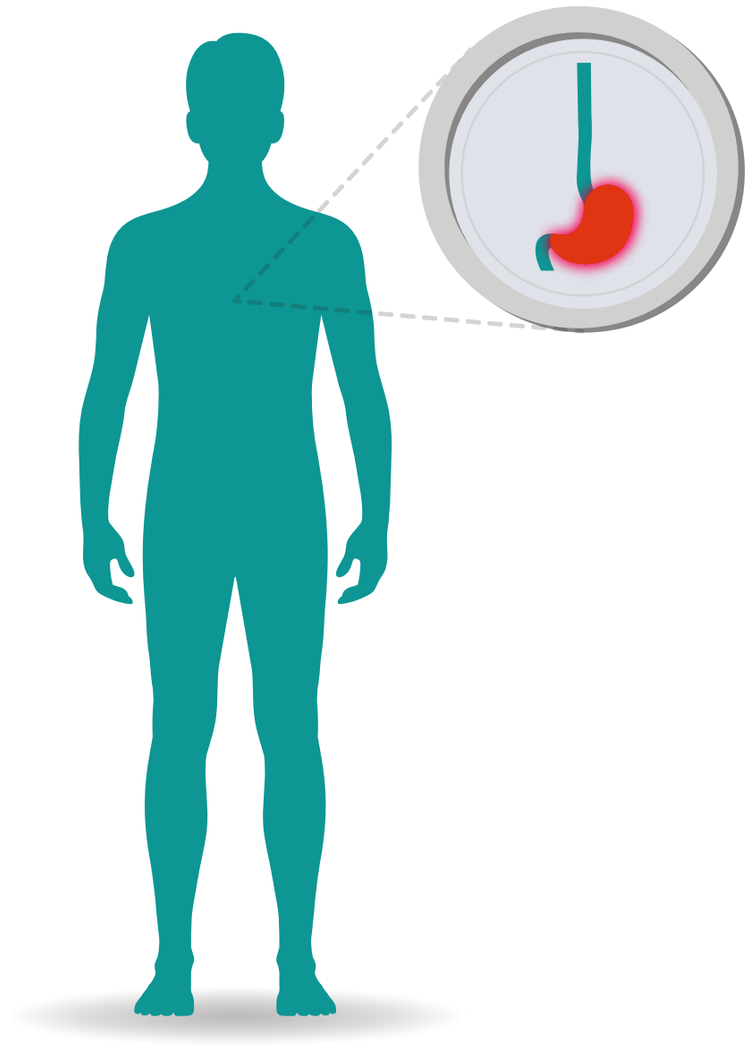
Dupilumab Improves Multiple Outcomes in Adults and Adolescents with Eosinophilic Gastritis (EoG)

Dupilumab demonstrated improvements in gastric eosinophil count, endoscopic and histologic features of EoG, symptoms of EoG, and gene expression profiles; improvements were maintained through 36 weeks of treatment. Dupilumab was well tolerated

Eosinophilic Gastritis

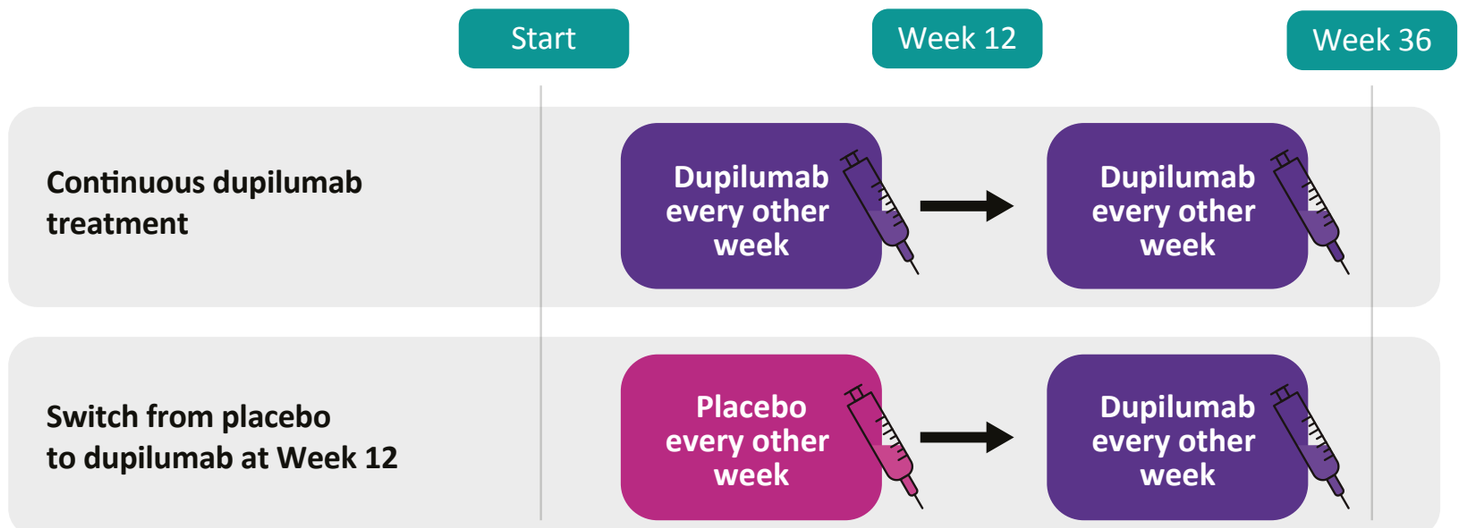


The Disease

- Eosinophilic gastritis (EoG) is a long-term, inflammatory disease of the stomach that affects people of all ages
- It causes symptoms such as stomach pain, heartburn, nausea, and vomiting, and significantly impacts quality of life
- There are currently no approved treatments for EoG

The Study

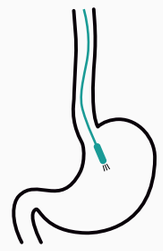
- Dupilumab is a biologic medication that blocks the pathways leading to inflammation in EoG
- The DEGAS study assessed whether treatment with dupilumab every other week improved EoG outcomes compared with inactive medication (placebo) in 41 adults and adolescents



Improvements were seen with dupilumab at Week 12 and maintained through 36 weeks of treatment.

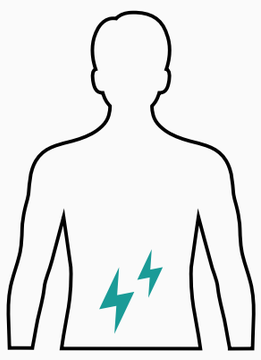
Decrease in gastric eosinophil count

Improvement in features of EoG in biopsies of the stomach seen under a microscope



Improvement in endoscopic features seen by a camera in the stomach

With dupilumab treatment



Symptoms of EoG show signs of improvement

Improvement in gene expression profile

Adverse Events

The incidence of adverse events was 81–89% across treatment groups and trial phases. Common adverse events included blood eosinophilia (which had similar incidence with dupilumab and placebo), injection-site reaction, and sinusitis. There were no serious adverse events.

Gonsalves NP, et al. Dupilumab improves histologic and endoscopic features of eosinophilic gastritis: Results from the multicenter, randomized, double-blind, placebo-controlled phase 2 DEGAS trial. Presented at Digestive Disease Week (DDW) 2025: San Diego, CA, USA; May 3–6, 2025.

CEGiR Consortium of Eosinophilic Gastrointestinal Disease Researchers

Dupilumab Improves Histologic and Endoscopic Features of Eosinophilic Gastritis: Results from the Multicenter, Randomized, Double-blind, Placebo-controlled Phase 2 DEGAS Trial

Nirmala P. Gonsalves[1], Evan S. Dellon[2], Kara L. Kliewer[3], Regina Yearout[3], Seema Aceves[4], Nicoleta C. Arva[5], John A. Besse[3], Julie M. Caldwell[3], Mirna Chehade[6], Amaziah Coleman[7], Margaret H. Collins[8], Sara Anvari[9], Gary W. Falk[10], Sandeep K. Gupta[11], Girish Hiremath[12], David A. Katzka[13], Paneez Khoury[14], John Leung[15], Calies Menard-Katcher[16], Paul Menard-Katcher[17], Kathryn A. Peterson[18], Maria Pletneva[19], Tetsuo Shoda[3], Amanda K. Rudman Spergel[7], Jonathan M. Spergel[20], Tatyana Vaysman[7], Joshua B. Wechsler[21], Benjamin L. Wright[22], Guang-Yu Yang[23], Xue Zhang[24], Meijian Zhou[25], Ashish Bansal[25], Bram P. Raphael[25], Amr Radwan[25], Jennifer Maloney[25], Antonio Martin[26], Yamo Deniz[25], Glenn T. Furuta[16], Lisa J. Martin[24], Marc E. Rothenberg[3]

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Disclosure Information

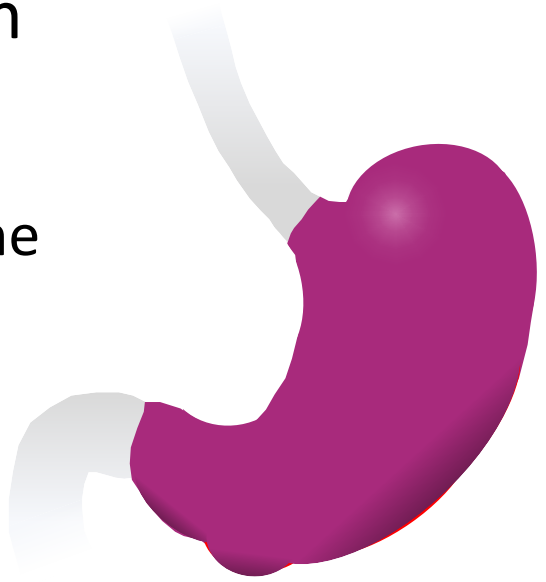
Nirmala P. Gonsalves, MD

I disclose the following financial relationship(s) with a commercial interest

- Consulting fees: Allakos, AstraZeneca, Bristol Myers Squibb, Exact Sciences, Regeneron Pharmaceuticals Inc., Sanofi, Takeda
- Speaker fees: Regeneron Pharmaceuticals Inc., Sanofi, Takeda

