Novel Regulatory T-cell Enhancing Biologic Rezpegaldesleukin: Phase 2b Efficacy and Safety Results Following 36-Weeks of Therapy in Severe-to-Very-Severe Alopecia Areata (Rezolve-AA)

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Conflict of Interest Disclosures:

- Consultant (with honoraria) : AbbVie, Abcuro, Ability Biologics, Almirall, AltruBio, Arena, Astria, Boehringer-Ingelheim, Bristol Meyers Squibb, Celgene, Concert, CSL Behring, Dermavant, Dermira, Dualitas, Edesa Biotech, EMD Serono, Forte Biosciences, Incyte, Inmagene, Janssen, Kymera, Kyowa Kirin, Lilly, Nektar, Novartis, Pfizer, Phothera, RAPT, Regeneron, Recludix, Revolo Biotherapeutics, Sanofi, Sun Pharmaceuticals, Takeda, UCB, VielaBio, Zura Bio
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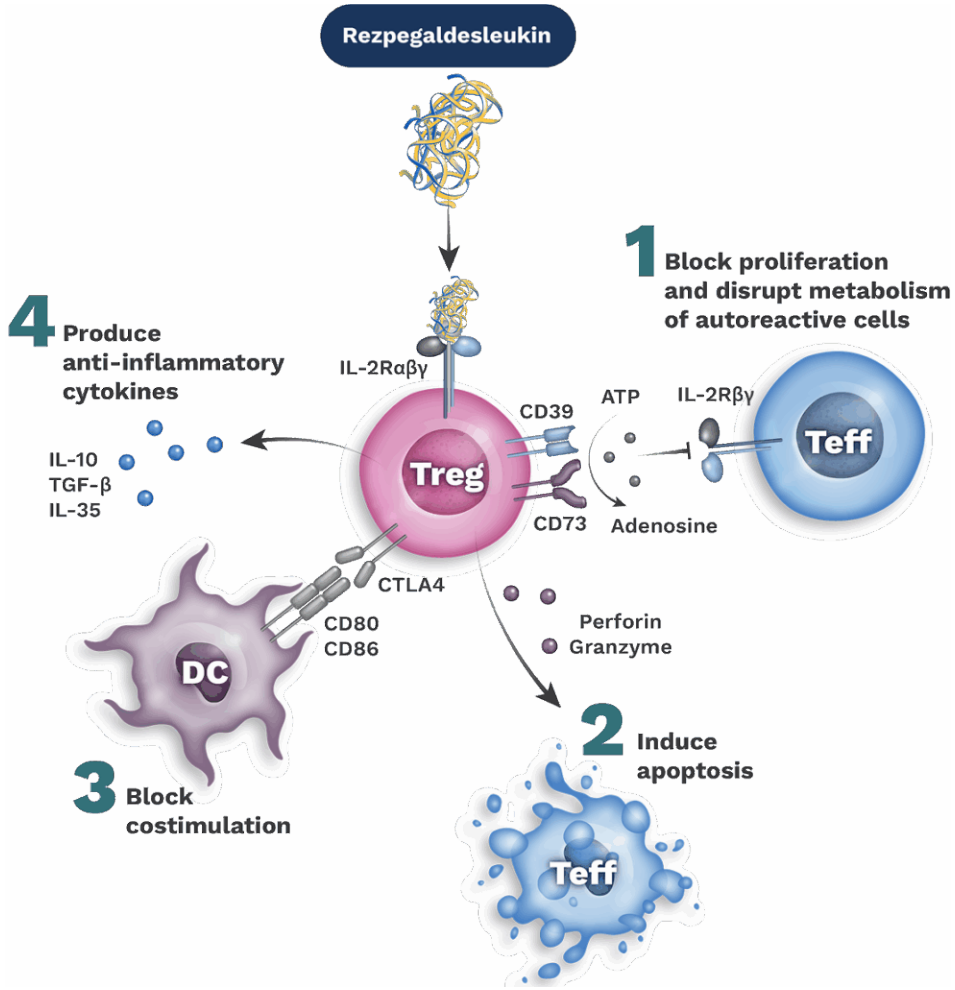
Rezpegaldesleukin

Il-2 receptor agonist

Rezpegaldesleukin (rezpeg) is a novel, first-in-class biologic targeting regulatory T cells (Tregs)

- Administered as an active drug, with extended half-life[1]
- Preferential binding to IL-2 receptor complex on Tregs compared to conventional T cells (Tcons)[1]
- *In vivo* selectively expands and enhances the function of Tregs[1,2]
- Previously demonstrated clinical activity in atopic dermatitis (AD), psoriasis, systemic lupus erythematous[2-5]

As a Treg agonist, Rezpegaldesleukin is differentiated from biologics currently approved and in development for dermatologic indications.



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Phase 2b REZOLVE-AA Study Evaluating REZPEG for Alopecia Areata

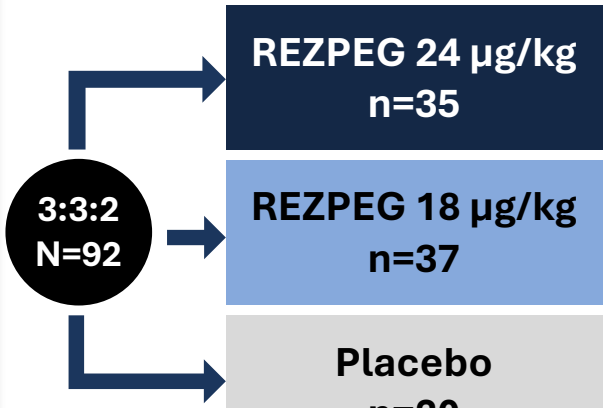
*Severe-to-very-severe alopecia areata (*NCT06340360)

Rezolve AA

Key Eligibility Criteria	Treatment Q2W (Weeks 0-36)	Week 36 Endpoints	Extension and Follow-up

- Adult patients (18+)
- Severe-to-very-severe AA
- SALT ≥50
- >6 months since diagnosis to exclude unstable AA
- No spontaneous improvement over the past 6 months
- 8-week washout of prior medication for AA

