Symptomatic Improvement Observed in Patients Treated with Etrasimod in the ELEVATE UC 52 and UC 12 Program

Pfizer Inflammation & Immunology Medical Affairs

This post hoc analysis evaluated the onset of symptomatic improvement as measured by rectal bleeding and stool frequency subscores, using daily patient e-diary data from ELEVATE UC 52 and UC 12 clinical trials

Collection of e-diary data

Patient e-diary responses were collected daily during the first 28 days of therapy

Data from patients in the full analysis set were pooled from ELEVATE UC 52 and ELEVATE UC 12

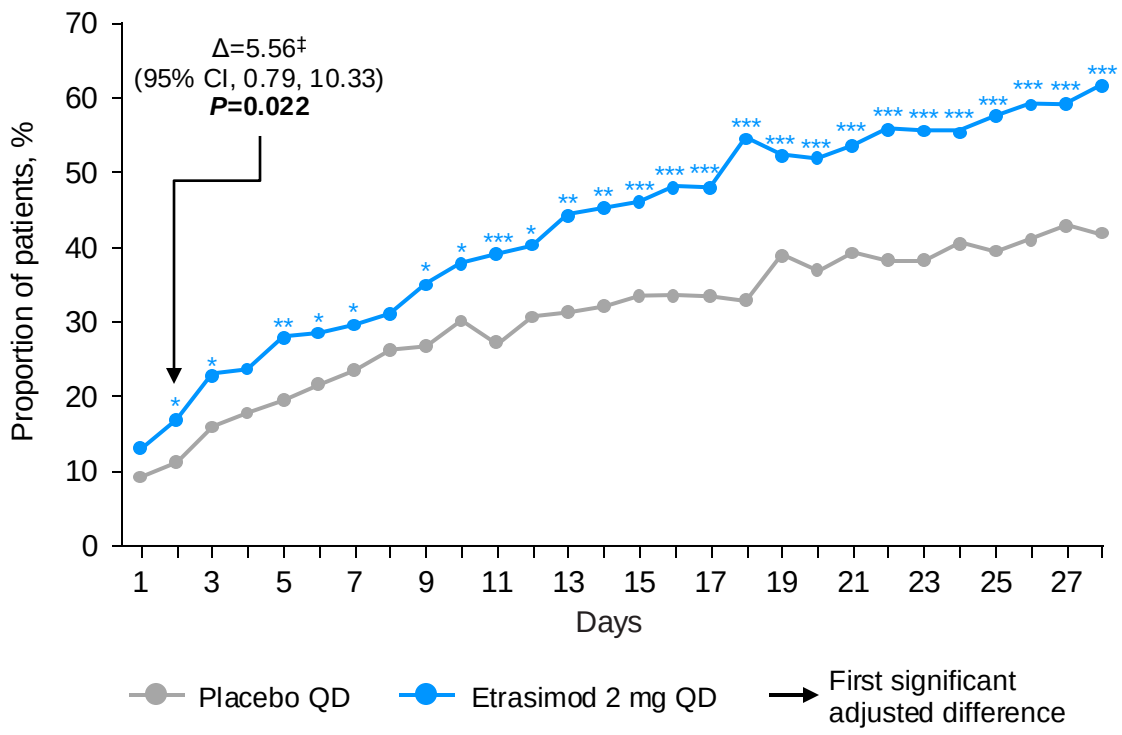
Clinical endpoints

Endpoint	Definition
Symptomatic response	≥30% decrease from baseline in RBS + SFS
Symptomatic remission	RBS=0 + SFS=0 or 1 with a ≥1-point improvement from baseline
RB normalisation	RBS=0
SF normalisation	SFS=0