Background: Eosinophilic Gastritis (EoG)

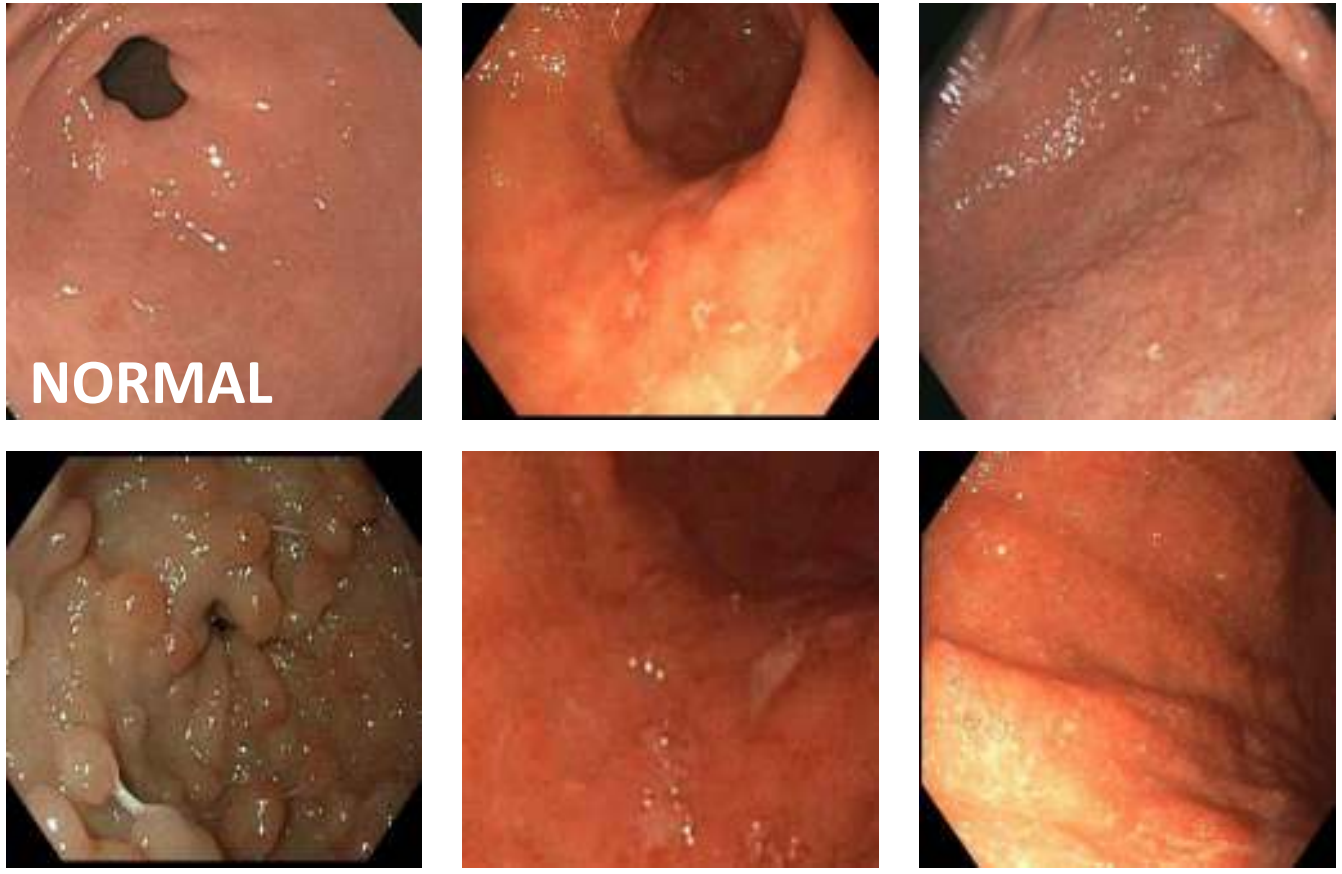
- EoG is a rare, chronic disease characterized by eosinophilia of the stomach and GI symptoms that can significantly impact QoL[1–8]
  - Pathophysiology driven by food antigens and type 2 immune dysregulation, with upregulation of IL-4 and IL-13[9–11]
  - Symptoms include abdominal pain, nausea, vomiting, early satiety, bloating, and diarrhea[3,4,12]



EoG, eosinophilic gastritis; GI, gastrointestinal; IL, interleukin; QoL, quality of life.

Background: Endoscopic Features of EoG

Eosinophilic **G**astritis **E**ndoscopic **R**eference **S**ystem (**EoG-REFS**)[13]

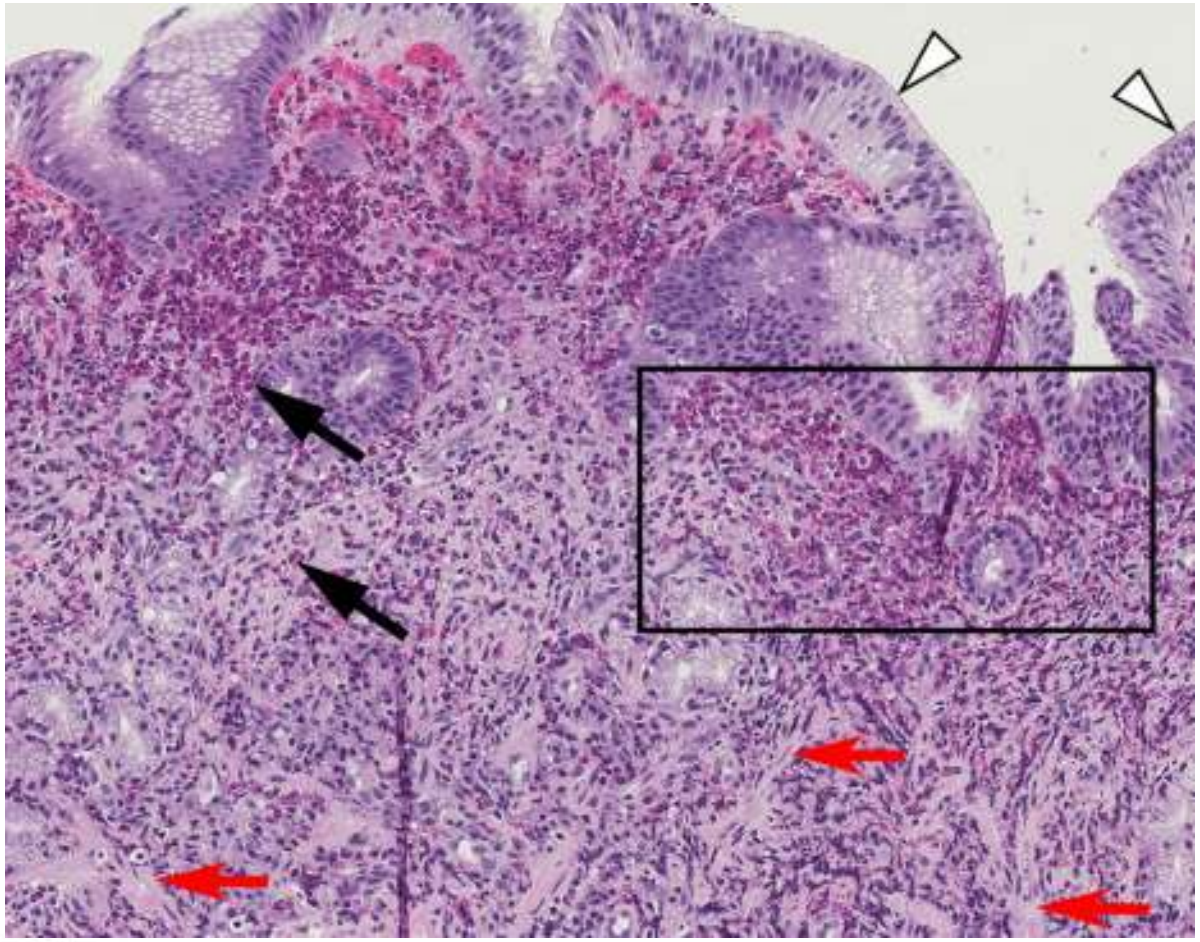


- **Erosion/Ulceration**
- **Granularity**
- **Raised lesion/nodule**
- **Erythema**
- Thickened **Folds**
- **Friability**
- Pyloric **Stenosis**

EoG-REFS, Eosinophilic Gastritis Endoscopic Reference System.

Background: Histopathologic Features of EoG

Eosinophilic **G**astritis **H**istology **S**coring **S**ystem **(EoG-HSS)**[14]



- **Eosinophil sheets** (rectangle)
- **Numerous individual eosinophils** (black arrows)
- **Smooth muscle bundles** (red arrows)
- **Reactive surface epithelial cells** (arrowheads)
  - Additional components (e.g. eosinophils in muscularis mucosa) not illustrated here

EoG-HSS, Eosinophilic Gastritis Histology Scoring System.

