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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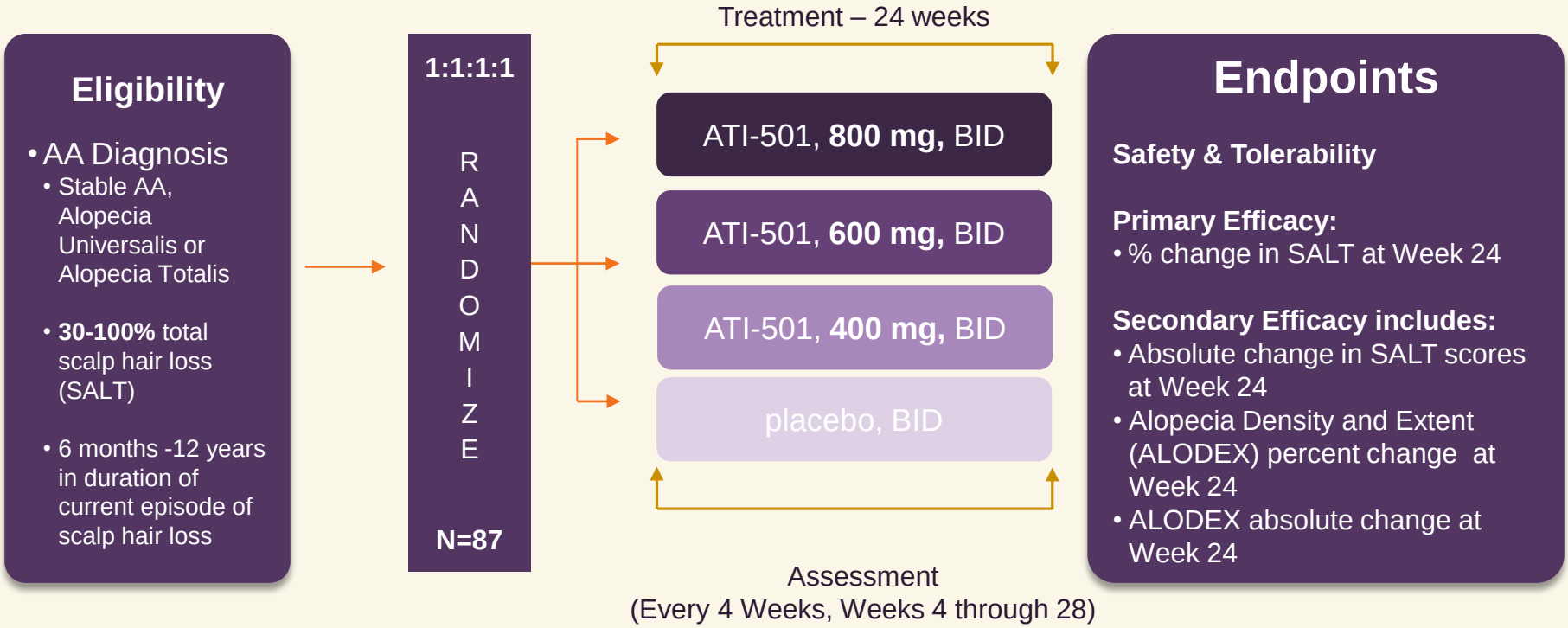
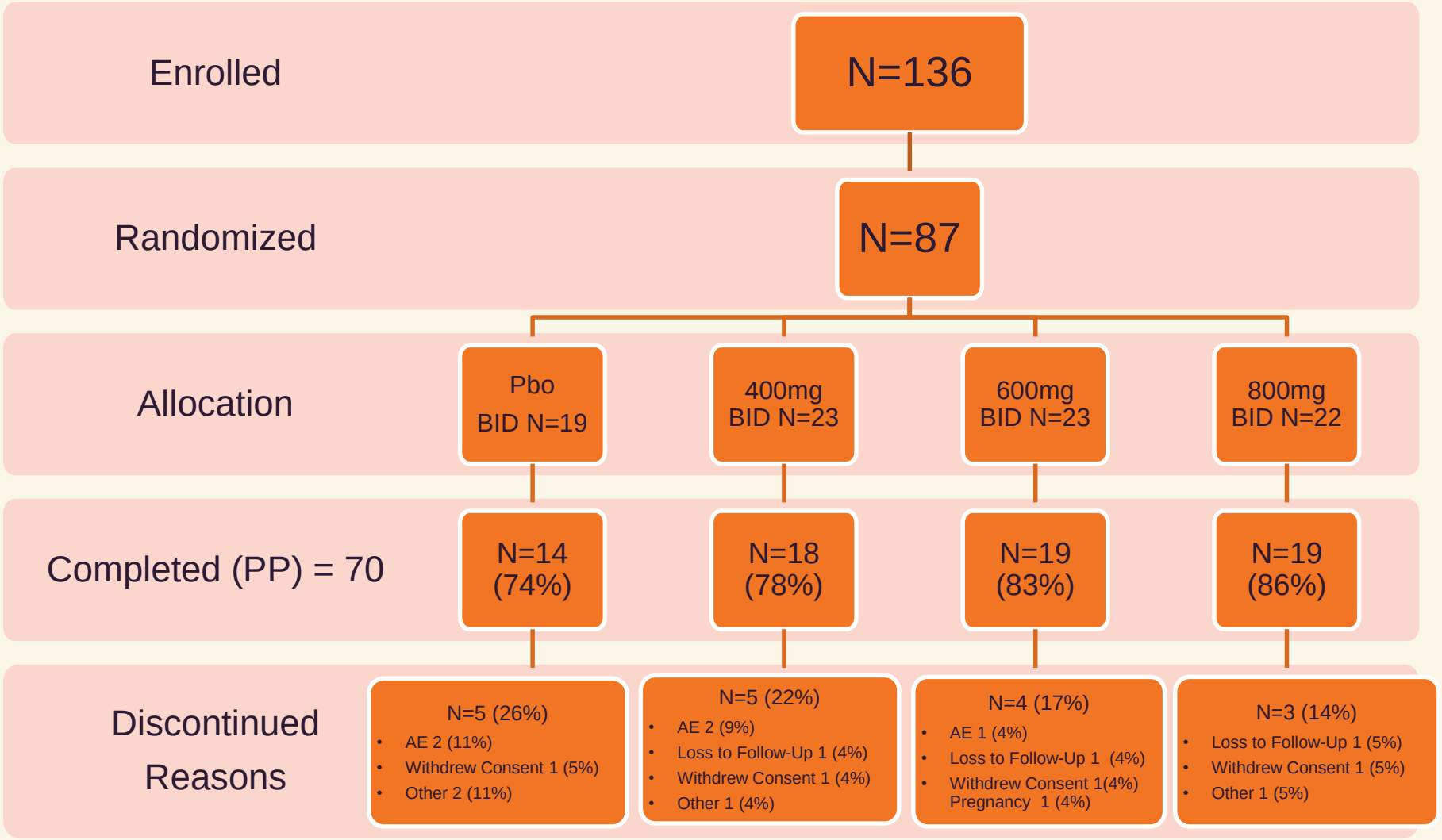
AUAT-201: Study Design