Stratification by baseline SALT score ≥50 to <95 vs ≥95 to 100



Primary:
- Mean % SALT reduction at Week 36

Secondaries:
- Absolute SALT ≤ 30
- Absolute SALT ≤ 20
- Absolute SALT ≤ 10
- Clinician-Reported Outcome (ClinRO) Eyebrow and Eyelash (exploratory)
- Safety

Blinded 16-week treatment extension for patients who demonstrated partial hair growth

24-week follow-up period after treatment

Severity of Alopecia Tool (SALT) is a validated endpoint to assess the extent of scalp-hair loss in patients with alopecia areata

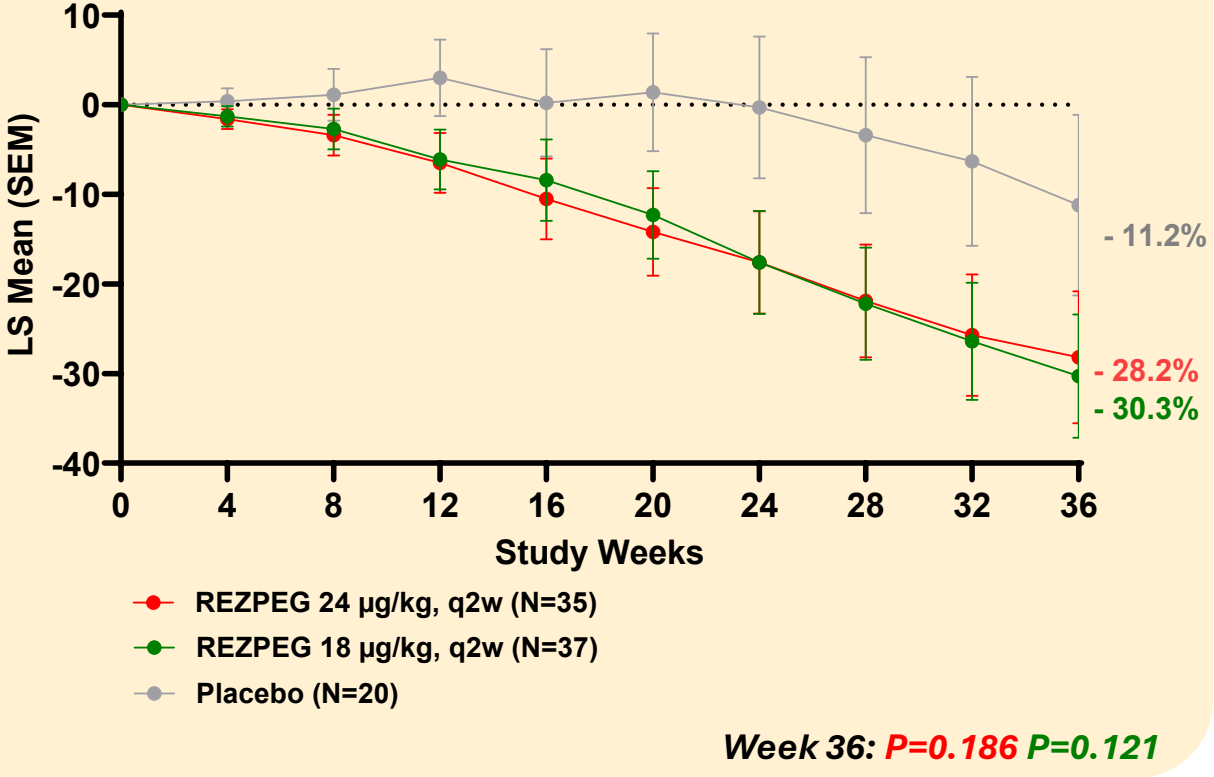
Clinical cutoff date (CCOD) for this presentation: November 13, 2025

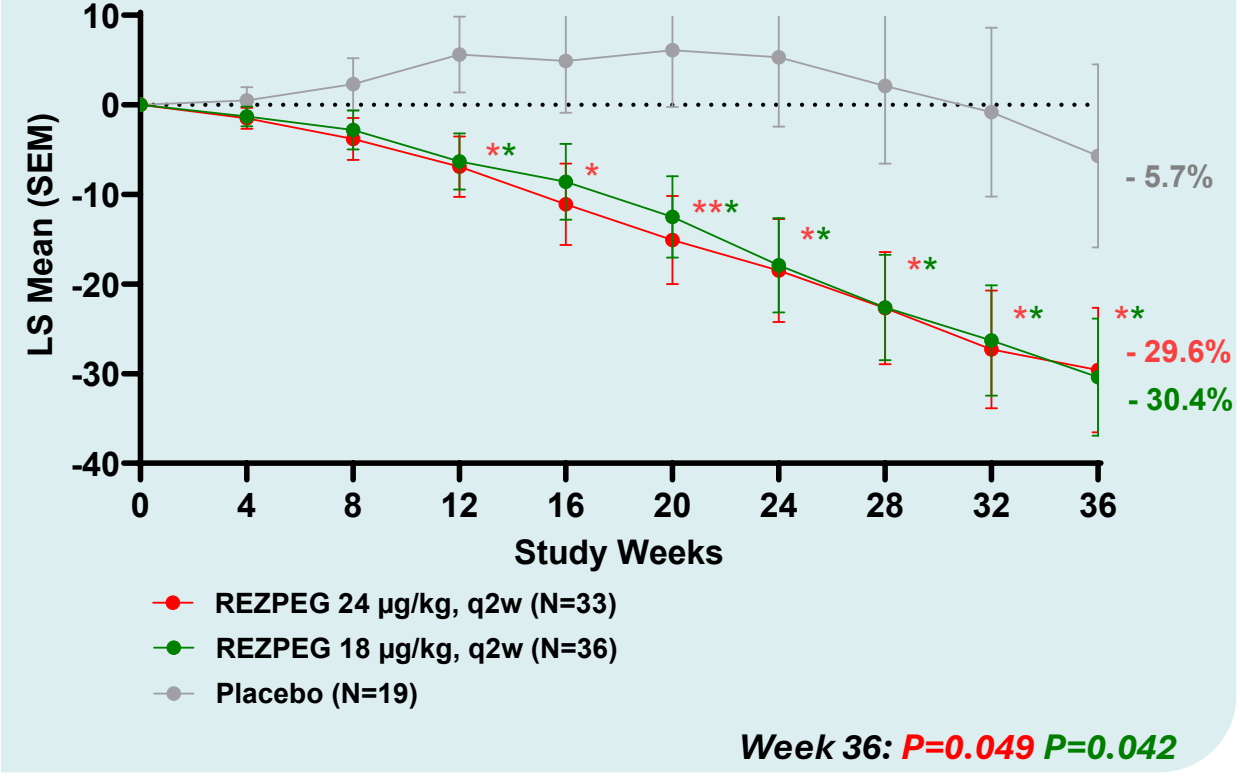
Baseline Demographics & Disease Characteristics