Background: Dupilumab

- There are currently no FDA-approved treatments for EoG
- Dupilumab is a fully human monoclonal antibody that blocks the IL-4/IL-13 shared receptor component
  - Efficacious in multiple type 2 inflammatory diseases including eosinophilic esophagitis (EoE)[15,16]

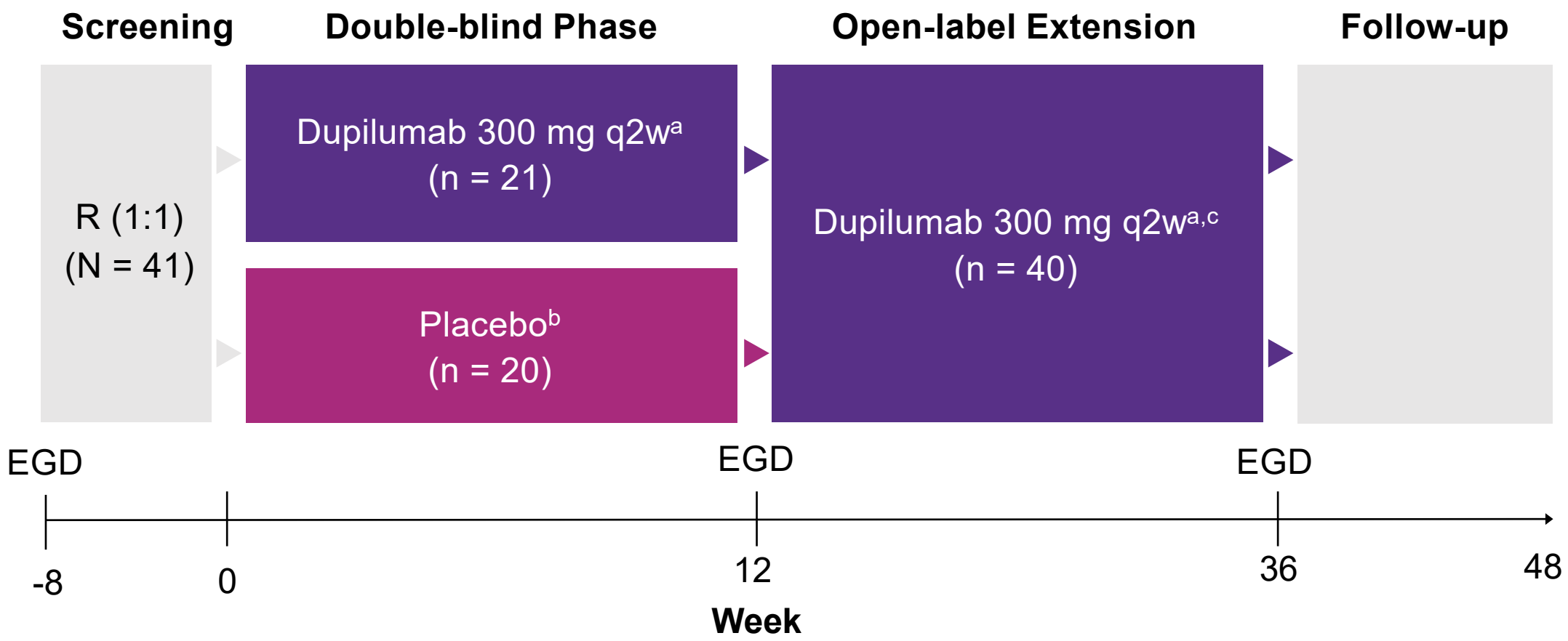
EoE, eosinophilic esophagitis; EoG, eosinophilic gastritis; FDA, US Food and Drug Administration.

Aim

- Consortium of Eosinophilic Gastrointestinal Disease Researchers (CEGIR), in collaboration with the NIH, Regeneron and Sanofi[a], designed the study to assess efficacy and safety of dupilumab vs placebo in adults and adolescents with symptomatic, histologically active EoG

[a]Regeneron Pharmaceuticals Inc. and Sanofi were involved in review and approval of the protocol.
CEGIR, Consortium of Eosinophilic Gastrointestinal Disease Researchers; EoG, eosinophilic gastritis; NIH, National Institutes of Health.

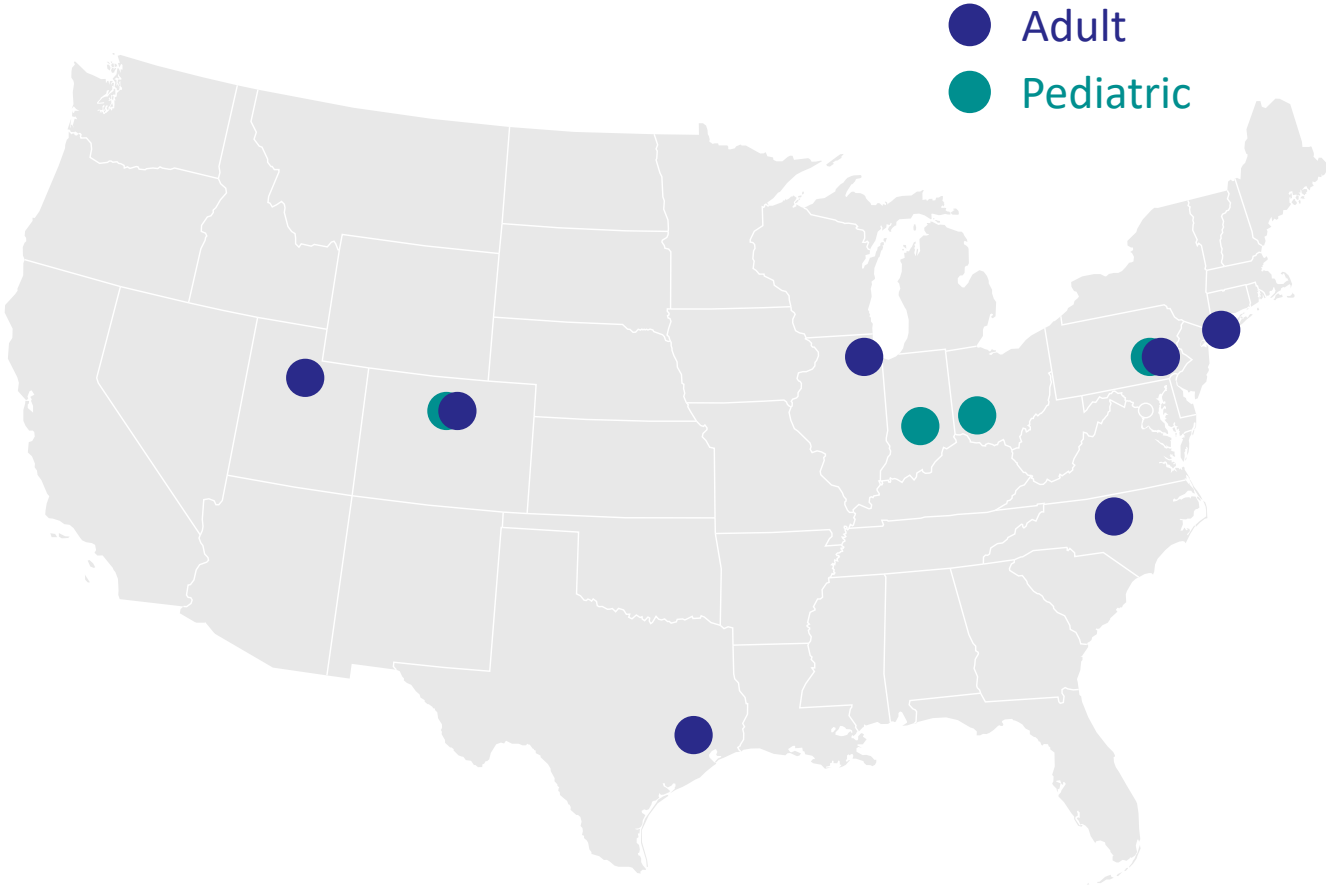
Phase 2 DEGAS Trial (NCT03678545)



[a]An initial dose of 600 mg was administered at baseline and at Week 12 for patients switching from placebo to dupilumab, followed by 300 mg q2w. [b]One patient discontinued placebo due to worsening EoG symptoms. [c]Three patients discontinued dupilumab in the OLE: one patient discontinued due to personal reasons, one patient discontinued due to arthritis, and one patient discontinued due to arthritis, eye disorder, and gastroesophageal reflux disease.
DBP, double-blind phase; EGD, esophagogastroduodenoscopy; EoG, eosinophilic gastritis; OLE, open-label extension; q2w, every 2 weeks; R, randomized.

Study Sites across the US

- Cincinnati Children's Hospital Medical Center
- University of North Carolina
- Northwestern University
- Icahn School of Medicine at Mount Sinai
- Children's Hospital Colorado
- Riley Children's Hospital
- Children's Hospital of Philadelphia
- University of Pennsylvania
- Baylor College of Medicine
- University of Utah
- University of Colorado



Inclusion Criteria

Key inclusion criteria:

- Aged ≥12 to <71 years
- Gastric eosinophil count of ≥30 eos/hpf in ≥5 hpfs in the gastric antrum and/or body at screening
- History of moderate-to-severe EoG symptoms[a] occurring ≥2 days/week in the 2 weeks prior to screening
- EoG symptoms ≥2 days/week in the 2 weeks prior to randomization using daily EoG symptoms diary
- Asthma Control Test score ≥20

[a]Symptoms included stomach pain/cramping, nausea, bloating, burning feeling in the chest, early satiety, appetite loss, vomiting, and diarrhea.
EoG, eosinophilic gastritis; eos/hpf, eosinophils per high-power field; hpf, high-power field.