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)

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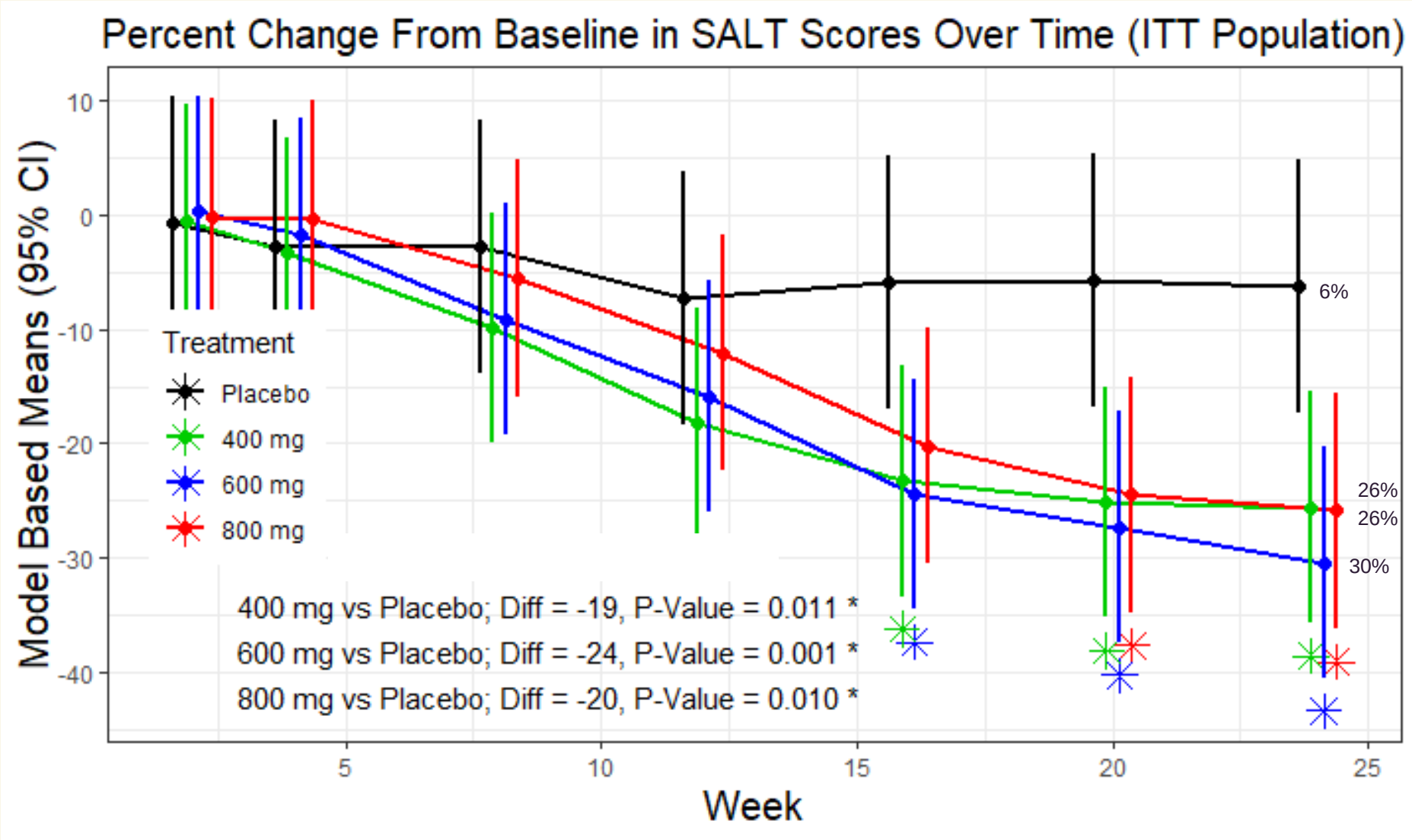
Primary Endpoint