	REZPEG 18 µg/kg q2w N = 37	REZPEG 24 µg/kg q2w N = 35	Placebo N=20
Age, Mean (SD)	39.5 (16.3)	40.2 (13.0)	40.8 (16.0)
Sex, Female (%)	29 (78.4%)	22 (62.9%)	14 (70.0%)
Race, White	32 (86.5%)	28 (80.0%)	17 (85.0%)
Country			
Canada	8 (21.6%)	10 (28.6%)	3 (15.0%)
United States	5 (13.5%)	6 (17.1%)	1 (5.0%)
Poland	24 (64.9%)	19 (54.3%)	16 (80.0%)
Baseline SALT Score			
Mean (SD)	80.7 (16.1)	76.3 (18.9)	76.6 (18.7)
Median (Min, Max)	80.7 (51.4, 100.0)	76.8 (50.0, 100.0)	77.7 (50.1, 100.0)
Duration of current AA episode (years)			
Mean (SD)	2.48 (1.9)	2.98 (2.5)	2.98 (2.1)
Duration of current AA episode category			
< 4 years	27 (73.0%)	22 (62.9%)	14 (70.0%)
≥ 4 years	10 (27.0%)	13 (37.1%)	6 (30.0%)
Time since onset of AA (years)			
Mean (SD)	11.9 (12.7)	12.3 (12.2)	8.2 (7.9)
Median (Min, Max)	7.0 (0.7, 60.0)	6.8 (0.2, 39.0)	6.1 (0.4, 31.0)
SALT stratification factor			
≥ 50 to <95	26 (70.3%)	25 (71.4%)	16 (80.0%)
≥ 95 to 100	11 (29.7%)	10 (28.6%)	4 (20.0%)
Baseline Eyebrow ClinRO, ≥2, n(%)	18 (48.6%)	17 (48.6%)	12 (60%)
Baseline Eyelash ClinRO, ≥2, n(%)	16 (43.2%)	18 (51.4%)	12 (60%)

