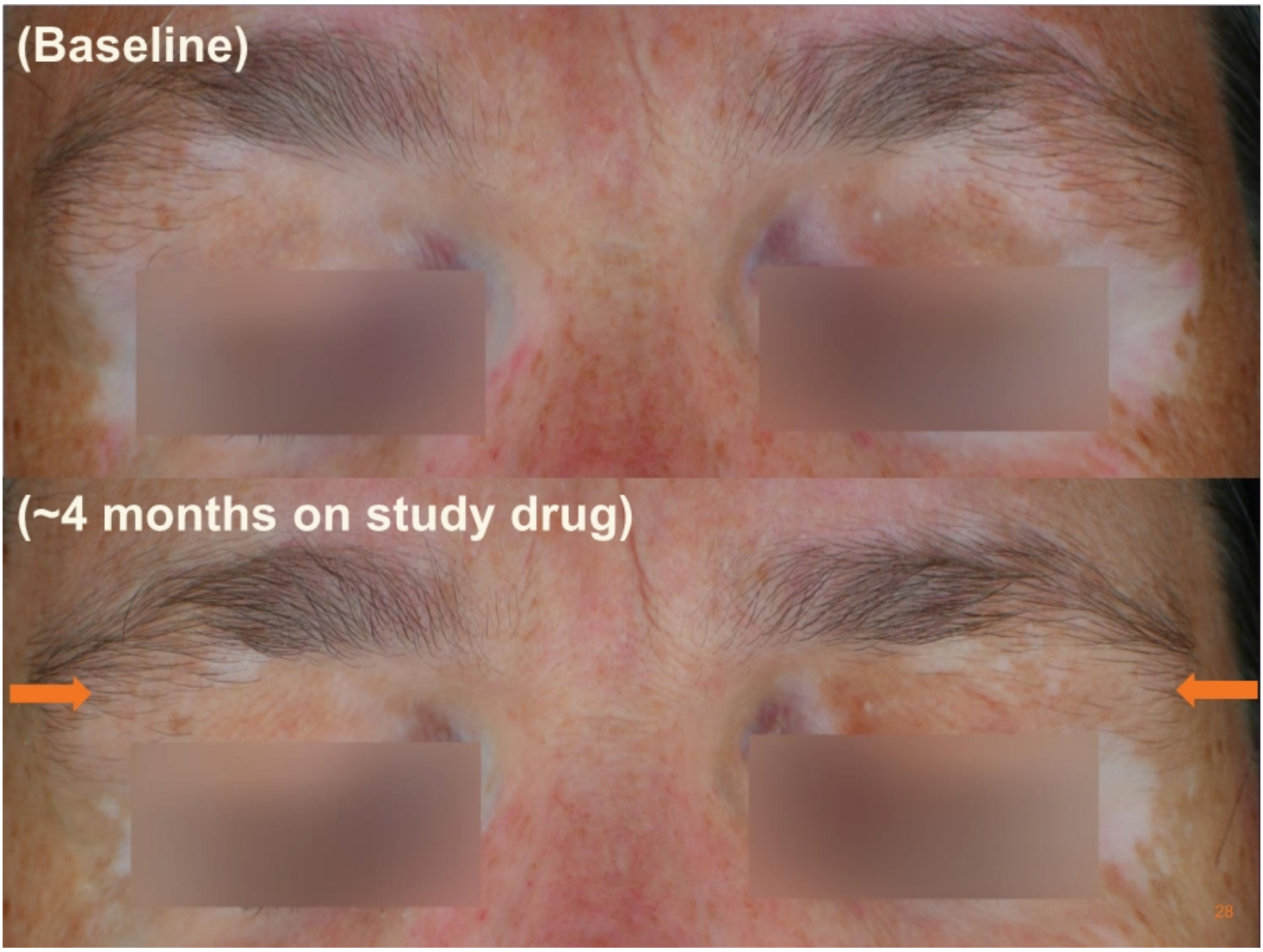
SYMPTOM FREQUENCY

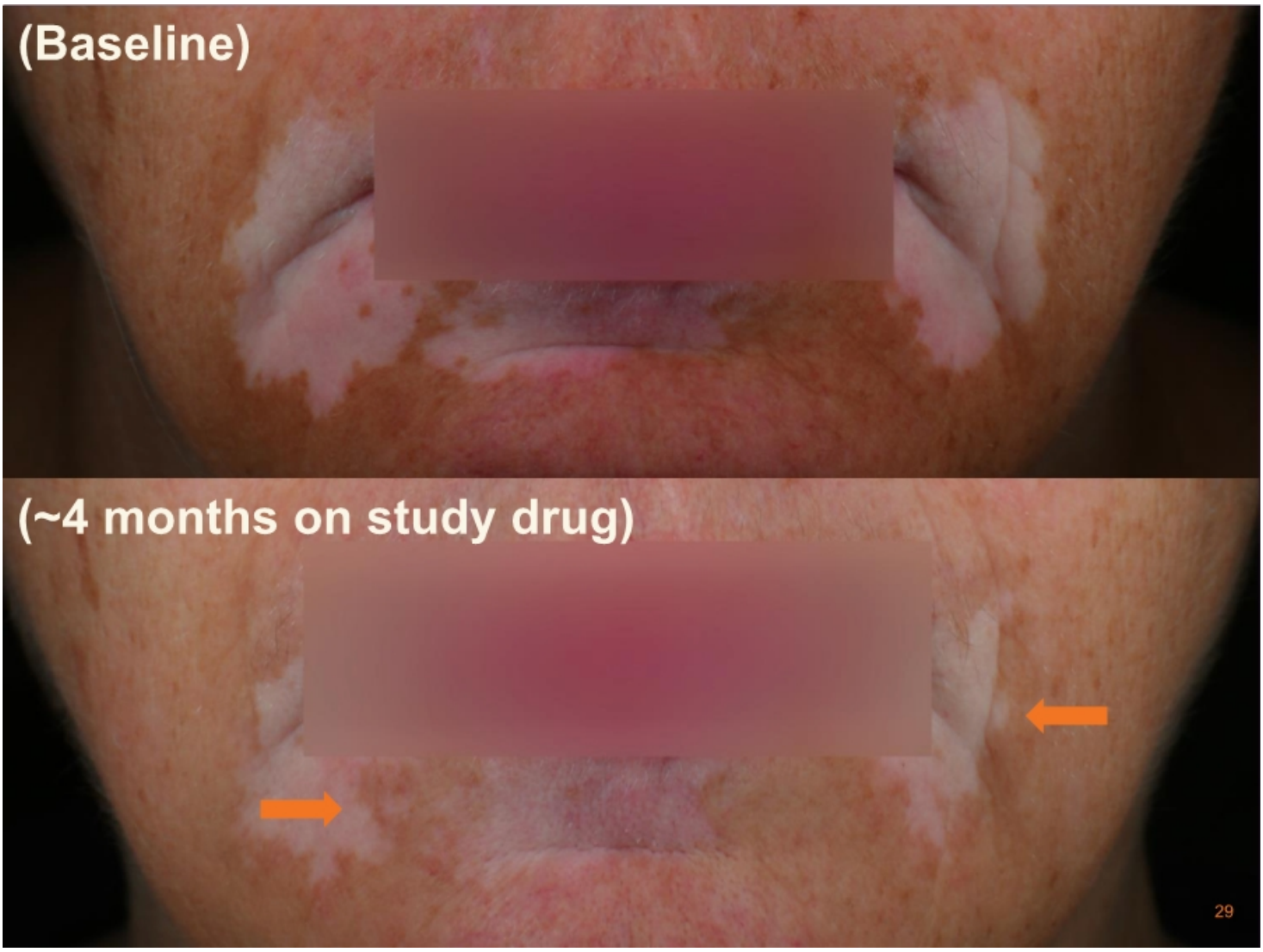
Always	**39%**
At least once per month	**16%**
Every few months	**19%**
At least once per year	**10%**
Less than once per year	**4%**
First occurrence	**12%**

Source: Phoenix Market Research, November 2018

aclaris THERAPEUTICS


(Baseline)
(~4 months on study drug)
27


(Baseline)
(~4 months on study drug)
28


(Baseline)
(~4 months on study drug)
29

Summary and Next Steps

- Alopecia areata
  - Established proof of principle for topical JAK inhibitor as a potential treatment
  - Topical JAK inhibitor could have role as first line therapy for patchy disease, second line maintenance therapy, or adjunctive treatment for more severe disease
  - Clinical response of topical JAK inhibitor in more severe phenotypes predicts faster and more complete response in mild to moderate phenotypes
- Vitiligo
  - Established proof of principle for topical JAK inhibitor as a potential treatment
- Oral JAK inhibitor dose range study in more severe phenotypes of alopecia areata is now fully enrolled
- Next steps:
  - AA-201 Topical – Phase 2 dose range trial of ATI-502 – topline data 2Q19
  - AUAT-201 Oral – Phase 2 dose range trial of ATI-501 – topline data 3Q19
  - Continue extension studies – all oral and topical patients are offered open label topical treatment post initial study completion