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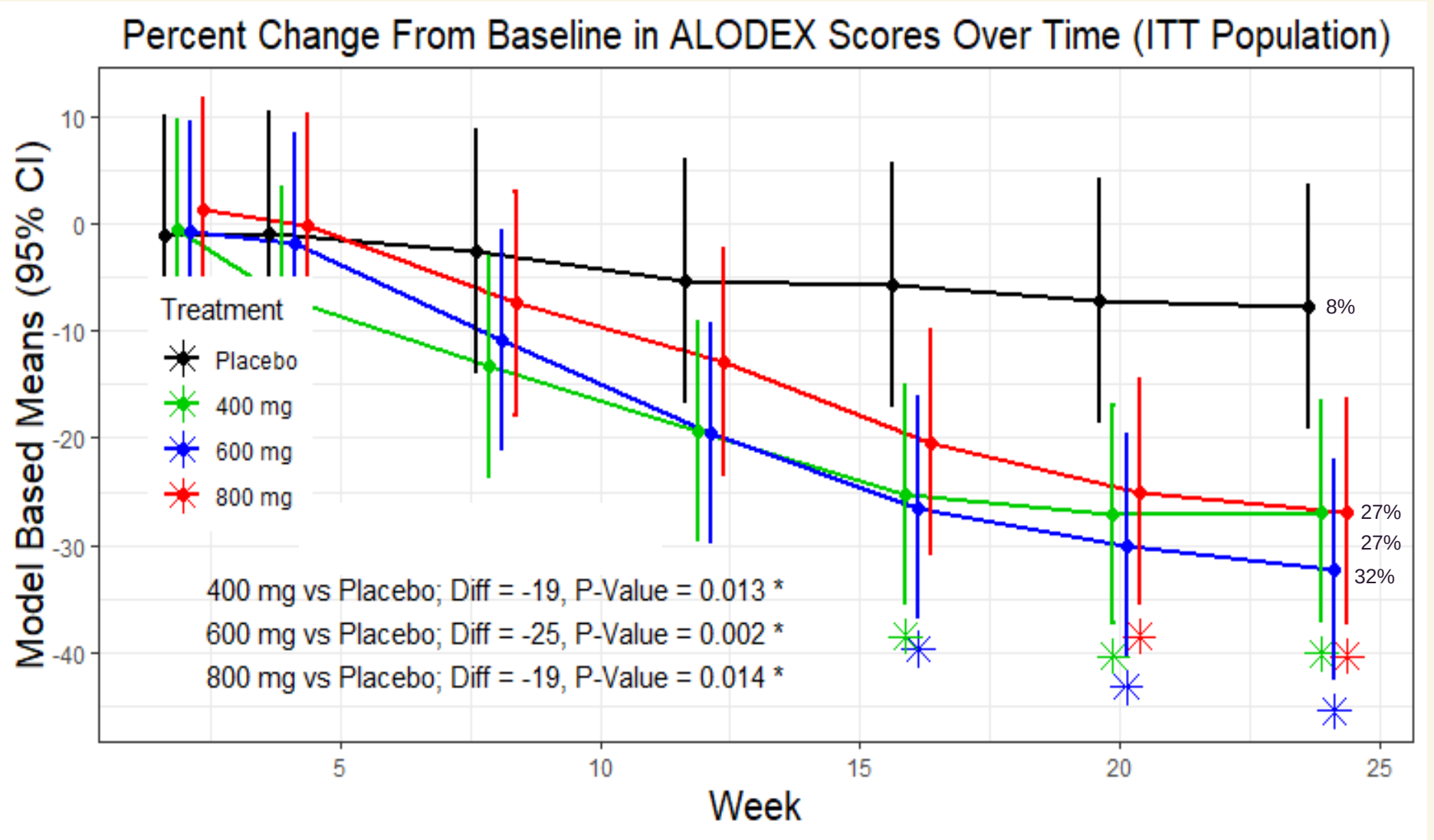

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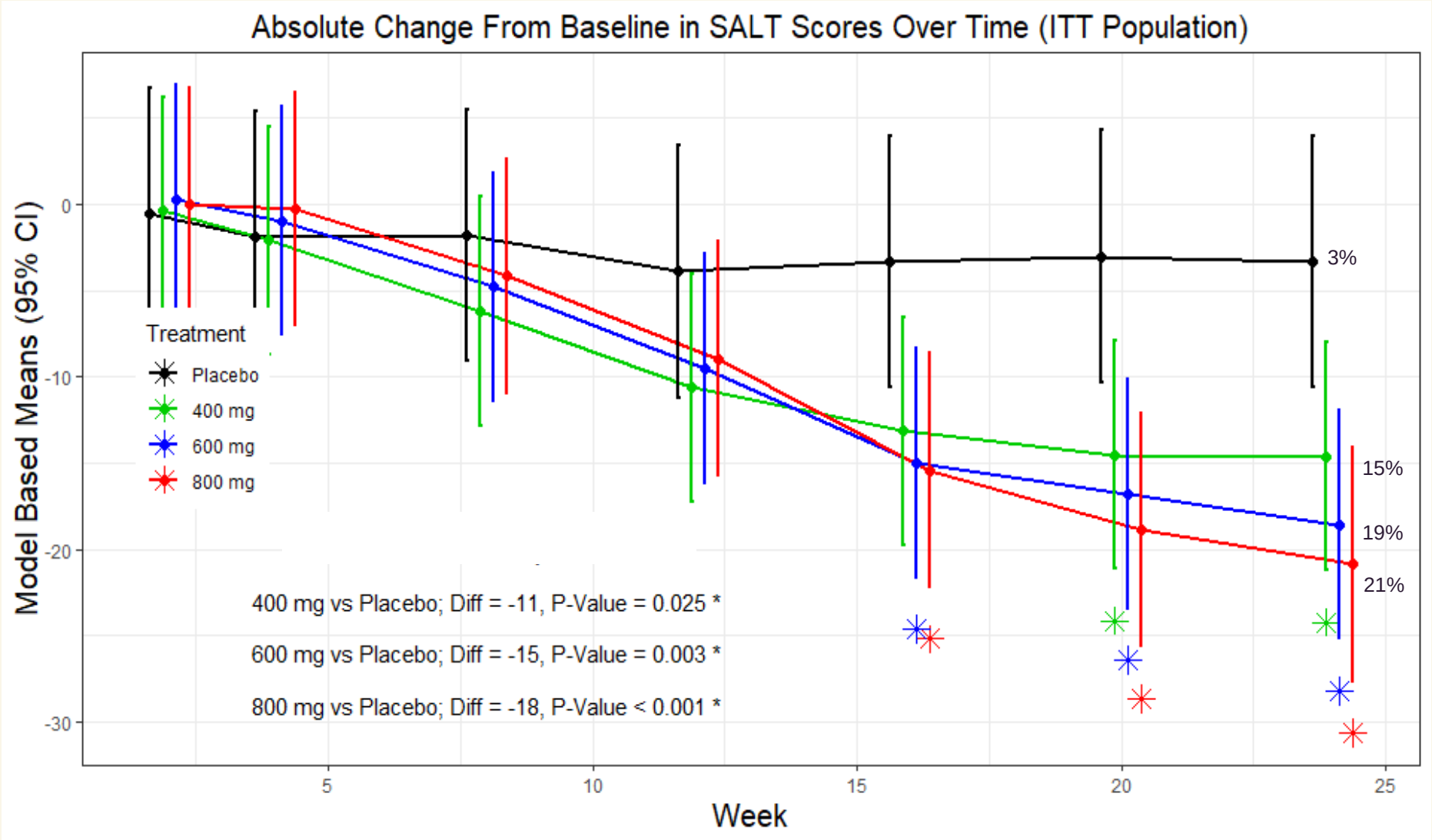
Secondary Endpoint