SD: Standard Deviation; Min: Minimum; Max: Maximum

Mean Percent Change in SALT Score: Treatment Arms Demonstrate Clear Efficacy

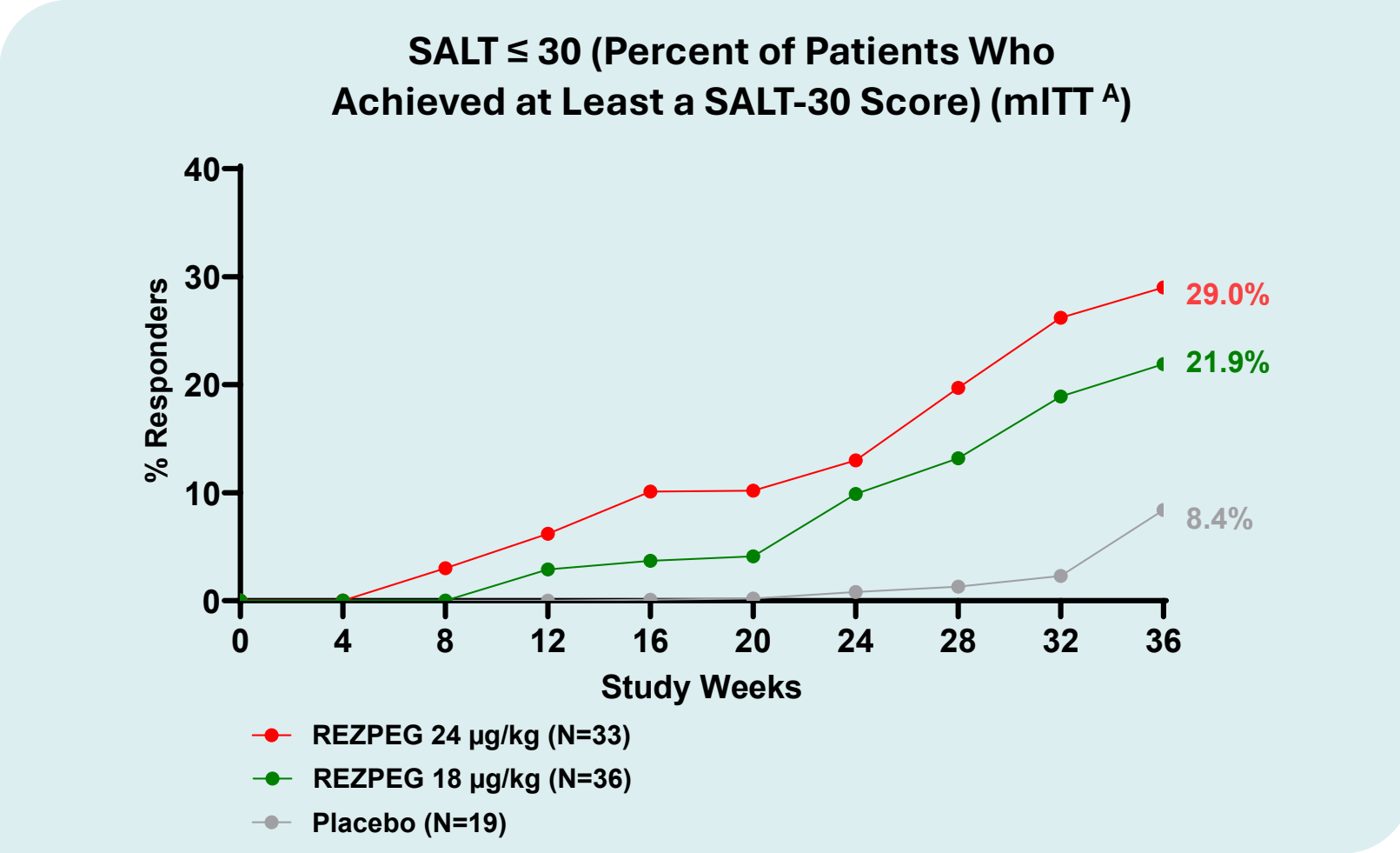




*p-value<0.05; **p-value<0.01

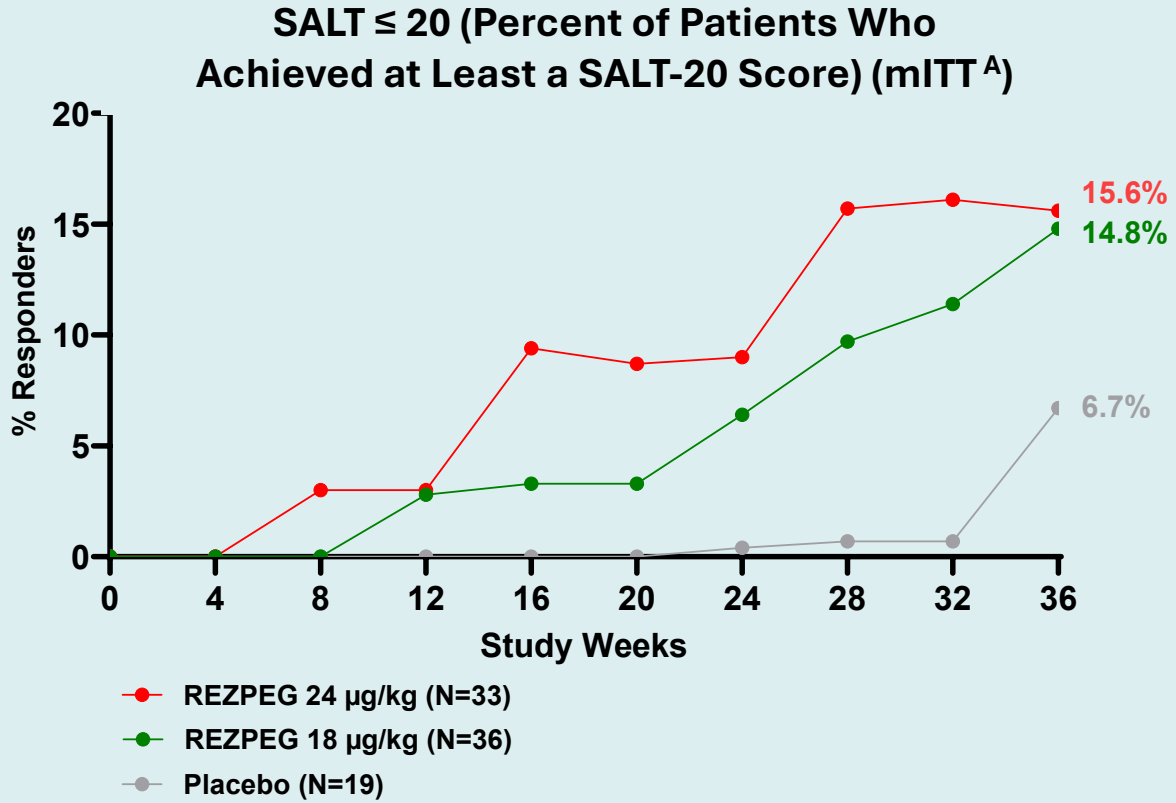
[A]*mITT excluding 4 patients with major study eligibility violations (post-hoc): 24 µg/kg (1 with unstable AA and 1 with inadequate washout of prior AA medication), 18 µg/kg (1 with inadequate washout of prior AA medication), placebo (1 with unstable AA)*