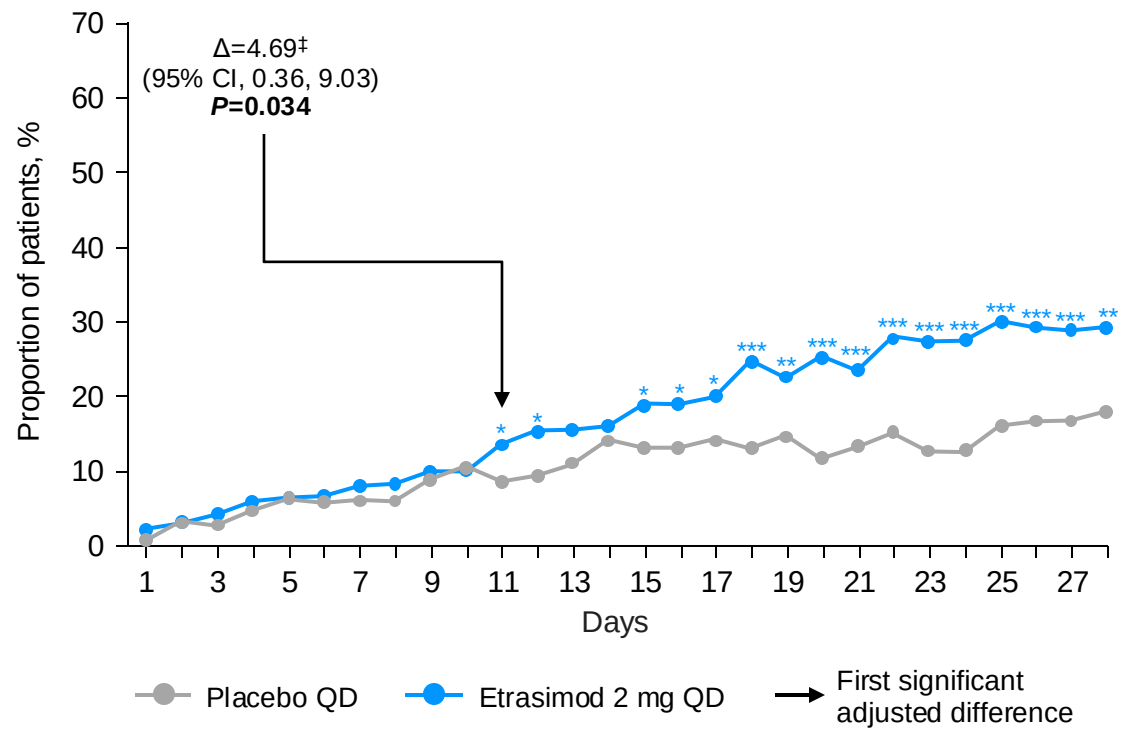
Baseline characteristics

	Placebo QD (N=260)	Etrasimod 2 mg QD (N=527)
Baseline RBS, mean (SD)	1.6 (0.68)	1.6 (0.69)
Baseline SFS, mean (SD)	2.4 (0.74)	2.4 (0.74)
Baseline RBS + SFS, mean (SD)	4.0 (1.07)	4.0 (1.07)