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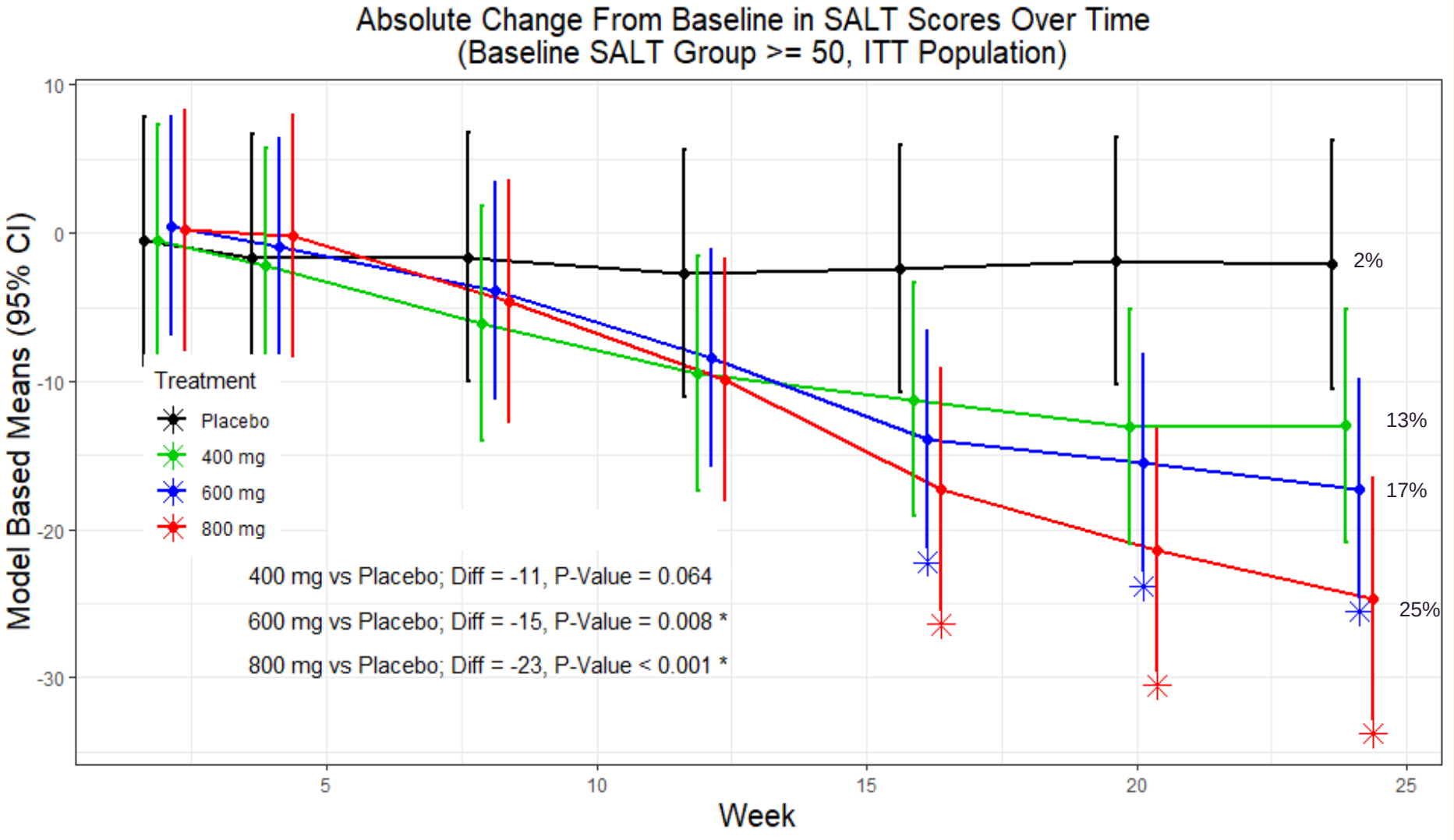
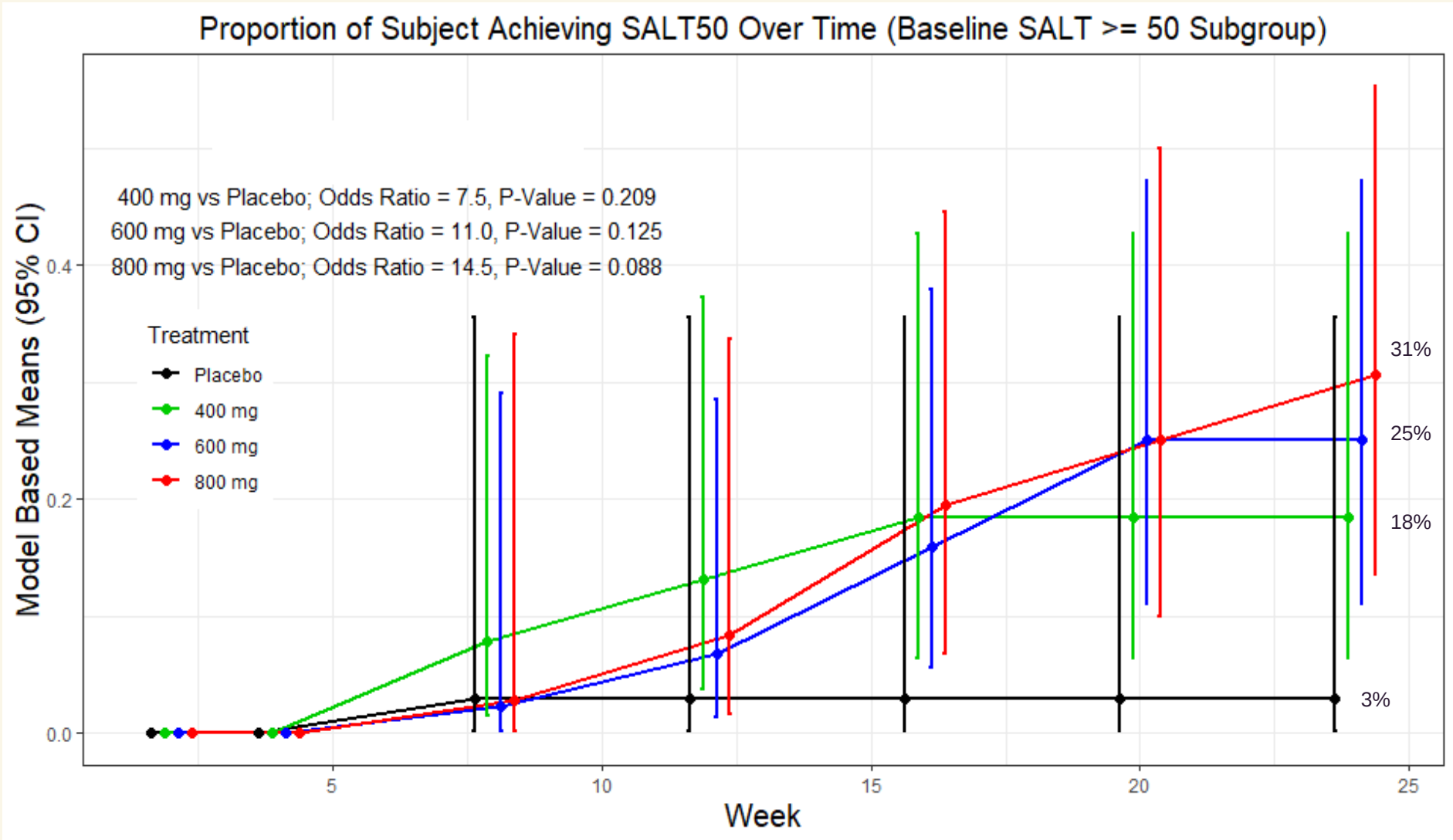
Secondary Endpoint