SALT ≤ 30: Clear Dose Response and Separation from Placebo



A. mITT excluding 4 patients with major study eligibility violations (post-hoc).

SALT ≤ 20: Clear Dose Response and Separation from Placebo

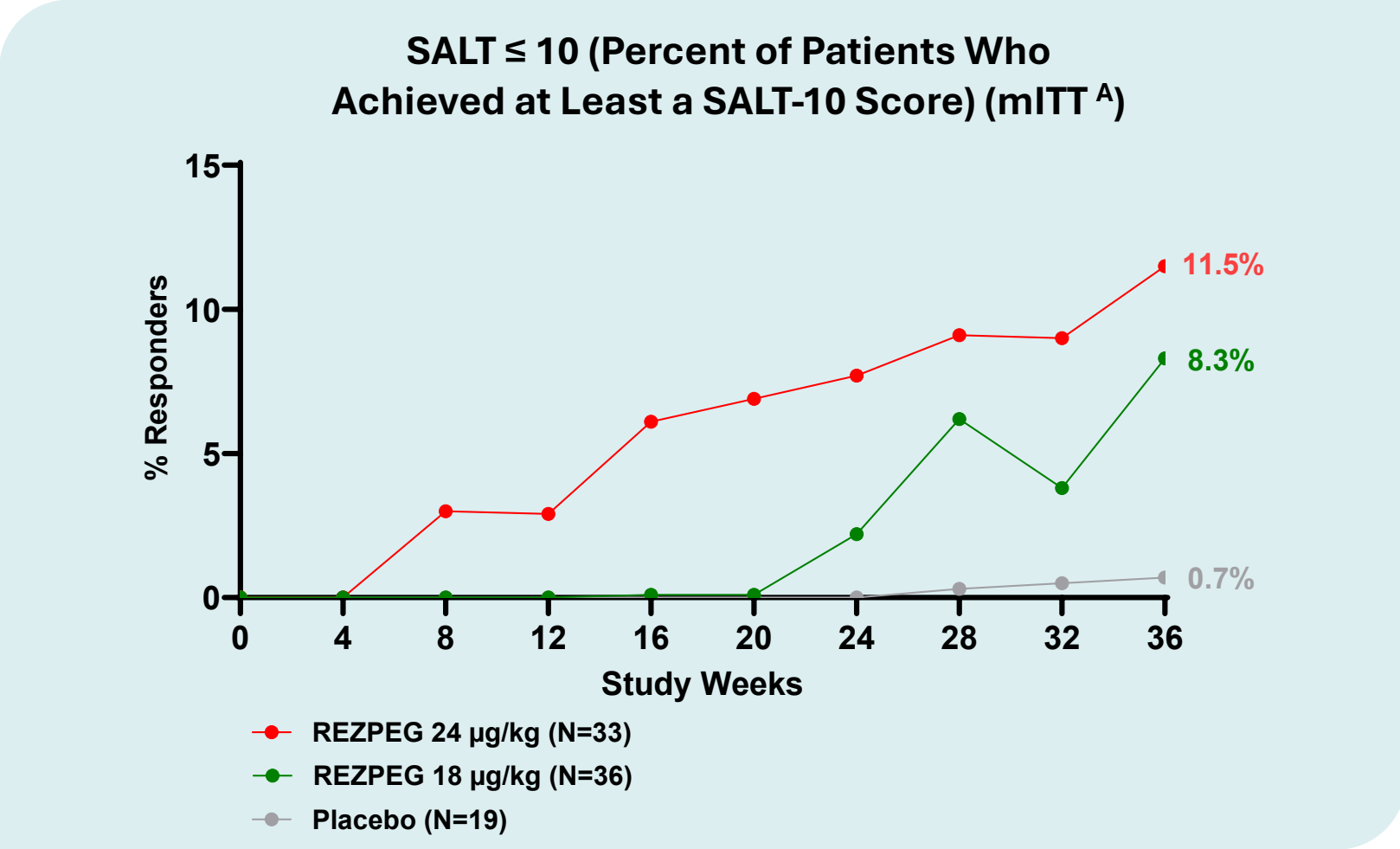


In the blinded treatment extension:

- 3 additional patients have already achieved a SALT ≤ 20 in the 16-week treatment extension with 2 patients ongoing treatment
- 7 additional patients who achieved SALT ≤ 30 are ongoing in the 16-week treatment extension

A. mITT excluding 4 patients with major study eligibility violations (post-hoc)

SALT ≤ 10: Clear Dose Response and Separation from Placebo



A. *mITT excluding 4 patients with major study eligibility violations (post-hoc)*

Eyebrow/Eyelash Regrowth with REZPEG

Endpoint at Week 36	REZPEG 18 µg/kg q2w	REZPEG 24 µg/kg q2w	Placebo
Number of Patients with Eyebrow Hair Loss at Baseline (≥2) [A]	N=18	N=15	N=12
% pts with ClinRO Eyebrow Score of 0 or 1 and a ≥2-point improvement from baseline	6% (1/18)	13% (2/15)	0
Placebo Adjusted [B]	7%	15%	-
Number of Patients with Eyelash Hair Loss at Baseline (≥2) [A]	N=15	N=16	N=12
% pts with ClinRO Eyelash Score of 0 or 1 and a ≥2-point improvement from baseline	13% (2/15)	19% (3/16)	0
Placebo Adjusted [B]	15%	18%	-

A. Excluding 4 patients with major study eligibility violations (post-hoc); B. Placebo Adjusted rate is estimated using the common Mantel–Haenszel (MH) difference adjusted for stratification factor. Missing data are imputed as non-responders

Summary of Treatment Emergent Adverse Events (TEAEs)

36-Week Treatment Period: ≥ 10% REZPEG Total or Placebo Arm

System Organ Class Preferred Term	REZPEG 18 µg/kg q2w N = 37	REZPEG 24 µg/kg q2w N = 35	REZPEG Total N = 72	Placebo N=20
Patients With at Least One TEAE[1]	35 (94.6%)	35 (100.0%)	70 (97.2%)	14 (70.0%)
General disorders and administration site conditions	35 (94.6%)	32 (91.4%)	67 (93.1%)	7 (35.0%)
Injection site reaction	34 (91.9%)	32 (91.4%)	66 (91.7%)	6 (30.0%)
Placebo-adjusted injection site reaction %	61.9%	61.4%	61.7%	-
Infections and infestations	15 (40.5%)	16 (45.7%)	31 (43.1%)	8 (40.0%)
Upper respiratory tract infection	5 (13.5%)	5 (14.3%)	10 (13.9%)	0
Nasopharyngitis	3 (8.1%)	4 (11.4%)	7 (9.7%)	2 (10.0%)
Oral herpes	2 (5.4%)	3 (8.6%)	5 (6.9%)	2 (10.0%)
Urinary tract infection	2 (5.4%)	3 (8.6%)	5 (6.9%)	2 (10.0%)
Musculoskeletal and connective tissue disorders	9 (24.3%)	10 (28.6%)	19 (26.4%)	4 (20.0%)
Arthralgia	4 (10.8%)	5 (14.3%)	9 (12.5%)	2 (10.0%)
Nervous system disorders	6 (16.2%)	8 (22.9%)	14 (19.4%)	3 (15.0%)
Headache	3 (8.1%)	5 (14.3%)	8 (11.1%)	3 (15.0%)
Skin and subcutaneous tissue disorders	5 (13.5%)	9 (25.7%)	14 (19.4%)	6 (30.0%)
Alopecia	0	1 (2.9%)	1 (1.4%)	2 (10.0%)
Blood and lymphatic system disorders	4 (10.8%)	9 (25.7%)	13 (18.1%)	1 (5.0%)
Eosinophilia	0	5 (14.3%)	5 (6.9%)	0
Respiratory, thoracic and mediastinal disorders	4 (10.8%)	7 (20.0%)	11 (15.3%)	2 (10.0%)
Eye disorders	3 (8.1%)	2 (5.7%)	5 (6.9%)	2 (10.0%)
Gastrointestinal disorders	3 (8.1%)	10 (28.6%)	13 (18.1%)	3 (15.0%)
Gastroesophageal reflux disease	0	0	0	2 (10.0%)
Investigations	3 (8.1%)	7 (20.0%)	10 (13.9%)	2 (10.0%)

1. One patient in the 18 µg/kg had a serious AE of a gun shot wound, and patient continued in the study. One patient in the 24 µg/kg had a severe ISR report AE, and the patient continued on treatment. One placebo patient discontinued treatment early due to worsening hair loss.