Exclusion Criteria

Key exclusion criteria:

- Active *Helicobacter pylori* infection
- Use of biologic agents within 4 months or 5 half lives, whichever is longer, prior to screening
- Use of systemic steroids (daily dose >10 mg) or steroid burst for >3 days within 1 month of screening
- Prior exposure to dupilumab

Outcomes

	Endpoints
Primary	Relative (percentage) change from baseline in mean gastric eosinophil count[a]
Key secondary	Absolute change from baseline in EoG Histology score[17,b]
	Absolute change from baseline in mean gastric eosinophil count[a]
	Absolute change from baseline in EoG Endoscopy score[13,c]
	Absolute change from baseline in EoG Symptom score[d]
	Proportion of patients achieving histopathologic remission (<30 eos/hpf in all 5 hpfs)
Exploratory	Absolute change from baseline in EoG Transcriptomic score[11,e]

[a]Mean of the eosinophil counts from the 5 most eosinophil-dense hpfs in the gastric antrum and/or body. [b]EoG-Histologic Scoring System total score. [c]EoG-Endoscopic Reference System total score. [d]Post-baseline EoG-Symptom Questionnaire Total Symptom Score was based on the summed daily severity scores recorded in an eDiary for stomach pain, stomach cramping, nausea, bloating, early satiety, and loss of appetite, averaged over a 7-day period. [e]EoG-Diagnostic Panel$_{18}$ score. EoG, eosinophilic gastritis; eos/hpf, eosinophils per high-power field; hpf, high-power field.

Baseline Demographic and Clinical Characteristics Were Generally Similar across Groups

Demographic/characteristic	Placebo (N = 20)	Dupilumab (N = 21)
Age (years), mean (SD)	30.7 (14.0)	30.3 (12.8)
<18 years, n (%)	4 (20)	3 (14)
Female sex, n (%)	10 (50)	15 (71)
Race, n (%)		
Asian	0 (0)	1 (5)
Black or African American	1 (5)	0 (0)
White	19 (95)	18 (86)
≥2 races[a]	0 (0)	2 (10)
Height (cm), mean (SD)	167.3 (12.3)	166.7 (13.0)
Body weight (kg), mean (SD)	72.1 (22.0)	70.9 (25.2)
Years since EoG diagnosis, median (IQR)	6.2 (3.2, 11.2)	2.8 (1.7, 8.1)

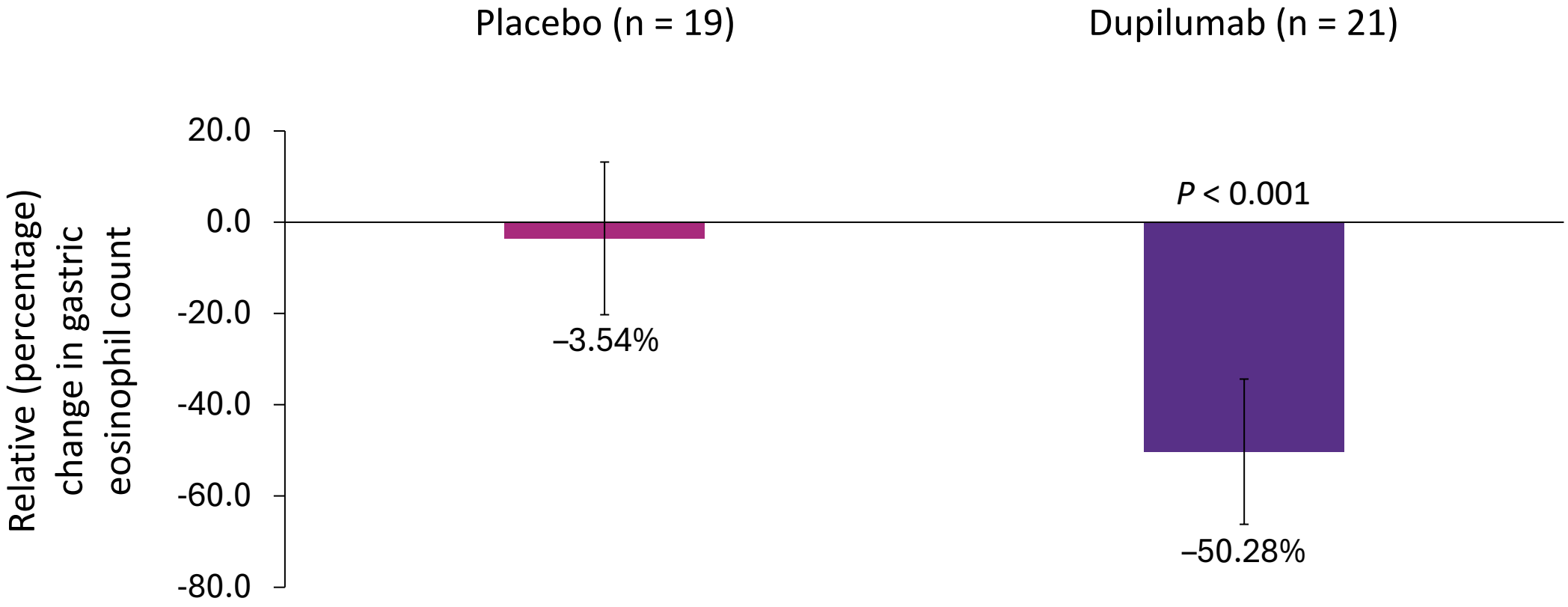
[a]Races include "White" and "Asian."
EoG, eosinophilic gastritis; IQR, interquartile range; SD, standard deviation.

Baseline Demographic and Clinical Characteristics Were Generally Similar across Groups

Demographic/characteristic	Placebo (N = 20)	Dupilumab (N = 21)
Mean gastric eosinophil count, median (IQR)	61.8 (40.1, 124.9)	66.0 (47.4, 132.0)
EoG Histology score, mean (SD)	0.39 (0.14)	0.39 (0.20)
EoG Endoscopy score, median (IQR)	5.5 (4.0, 11.0)	8.0 (6.0, 9.0)
EoG Symptom score, mean (SD)	23.9 (10.6)	18.8 (12.4)
History of EoE, n (%)	12 (60)	14 (67)
Atopic disease n (%)	14 (70)	13 (62)
Asthma, n (%)	7 (35)	8 (38)
Eczema/atopic dermatitis, n (%)	7 (35)	4 (19)
Allergic rhinitis/sinusitis, n (%)	2 (10)	1 (5)
Food allergy, n (%)	3 (15)	1 (5)
Current use of systemic corticosteroids, n (%)	1 (5)	0 (0)
Current use of topical corticosteroids, n (%)	3 (15)	5 (24)
Current use of food elimination diet, n (%)	13 (65)	15 (71)

EoE, eosinophilic esophagitis; EoG, eosinophilic gastritis; IQR, interquartile range; SD, standard deviation.

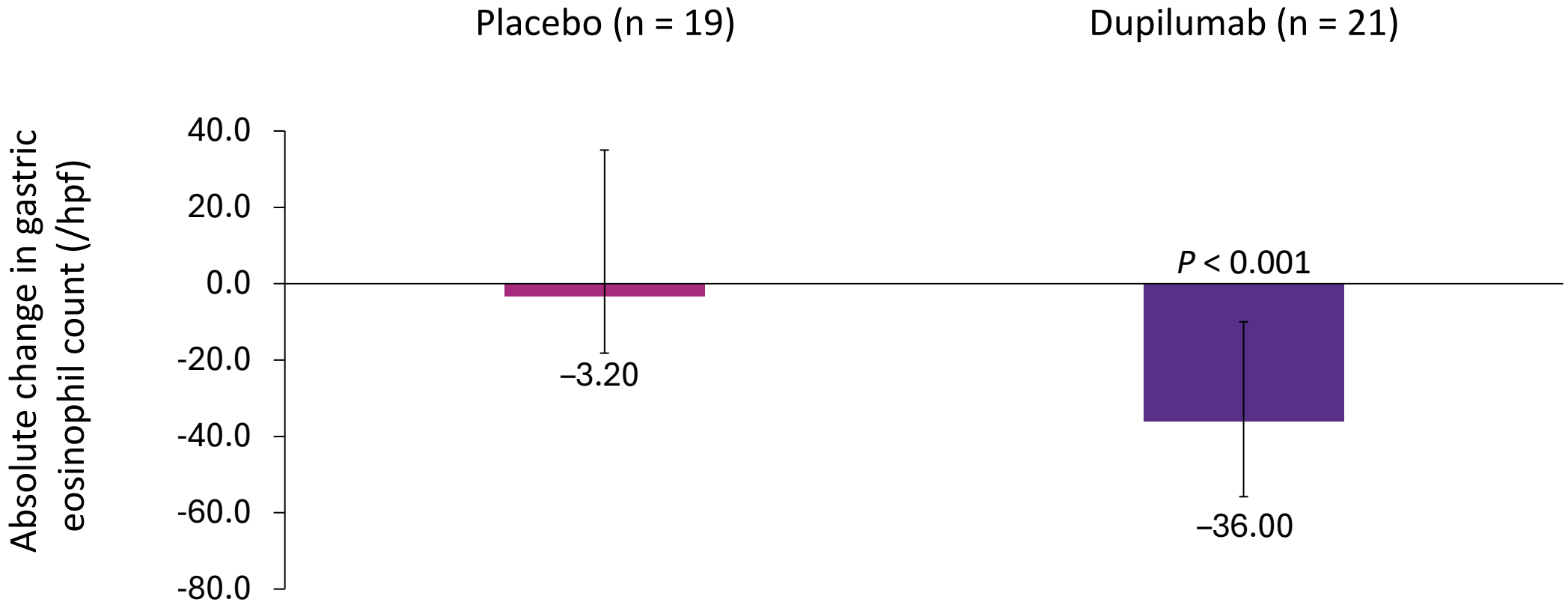
Primary Endpoint: Relative Change in Mean Gastric Eosinophil Count[a] Was Significantly Greater with Dupilumab vs Placebo at Week 12



Improvements were maintained at Week 36

[a]Mean of the eosinophil counts from the 5 most eosinophil-dense hpfs in the gastric antrum and/or body.
The relative change from baseline defined as Week 12 – baseline/baseline. LS means of each of the treatment groups (95% CIs) calculated using linear regression. Treatment was the only independent variable included in modeling. CI, confidence interval; hpf, high-power field; LS, least squares; q2w, every 2 weeks.