Secondary Endpoint



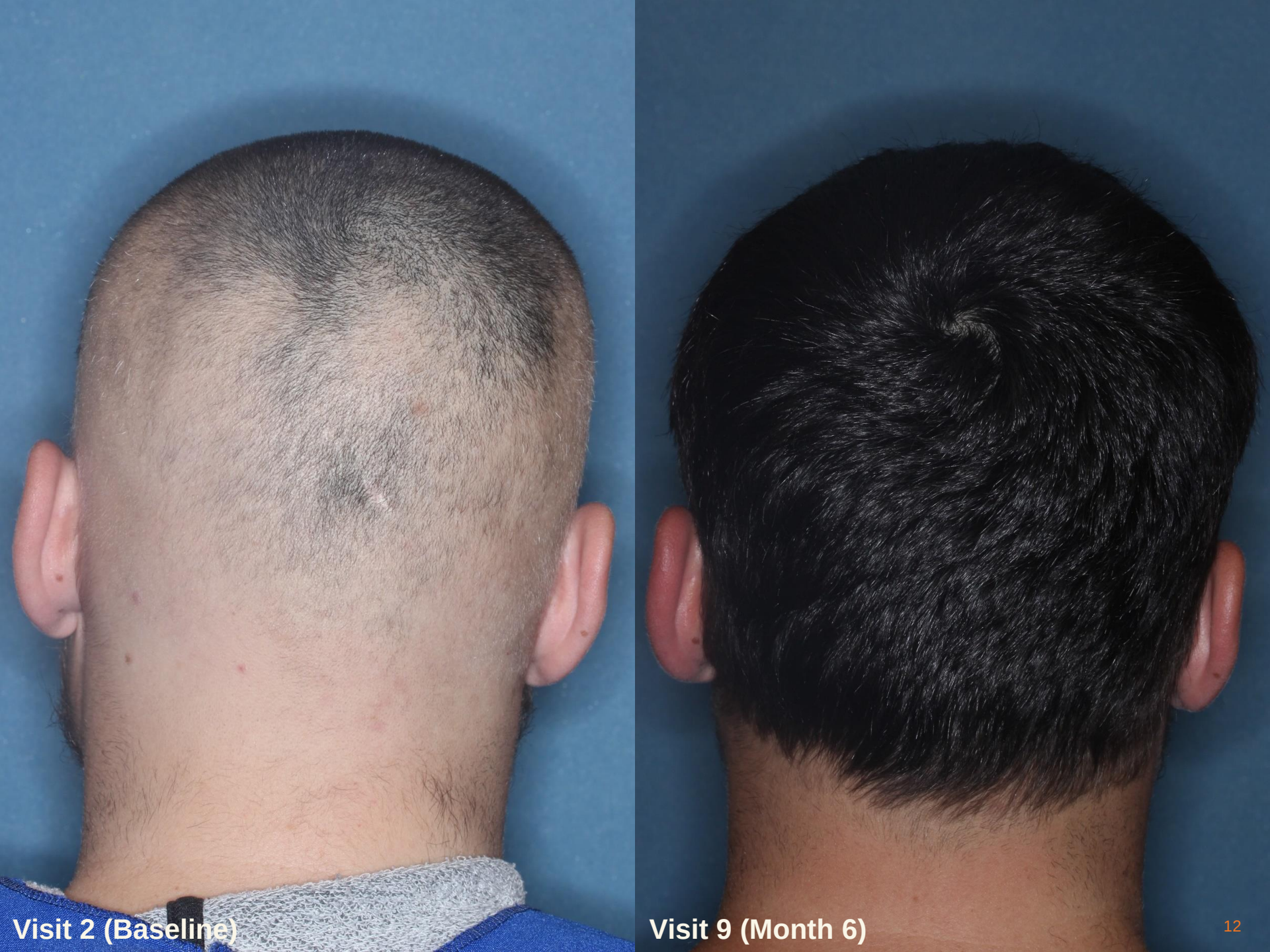
Overall Summary of Adverse Events (AEs)