Highly Differentiated Safety Profile

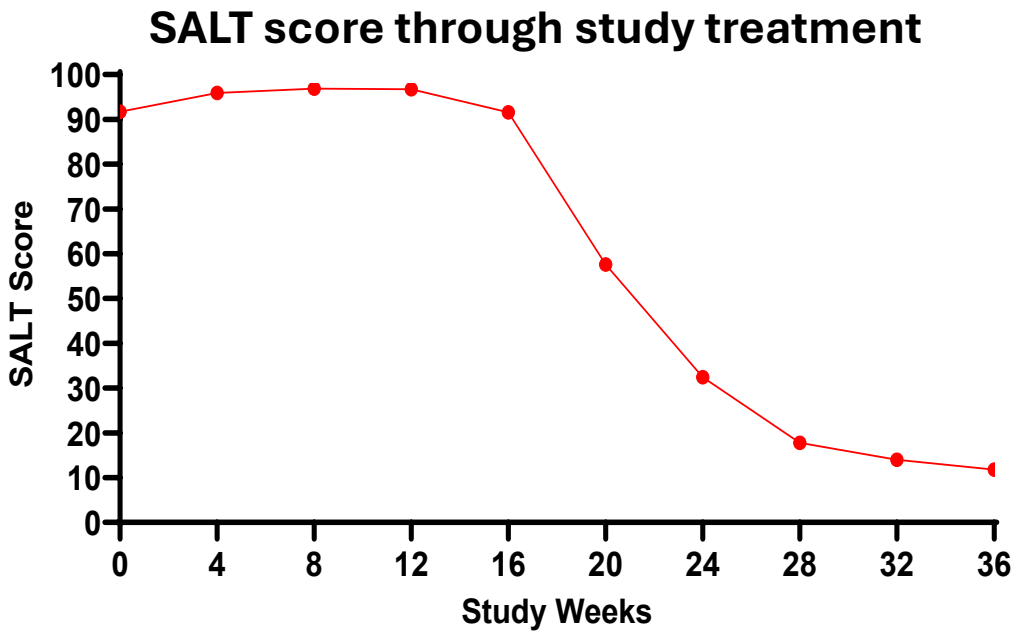
Across 11 Phase 1-2b Studies in Health Volunteers and Patients with Various Inflammatory Conditions

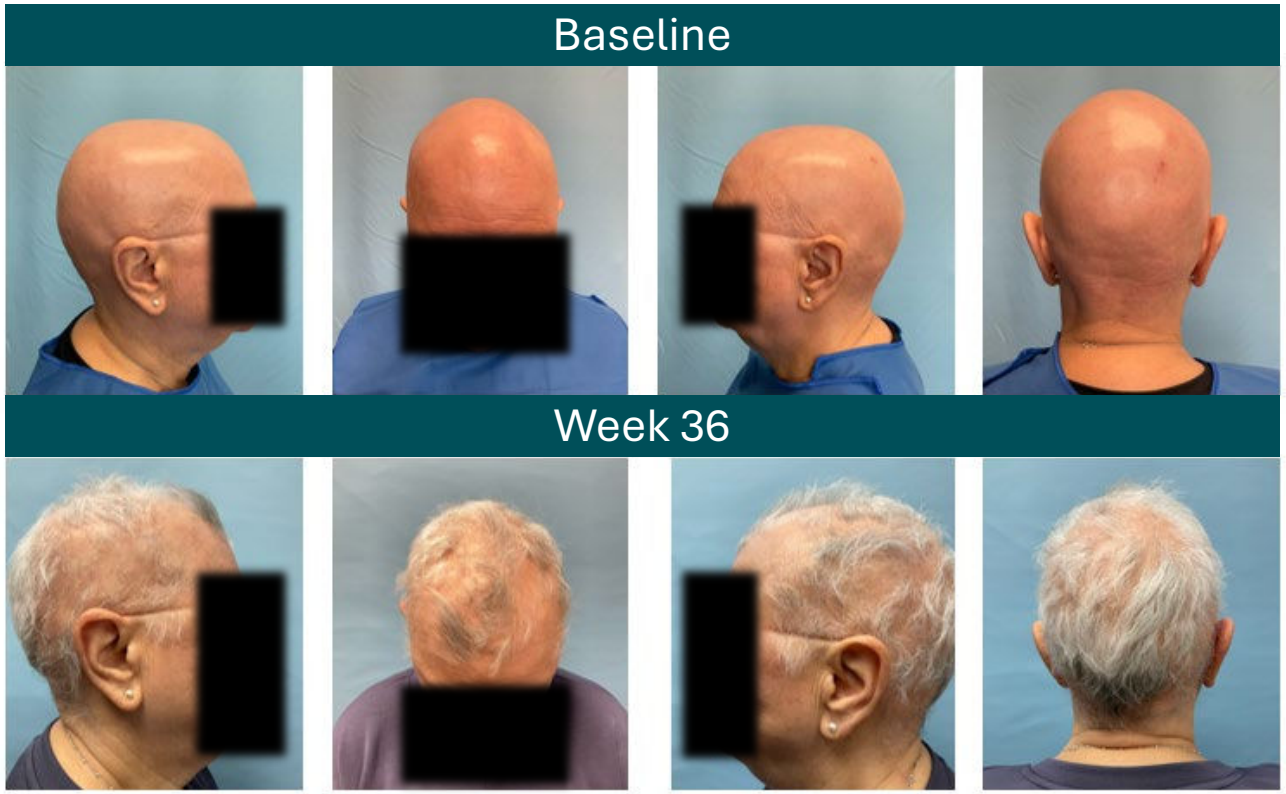
- Over 1,000 subjects exposed to REZPEG across 11 studies, with approximately 381 patient-years exposure