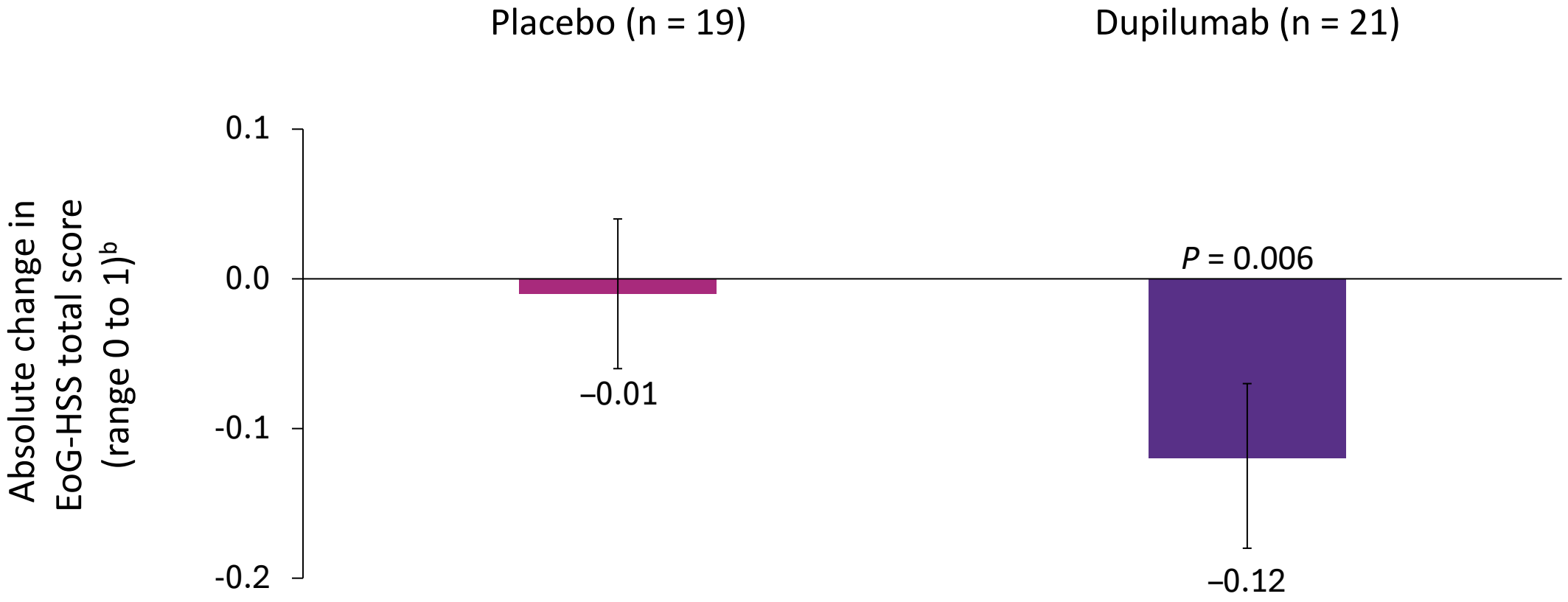
Secondary Endpoint: Absolute Reduction in Mean Gastric Eosinophil Count[a] was Significantly Greater with Dupilumab vs Placebo at Week 12



Improvements were maintained at Week 36

[a]Mean of the eosinophil counts from the 5 most eosinophil-dense hpfs in the gastric antrum and/or body. Median and IQR reported. *P* value calculated using Wilcoxon Rank Sum test.
hpf, high-power field; IQR, interquartile range.

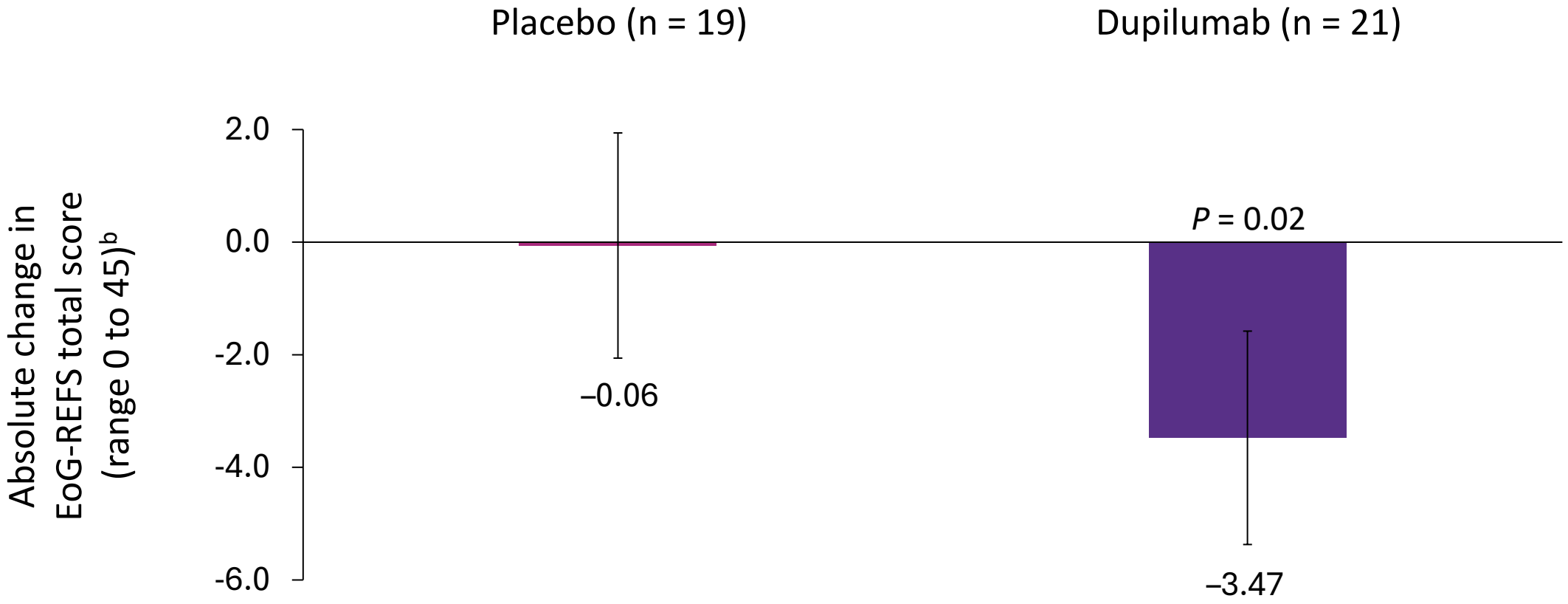
Secondary Endpoint: Absolute Reduction in Histopathologic Features of EoG[a] was Significantly Greater with Dupilumab vs Placebo at Week 12



Improvements were maintained at Week 36

[a]EoG-Histologic Scoring System total score. [b]Score ranges from 0 to 1, with higher scores indicating greater severity/extent of histopathologic changes.
LS means of each of the treatment groups (95% CIs) calculated using linear regression.
CI, confidence interval; EoG-HSS, EoG-Histologic Scoring System; LS, least squares.

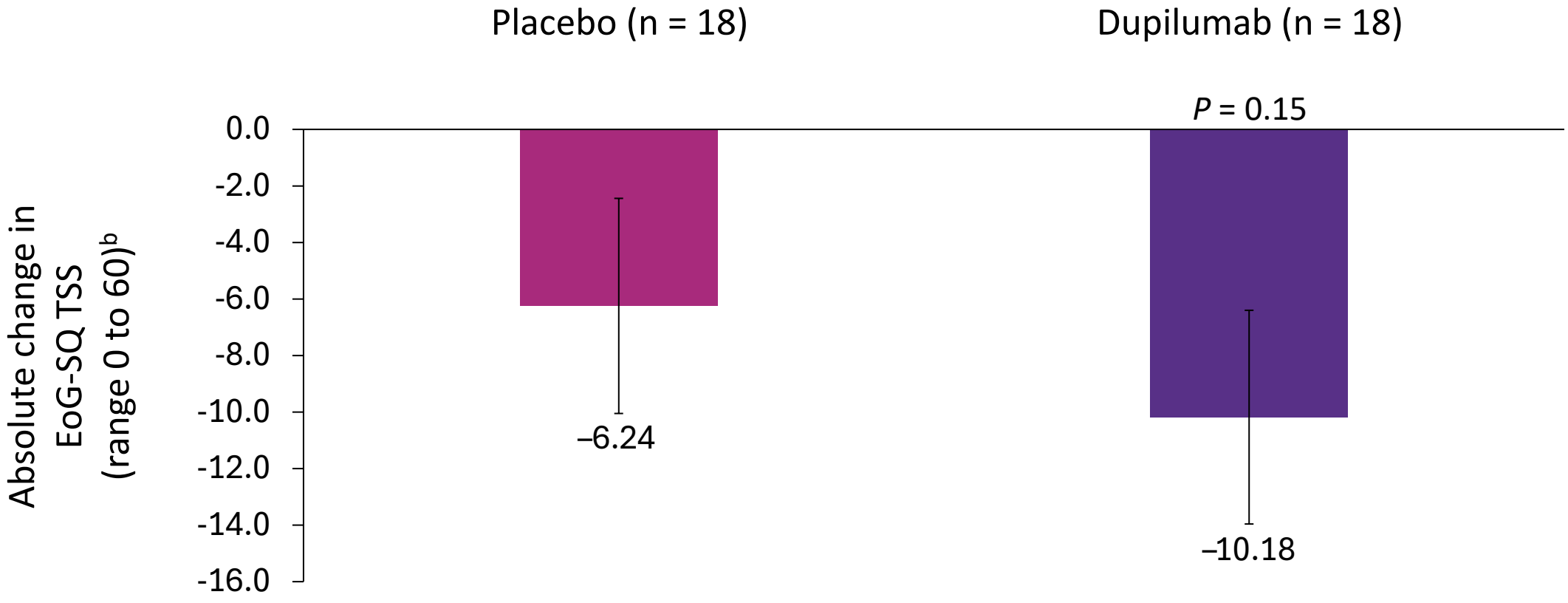
Secondary Endpoint: Absolute Reduction in Endoscopic Features of EoG[a] was Significantly Greater with Dupilumab vs Placebo at Week 12



Improvements were maintained at Week 36

[a]EoG-Endoscopic Reference System. [b]Score ranges from 0 to 45, with higher scores indicating greater severity of endoscopic features.
LS means of each of the treatment groups (95% CIs) calculated using linear regression.
CI, confidence interval; EoG-REFS, EoG-Endoscopic Reference System; LS, least squares.