	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%)

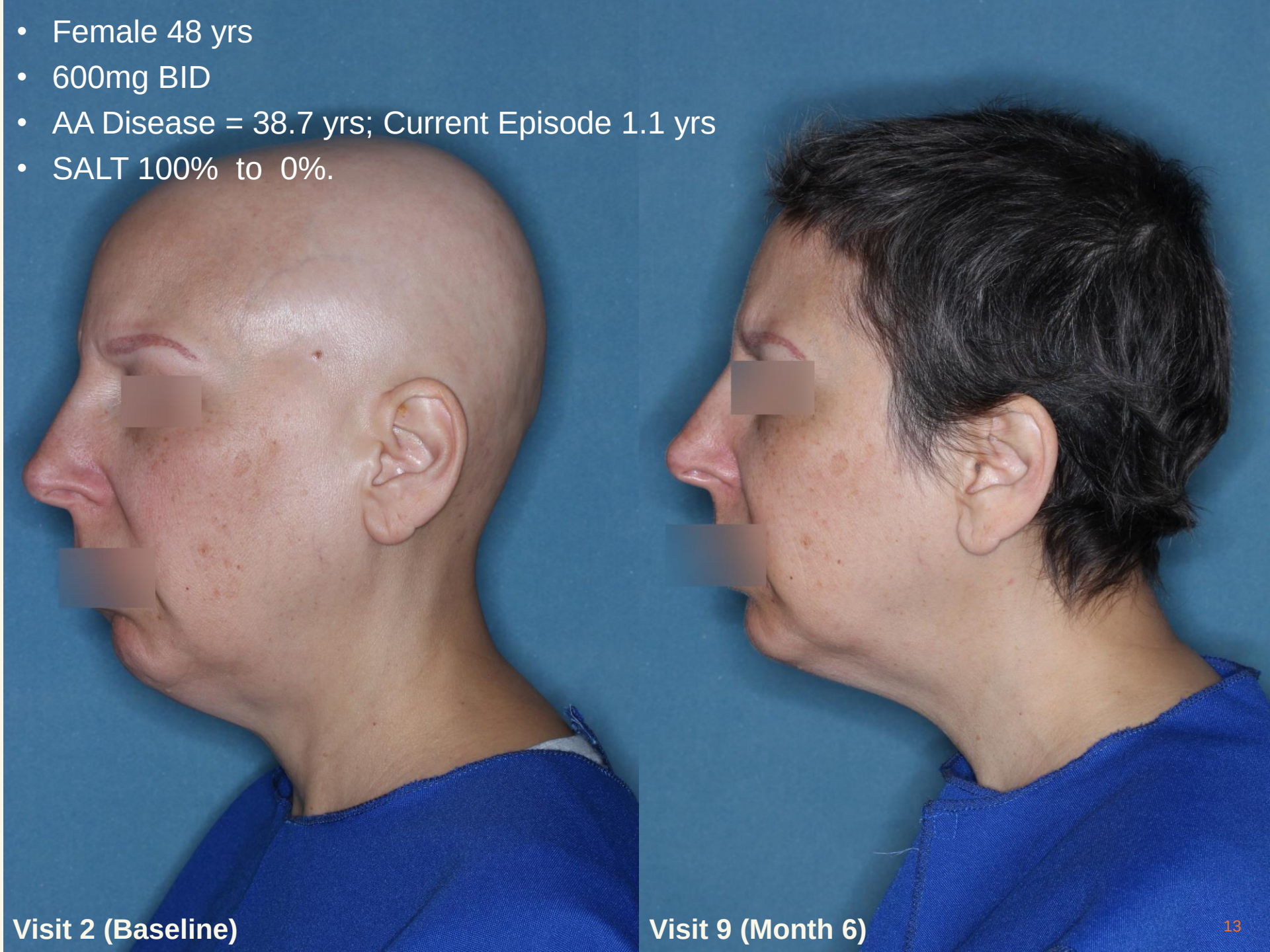
- Male 35 yrs
- 400mg BID
- AA Disease = 1.0 yrs; Current Episode 1.0 yrs.
- SALT 54% to 2%

Visit 2 (Baseline)

Visit 9 (Month 6)


Visit 2 (Baseline)
Visit 9 (Month 6)