- No increased risk observed for:
  - major adverse cardiovascular events (MACE)
  - Thrombosis
  - Infections including oral herpes
  - Malignancies
  - Acne
  - JAK-inhibitor like adverse events requiring laboratory testing and monitoring

Case Study #1: Patient Achieved SALT ≤ 20 by Week 28

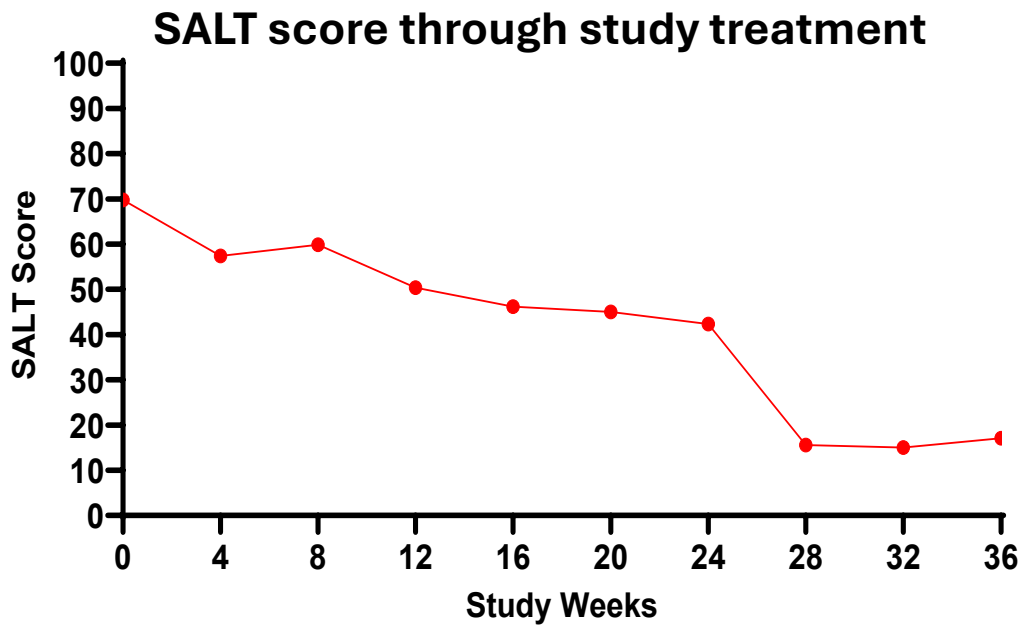
- 66-year-old white female
- Diagnosed 1.8 years prior to treatment
- 36 weeks of REZPEG 24 µg/kg treatment