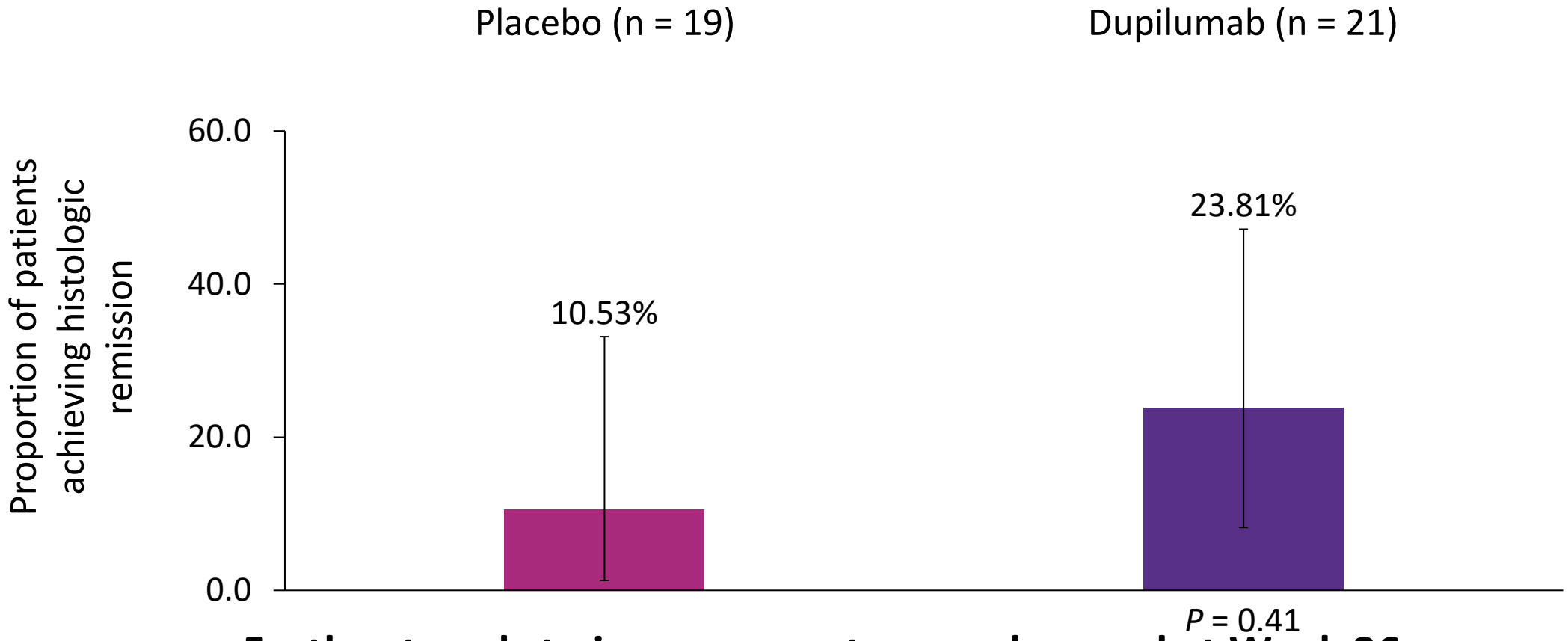
Secondary Endpoint: There was a Numeric Reduction in EoG Symptoms[a] with Dupilumab at Week 12



Further trends to improvement were observed at Week 36

[a]EoG-Symptom Questionnaire Total Symptom Score. [b]Score ranges from 0 to 60, with higher scores indicating greater symptom severity.
LS means of each of the treatment groups (95% CIs) calculated using linear regression.
CI, confidence interval; EoG-SQ TSS, EoG-Symptom Questionnaire Total Symptom Score; LS, least squares.

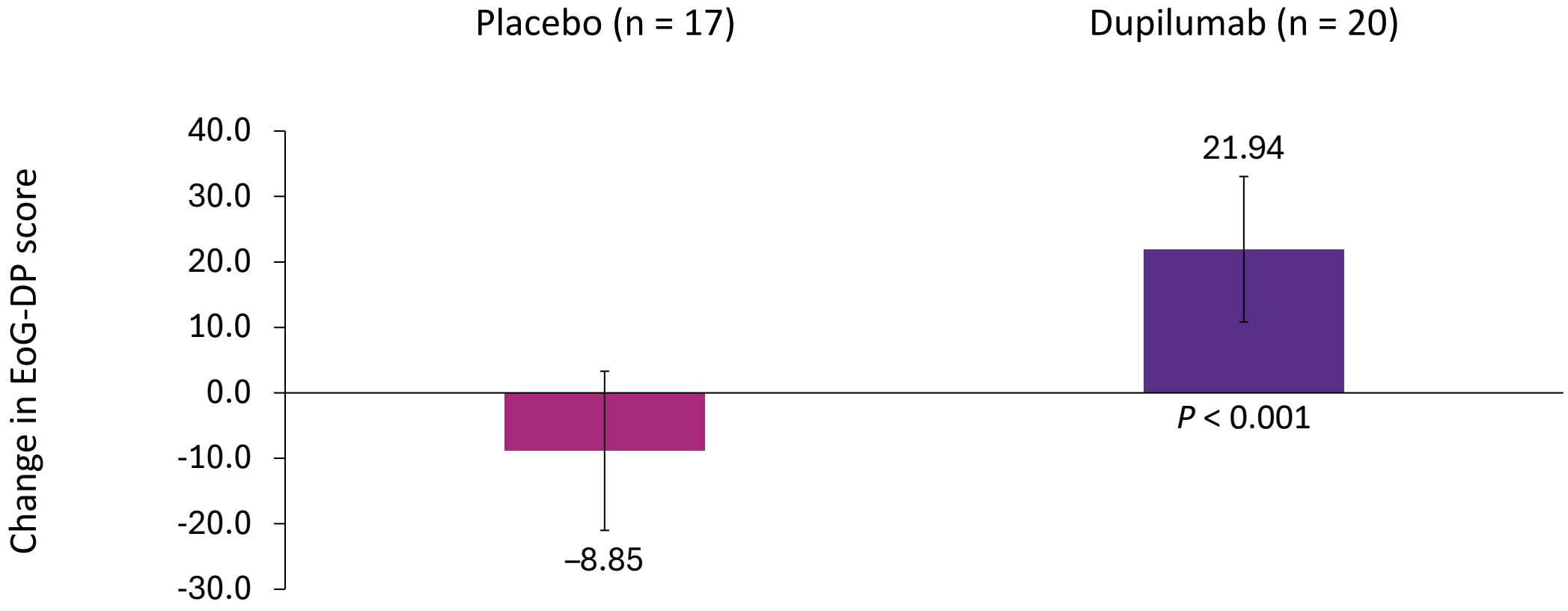
Secondary Endpoint: The Proportion of Patients Achieving Histopathologic Remission[a] Trended to Be Greater with Dupilumab vs Placebo at Week 12



Further trends to improvement were observed at Week 36

[a]Defined as peak eosinophil count <30 eos/hpf in all hpfs.
Data reported as proportion of patients (exact 95% CI).
CI, confidence interval; eos/hpf, eosinophils per high-power field; hpf, high-power field.