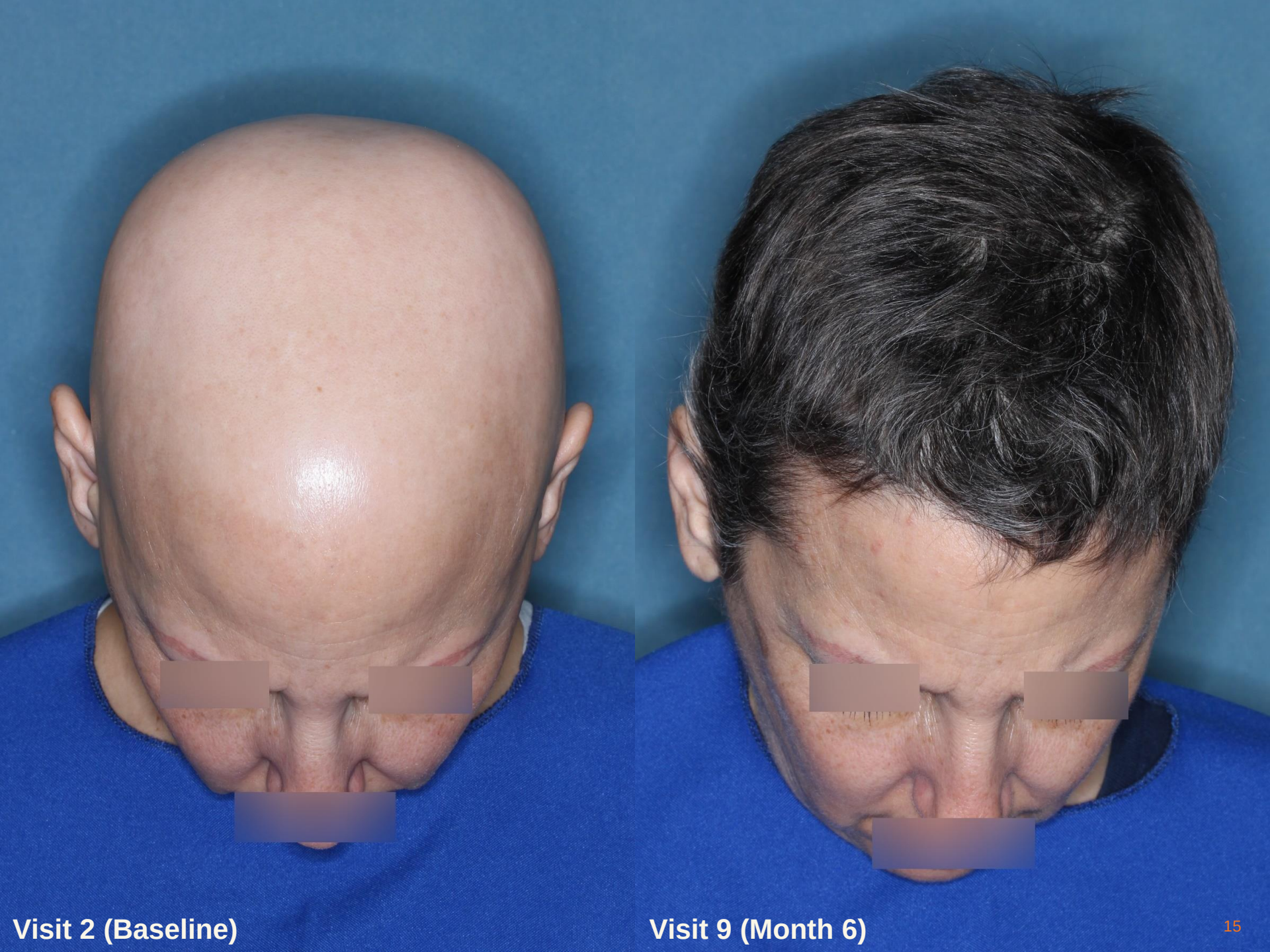
- Female 48 yrs
- 600mg BID
- AA Disease = 38.7 yrs; Current Episode 1.1 yrs
- SALT 100% to 0%.



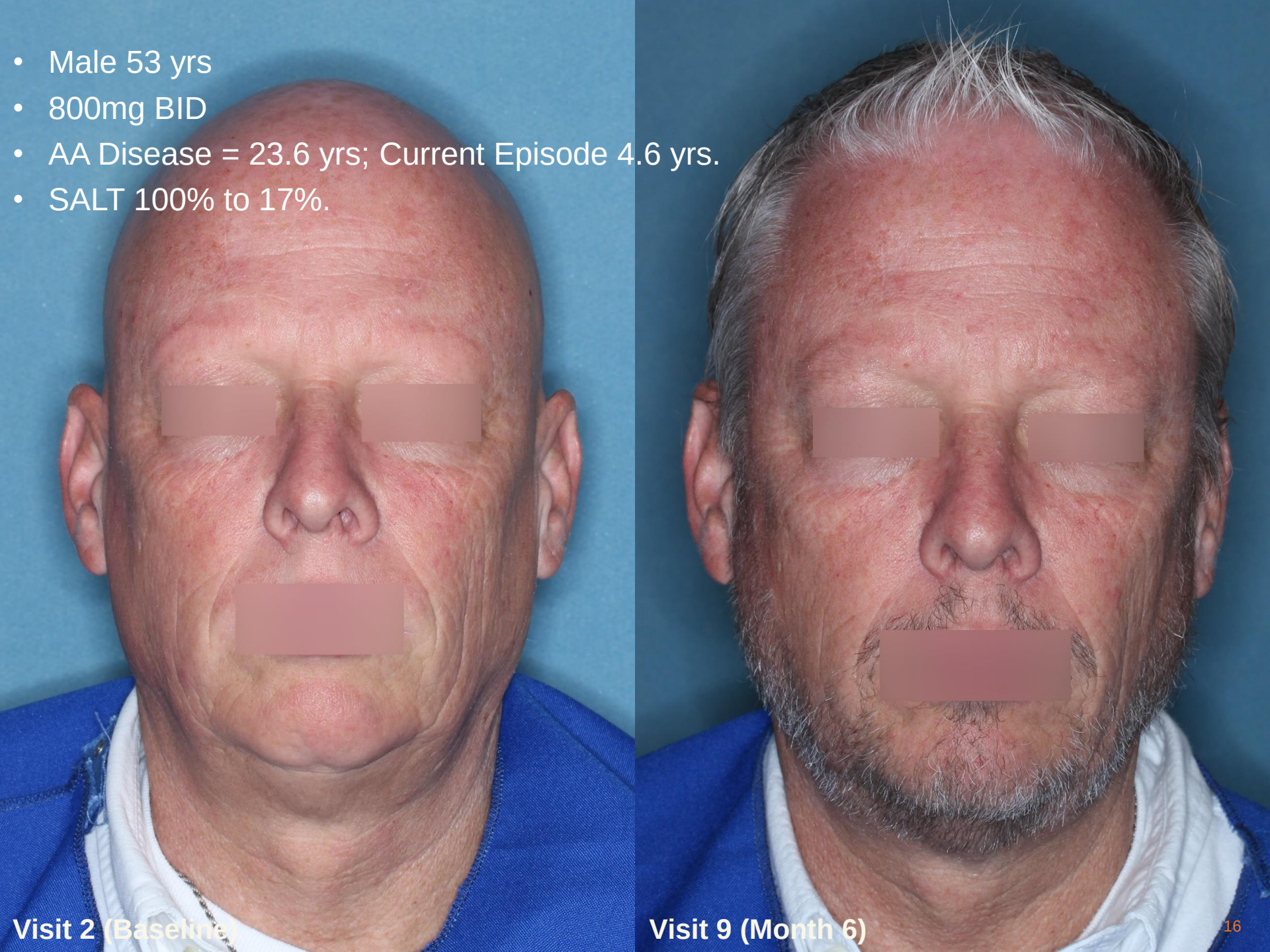
Visit 2 (Baseline)