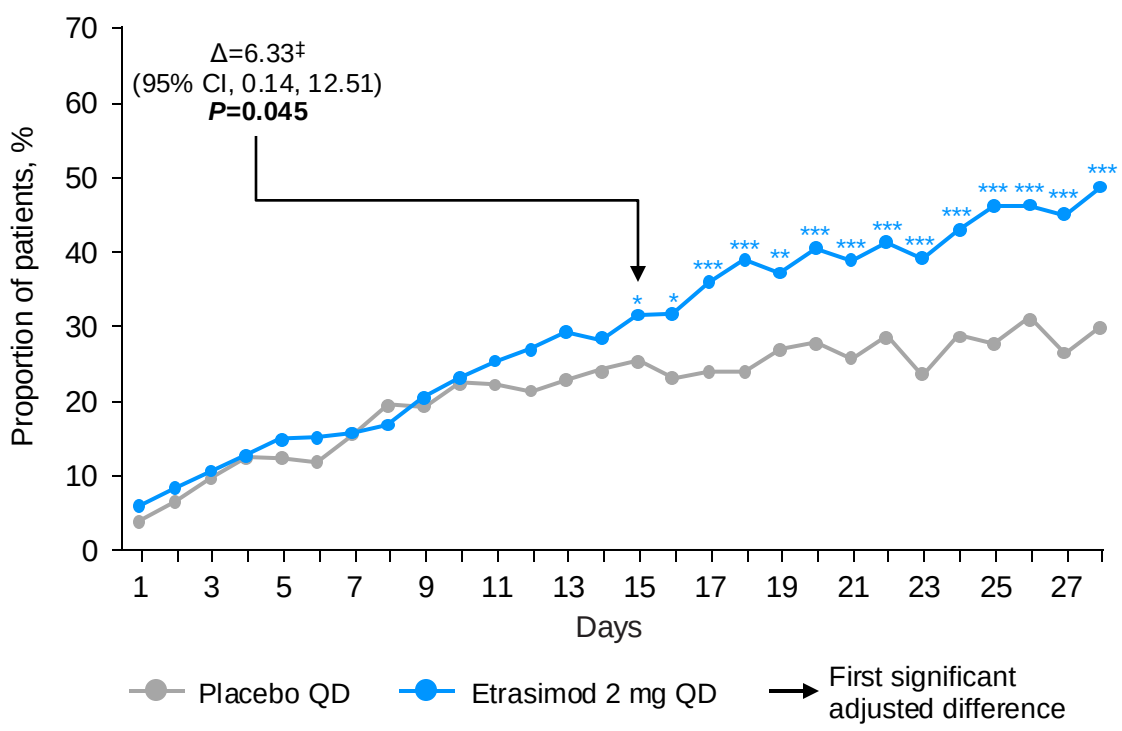
Symptomatic response†



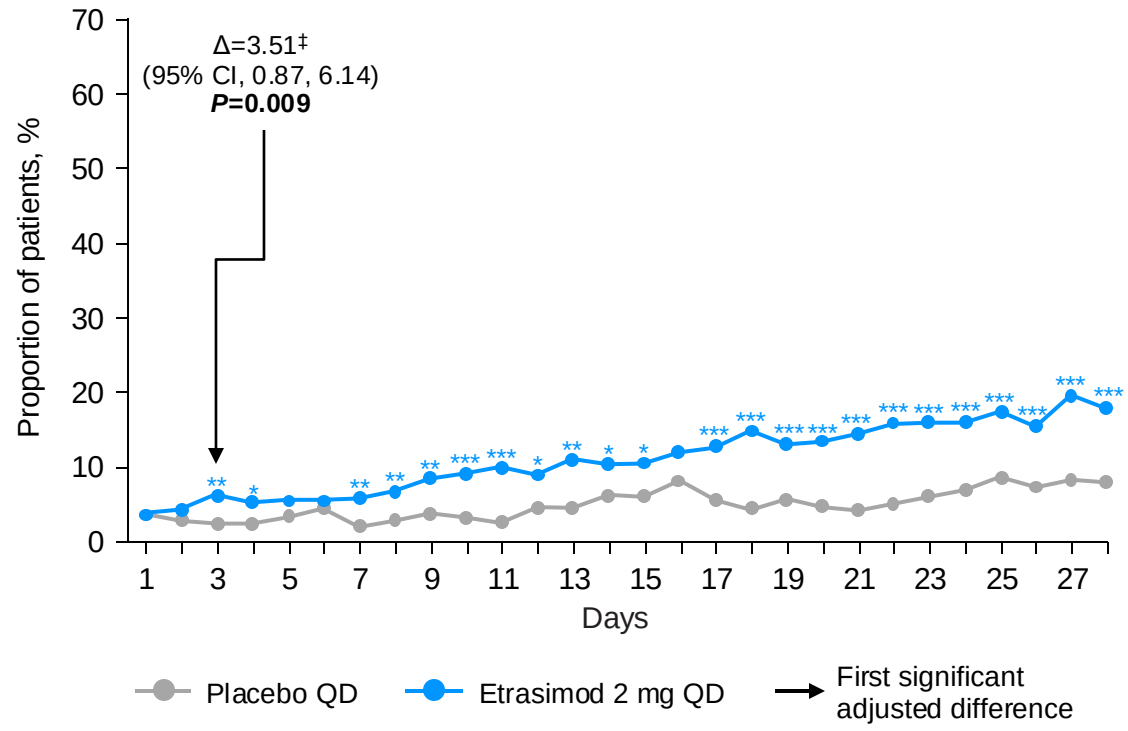
Symptomatic remission†



RB remission†



SF normalisation†



SUMMARY

Etrasimod demonstrated symptomatic improvements in patients with UC as early as day 2, suggesting that etrasimod has a rapid treatment effect with early symptomatic response.

This is a post hoc analysis with limited interpretations. Endpoints were not controlled for type I error.

*P<0.05; **p<0.01; *** P<0.001.

†Differences (%) were based on estimated common risk difference using Mantel–Haenszel weights and stratified by actual naive to biologic/JAKi therapy at trial entry, actual baseline corticosteroid use, and actual baseline disease activity (MMS 4–6 or 7–9). Two-sided *p* values tested the hypothesis of the risk difference being 0. Patients missing an assessment at the specified day were considered nonresponders.

‡First day of a significant difference from placebo.

CI, confidence interval; JAKi=Janus kinase inhibitor; pMMS=partial modified Mayo score; QD=once daily; RB=rectal bleeding; RBS=rectal bleeding subscore; SD=standard deviation; SF=stool frequency;
SFS=stool frequency subscore; UC=ulcerative colitis.

Dubinsky MC, et al. Poster MP359 presented at: United European Gastroenterology Week 2023; October 14-17, 2023; Copenhagen, Denmark.

Visit Pfizer Medical Portal To Learn More