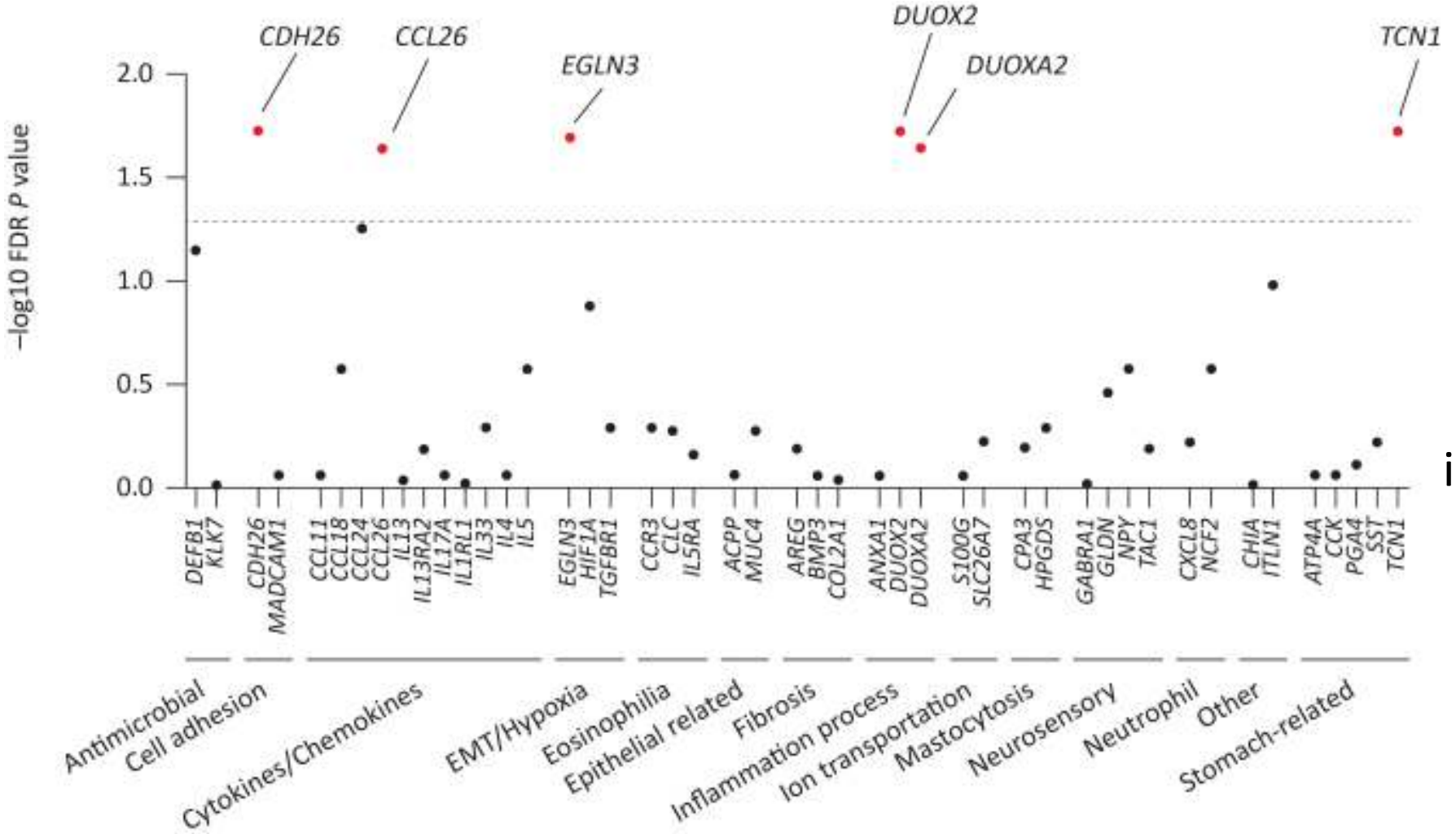
Exploratory Endpoint: EoG Transcriptome Score[a] Increased with Dupilumab at Week 12, Indicating Improvement of the Gene Signature



Further trends to improvement were observed at Week 36

[a]EoG-Diagnostic Panel$_{18}$ score.
LS means of each of the treatment groups (95% CIs) calculated using linear regression. Increased scores indicate improvement.
CI, confidence interval; EoG-DP, EoG-Diagnostic Panel; LS, least squares.

Dupilumab Normalized the Expression of Specific Genes at Week 12



Red markers indicate genes that significantly improved versus baseline

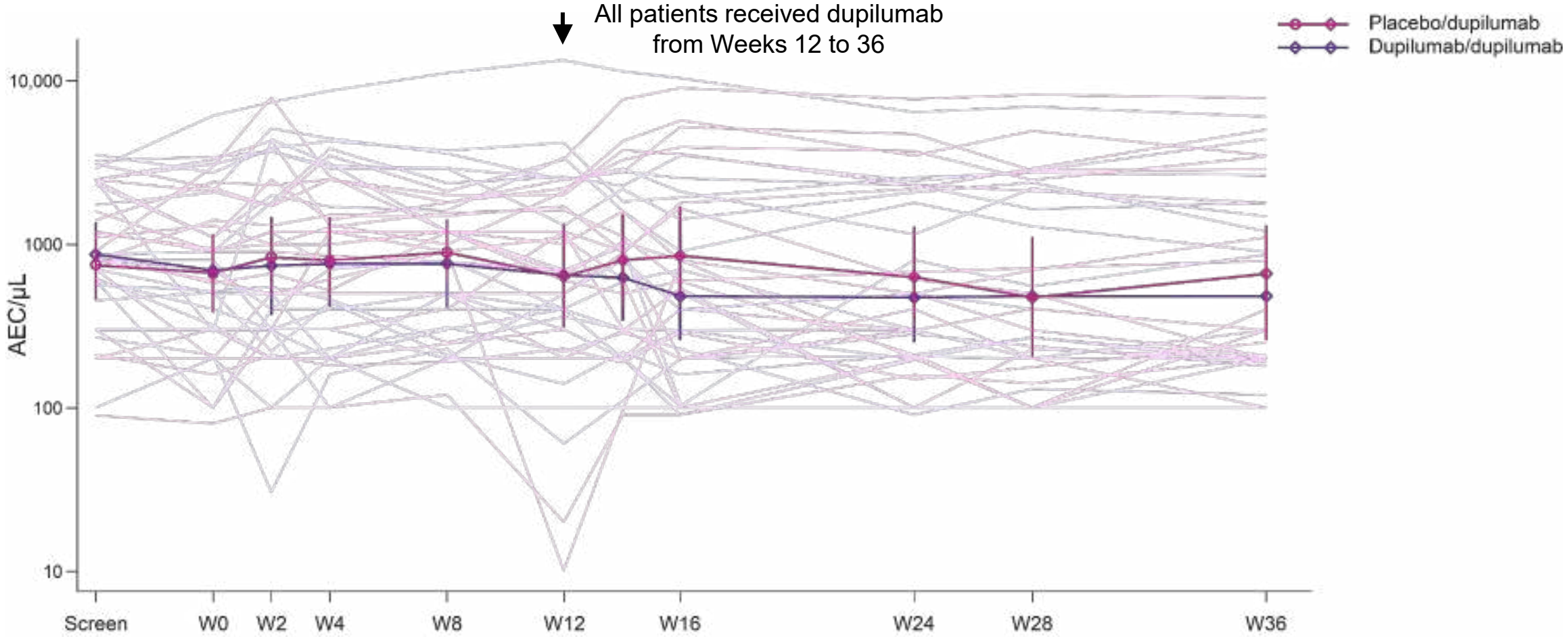
Y-axis represents the negative log10 false discovery rate *P* value determined by differential expression; red indicates genes that significantly improved versus baseline. X-axis represents genes organized within functional groupings. EMT, epithelial-to-mesenchymal transition; FDR, false discovery rate.

No Serious Adverse Events Were Reported

n (%)	DBP: Week 12		OLE: Week 36	
	Placebo (N = 20)	Dupilumab (N = 21)	Placebo – Dupilumab (N = 19)	Dupilumab – Dupilumab (N = 21)
Any TEAE	17 (85)	17 (81)	17 (89)	17 (81)
Any SAE	0 (0)	0 (0)	0 (0)	0 (0)
Any TEAE leading to permanent discontinuation of placebo or dupilumab	0 (0)	0 (0)	2 (11)	0 (0)
Any TEAE leading to death	0 (0)	0 (0)	0 (0)	0 (0)
TEAEs occurring in ≥15% of patients in any group				
Eosinophilia	7 (35)	6 (29)	5 (26)	3 (14)
Injection-site reaction	3 (15)	7 (33)	4 (21)	5 (24)
Sinusitis	3 (15)	1 (5)	3 (16)	3 (14)

Adverse events were reported according to Preferred Terms in the Medical Dictionary for Regulatory Activities, with the exception of elevated peripheral eosinophilia, which was graded according to the increase in eosinophil count from screening.
DBP, double-blind phase; OLE, open-label extension; SAE, serious adverse event; TEAE, treatment-emergent adverse event.

There Was No Overall Trend in Blood Eosinophil Count with Dupilumab or Placebo Over 36 Weeks



All patients received dupilumab from Week 12. Individual data are shown as light purple and light pink lines. Purple and pink markers/lines represent the group geometric means at each week.
AEC, absolute eosinophil count; W, week.

Conclusions

- Dupilumab significantly improved gastric eosinophil counts and histopathologic, endoscopic, and transcriptomic outcomes vs placebo in adults/adolescents with EoG
  - Improvements at Week 12 were maintained or further improved at Week 36
- Symptoms and histopathologic remission should be assessed in a study powered for those outcomes
  - Based on a study of dupilumab in EoE,[18] a dose of dupilumab 300 mg qw may be needed to alleviate EoG symptoms
- The DEGAS study provides proof-of-principle for the potential value of dupilumab for EoG, suggesting that the benefit of dupilumab for EoE may extend to additional eosinophilic gastrointestinal diseases

Supplementary materials & presentation
Copies of this presentation obtain through Quick Response (QR) Code are for personal use only

EoE, eosinophilic esophagitis; EoG, eosinophilic gastritis; qw, weekly.

CEGiR Consortium of Eosinophilic Gastrointestinal Disease Researchers
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Acknowledgments

RARE DISEASES CLINICAL RESEARCH NETWORK

NIH National Center for Advancing Translational Sciences

NIH National Institute of Allergy and Infectious Diseases

NIH National Institute of Diabetes and Digestive and Kidney Diseases

CURED Campaign Urging Research for Eosinophilic Disease

Apfed American Partnership for Eosinophilic Disorders

Eosinophilic Family Coalition

EOSNETWORK ausEE Inc.