Visit 9 (Month 6)


Visit 2 (Baseline)
Visit 9 (Month 6)


Visit 2 (Baseline)
Visit 9 (Month 6)

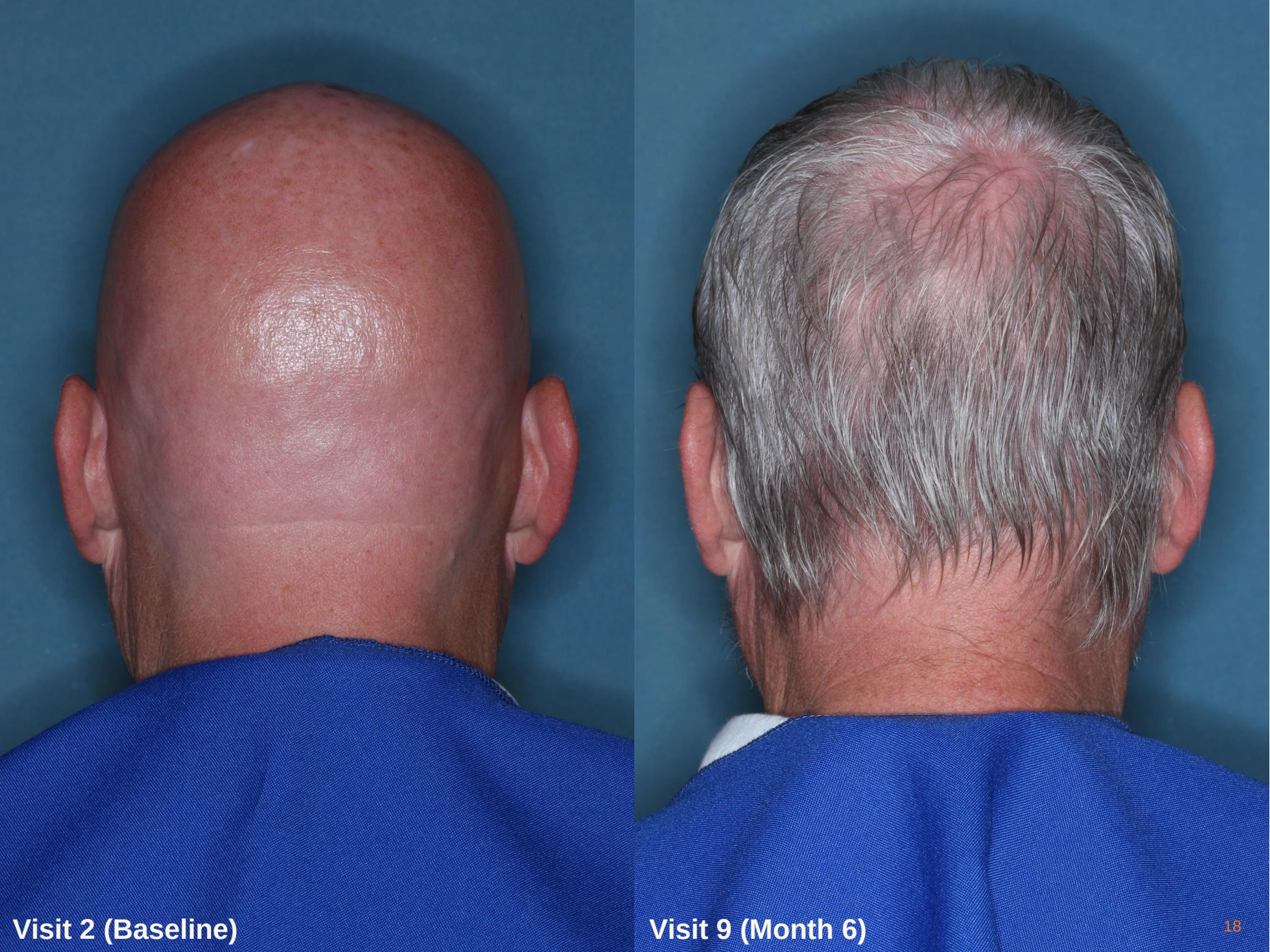
- Male 53 yrs
- 800mg BID
- AA Disease = 23.6 yrs; Current Episode 4.6 yrs.
- SALT 100% to 17%.



Visit 2 (Baseline)

Visit 9 (Month 6)


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

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THANK YOU

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