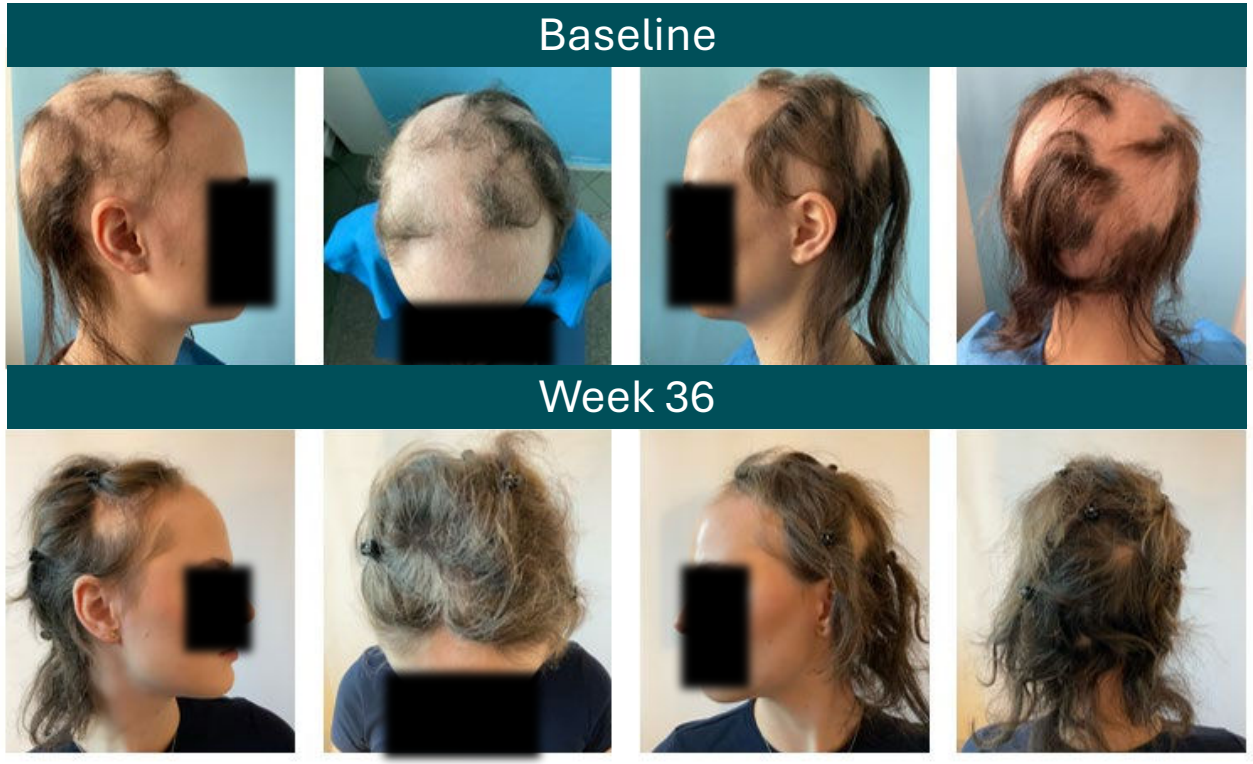




Case Study #2: Achieved SALT ≤ 20 by Week 28

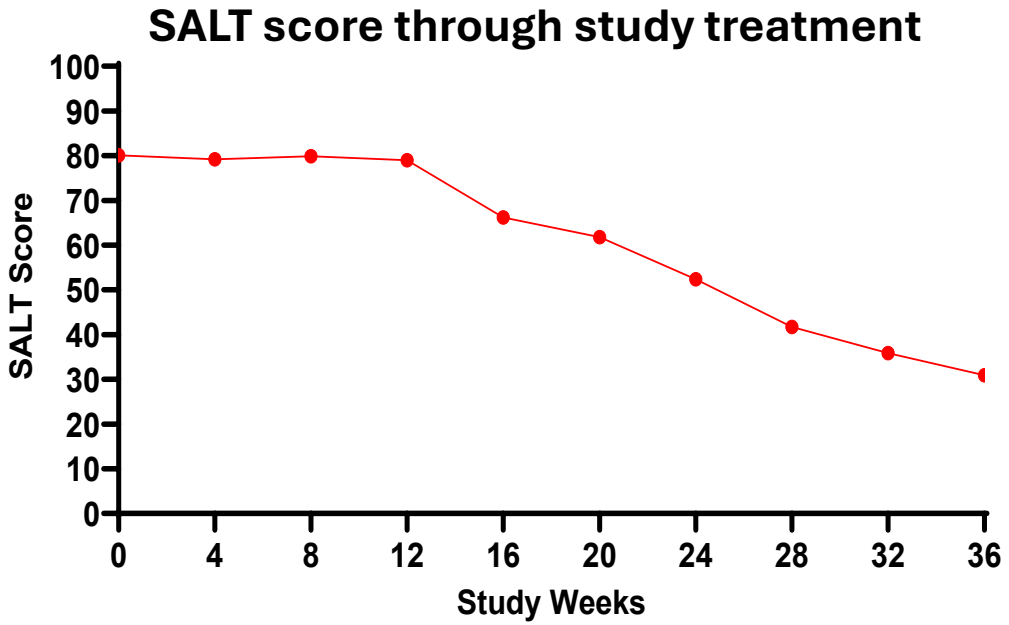
- 20-year-old white female
- Diagnosed 17 years prior to treatment
- 36 weeks of REZPEG 18 µg/kg treatment

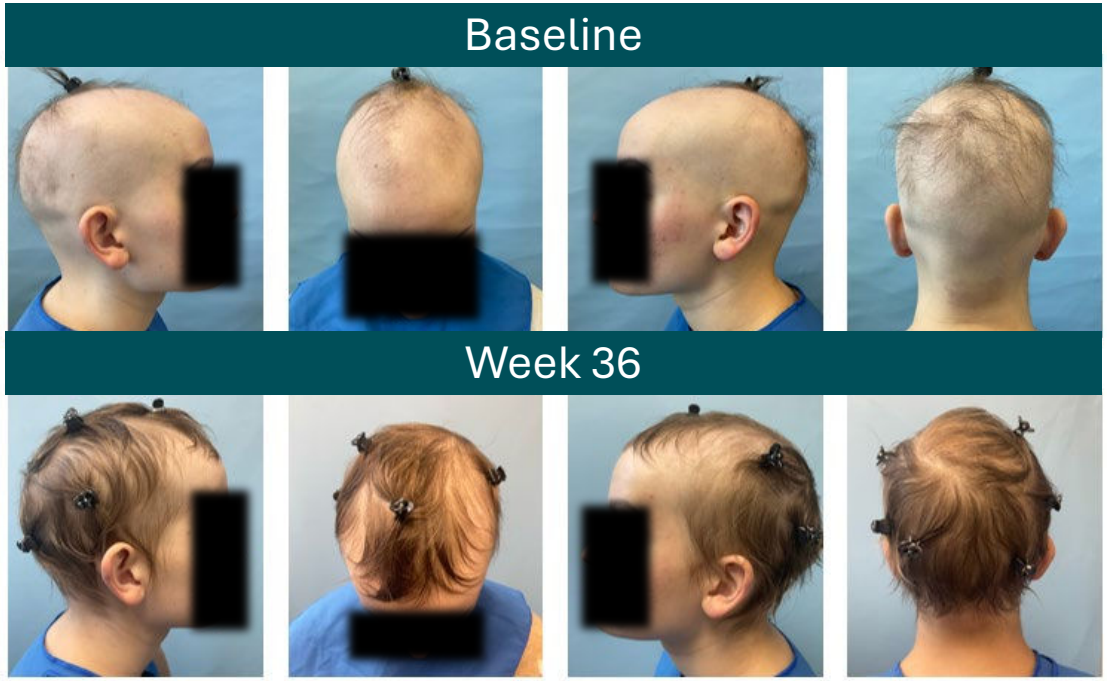




Case Study #3: Consistent Hair Growth

- 20-year-old white female
- Diagnosed 6 years prior to treatment
- 36 weeks of REZPEG 24 µg/kg treatment
- SALT-20 not achieved at Week 36 and patient continued treatment into extension





Summary & Conclusion

Rezolve AA: Results following 36-weeks of Treatment

- Proof of concept demonstrated for REZPEG as a potential first-in-class biologic for alopecia areata
  - Mean % change in SALT at Week 36 was -30% for REZPEG arms vs -6% for placebo ($p<0.05$), with consistent separation at each time point from placebo[1]
  - Treatment arms shows consistent dose response and separation from placebo for SALT≤30, SALT≤20 and SALT≤10
  - Regrowth observed in eyebrows and eyelashes
  - No plateau of SALT reduction by week 36
- REZPEG 24 µg/kg q2w identified as the Phase 3 dose
- Safety consistent with previously-reported safety profile (>1,000 subjects exposed) with no new safety concerns in study treatment arms
  - No increased risk of major adverse cardiovascular events (MACE) events, thrombosis, acne and infections including oral herpes
  - Most frequent AEs were injection site reactions (ISRs) that were mostly mild and self-resolving

Data from treatment extension to Week 52 is expected in April 2026

1. mITT excluding 4 patients with major study eligibility violation

Acknowledgements

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  - The investigators and their study teams
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