CEGiR Consortium of Eosinophilic Gastrointestinal Disease Researchers

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Improvements at Week 12 Were Maintained at Week 36 (1/2)

	Double-blind phase (Week 12)			Open-label extension (Week 36)	
	Placebo (N = 20)[a]	Dupilumab (N = 21)	*P* value	Placebo–Dupilumab (N = 19)	Dupilumab–Dupilumab (N = 21)
Relative (percentage) change in mean gastric eosinophil count[b]					
LS mean (95% CI) /mean (95% CI)[c]	n = 19 –3.54 (–20.27, 13.19)	–50.28 (–66.20, –34.37)	<0.001	n = 16[d] –46.2 (–60.3, –32.0)	n = 20 –61.9 (–77.0, –46.8)
Absolute change in mean gastric eosinophil count[b]					
Median (IQR)	n = 19 –3.2 (–18.2, 35.0)	–36.0 (–55.8, –10.0)	<0.001	n = 16[d] –29.4 (–72.7, –20.1)	n = 20 –49.5 (–88.5, –27.2)
Absolute change in EoG Histology score[e]					
LS mean (95% CI) /mean (95% CI)[c]	n = 19 –0.01 (–0.06, 0.04)	–0.12 (–0.17, –0.06)	0.006	n = 16[d] –0.11 (–0.19, –0.03)	n = 20 –0.21 (–0.30, –0.12)
Absolute change in EoG Endoscopy score[f]					
LS mean (95% CI) /mean (95% CI)[c]	n = 19 –0.06 (–2.06, 1.94)	–3.47 (–5.37, –1.58)	0.02	–1.84 (–4.56, 0.88)	n = 20 –3.70 (–5.41, –2.00)

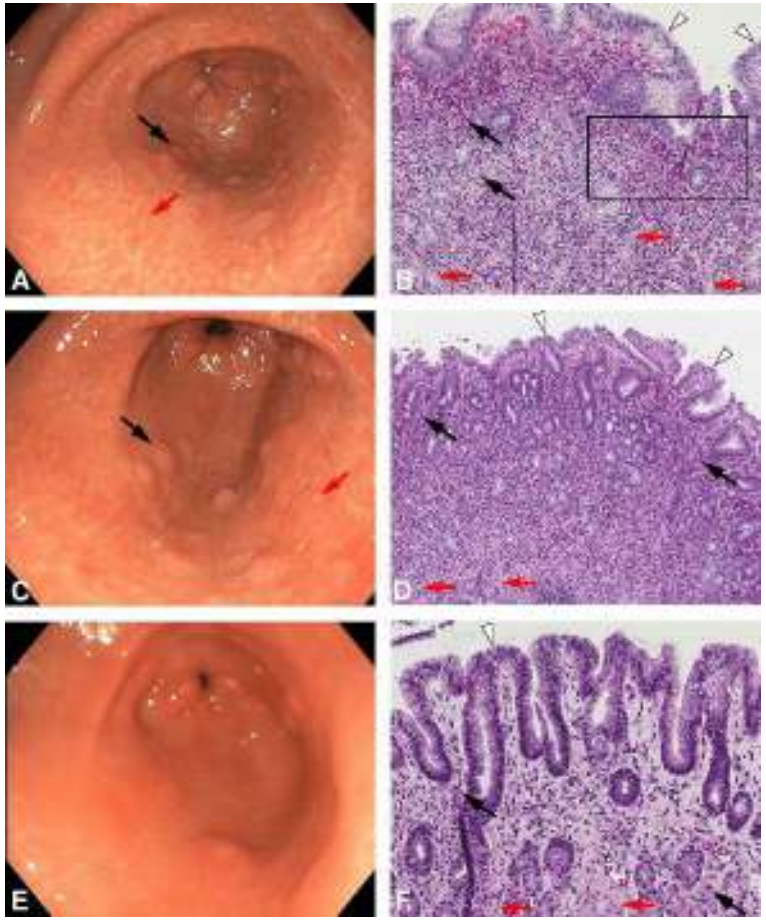
[a]Twenty patients were assigned to placebo, however one patient discontinued placebo during the double-blind period due to worsening symptoms of EoG. [b]Mean of the eosinophil counts from the 5 most eosinophil-dense hpfs in the gastric antrum and/or body. [c]LS mean (95% CI) is reported at Week 12, mean (95% CI) is reported at Week 36. [d]Three patients had missing data. [e]EoG-Histologic Scoring System total score. [f]EoG-Endoscopic Reference System total score. CI, confidence interval; EoG, eosinophilic gastritis; hpf, high-power field; IQR, interquartile range; LS, least squares.

Improvements at Week 12 Were Maintained at Week 36 (2/2)

	Double-blind phase (Week 12)			Open-label extension (Week 36)	
	Placebo (N = 20)[a]	Dupilumab (N = 21)	*P* value	Placebo–Dupilumab (N = 19)	Dupilumab–Dupilumab (N = 21)
Absolute change in the EoG Symptom score[b]					
LS mean (95% CI) /mean (95% CI)[c]	n = 18 –6.24 (–10.05, –2.44)	n = 18 –10.18 (–13.96, –6.40)	0.15	n = 10 –11.95 (–19.62, –4.29)	n = 9 –13.48 (–24.78, –2.19)
Proportion of patients achieving histopathologic remission (<30 eos/hpf in all 5 hpfs)					
n/N (% [95% CI])	2/19 (10.53 [1.3, 33.14])	5/21 (23.81 [8.22, 47.17])	0.41	5/16[d] (31.25 [11.02, 58.66])	8/20 (40.00 [19.12, 63.95])
Absolute change in EoG Transcriptomic score[e]					
LS mean (95% CI) /mean (95% CI)[c]	n = 17 –8.85 (–21.01, 3.31)	n = 20 21.94 (10.83, 33.06)	<0.001	n = 18 26.50 (7.94, 45.06)	n = 19 36.21 (21.42, 51.00)

[a]20 patients were assigned to placebo, however one patient discontinued placebo during the double-blind period due to worsening symptoms of EoG. [b]EoG-Symptom Questionnaire Total Symptom Score. [c]LS mean (95% CI) is reported at Week 12, mean (95% CI) is reported at Week 36. [d]Three patients had missing data. [e]EoG-Diagnostic Panel$_{18}$ score.
CI, confidence interval; EoG, eosinophilic gastritis; hpf, high-power field; LS, least squares.

Paired Endoscopic and Histologic Images Pre-/Post-Treatment: Placebo/Dupilumab Patient

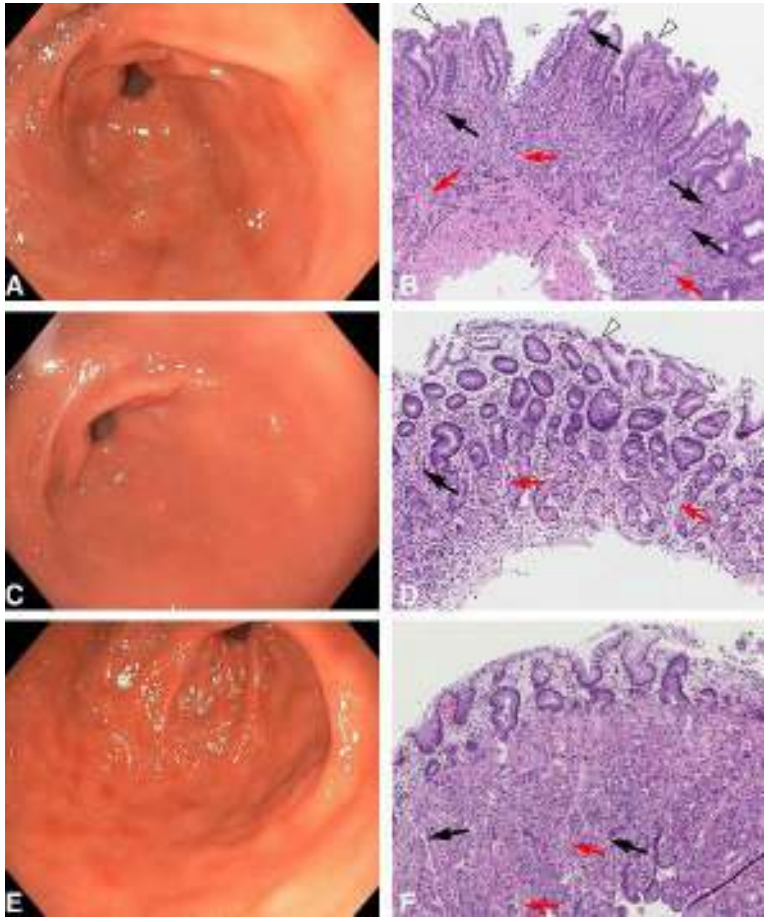


- A: Endoscopy image of antrum at baseline
- B: Biopsy at baseline

- C: Endoscopy image of antrum at Week 12
- D: Biopsy at Week 12

- E: Endoscopy image of antrum at Week 36
- F: Biopsy at Week 36

Paired Endoscopic and Histologic Images Pre-/Post-Treatment: Dupilumab/Dupilumab Patient



- A: Endoscopy image of antrum at baseline
- B: Biopsy at baseline
- C: Endoscopy image of antrum at Week 12
- D: Biopsy at Week 12
- E: Endoscopy image of antrum at Week 36
- F: Biopsy at Week 36

Absolute Eosinophil Count Adverse Event Grading Table

Grade	Screening AEC <500	Screening AEC 500–1000	Screening AEC 1000–1500	Screening AEC >1500
1	AEC >1000	AEC >1500	AEC >2000	Absolute increase >1000[a]
2	AEC >1500	AEC >3000	AEC >3000	Absolute increase >3000[a]
3	AEC >5000	AEC >5000	AEC >5000	Absolute increase >5000[a]
4	Hyper-eosinophilic disease requiring treatment	Hyper-eosinophilic disease requiring treatment	Hyper-eosinophilic disease requiring treatment	Hyper-eosinophilic disease requiring treatment
5	Death	Death	Death	Death

[a]Compared with screening.
AEC, absolute eosinophil count.