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Risankizumab results in improvements in disease activity scores in patients with Crohn's disease: post-hoc analysis of the phase 3 induction and maintenance studies

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OBJECTIVE

To evaluate disease activity in patients who received up to 52 weeks of risankizumab or placebo in the phase 3 FORTIFY Maintenance study.

CONCLUSIONS

RZB therapy led to marked improvements in disease activity over time and continued to show benefit compared to withdrawal/PBO at Week 52

The pronounced benefit of RZB over withdrawal/PBO at Week 52 for SES-CD, an objective endoscopic endpoint, contrasts with a relative lack of differentiation at Week 52 for the subjective SF and AP endpoints.

The prolonged symptom improvement in patients receiving PBO in maintenance is likely explained by the long half-life and pharmacodynamic effect of residual RZB exposure following induction therapy.

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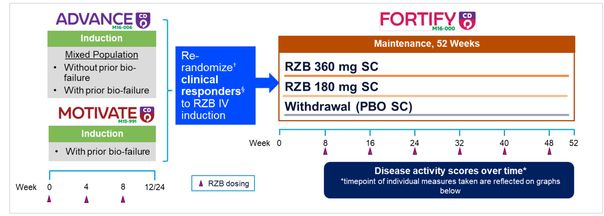
INTRODUCTION

- **The Phase 3 maintenance study (FORTIFY) was a re-randomized responder withdrawal study that demonstrated efficacy and safety of SC risankizumab (RZB), an anti-p19 IL-23 antibody, versus withdrawal/SC placebo (PBO) in patients with moderate to severe CD who clinically responded§ to RZB IV induction therapy.[1,2]**
- **Here, disease activity, as measured by Simple Endoscopic Score for CD (SES-CD), Crohn's Disease Activity Index (CDAI), and the patient reported symptoms (PROs) of liquid stool frequency (SF) and abdominal pain score (APS), was evaluated from Baseline of Induction onward through Maintenance in patients who received up to 52 weeks (wks) of RZB or PBO in FORTIFY**

METHODS

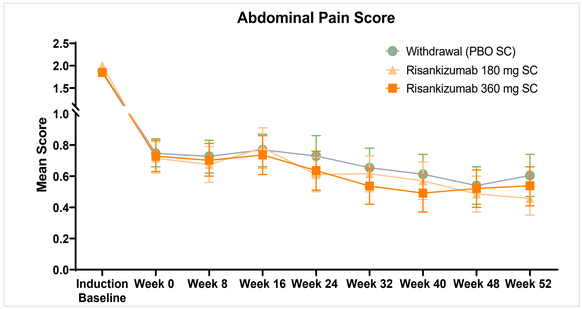
Study Design



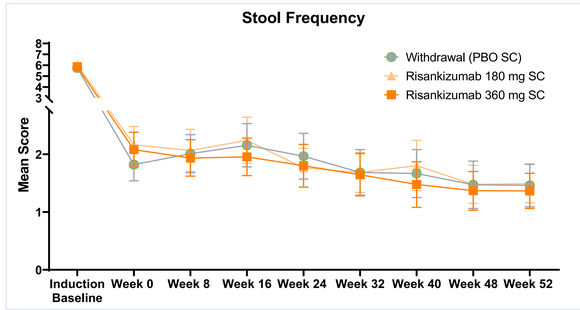
During the screening period, patients were provided with an electronic diary to record CD-related symptoms daily throughout the study; 7-day average daily stool frequency (**SF**) and average daily abdominal pain score (**APS**) were calculated; abdominal pain was rated as 0 = none, 1 = mild, 2 = moderate, 3 = severe.
§Clinical responders defined as patients with ≥ 30% decrease in average daily SF and/or ≥ 30% decrease in average daily APS and both not worse than baseline;
†Re-randomization stratified by endoscopic response, SF/APS clinical remission status at last visit of induction, and IV RZB induction dose (1200 mg, 600 mg). **Without prior bio-failure**, intolerance or inadequate response to conventional therapy; **With prior bio-failure**, intolerance or inadequate response to prior biologic therapy and/or conventional therapy; **IV**, intravenous; **SC**, subcutaneous; **CD**, Crohn's disease

RESULTS

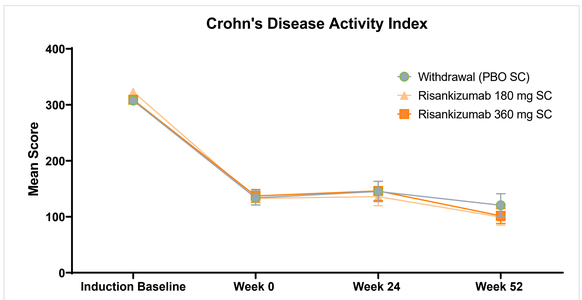
Mean APS at Induction Baseline and throughout Maintenance



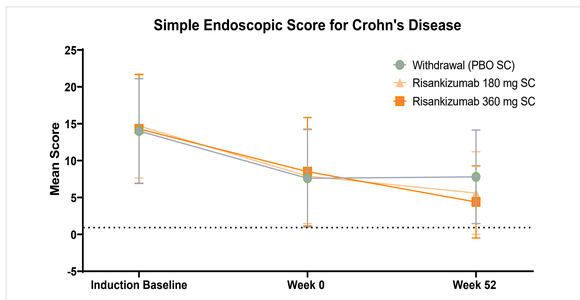
Mean SF at Induction Baseline and throughout Maintenance



Mean CDAI at Induction Baseline and throughout Maintenance



Mean SES-CD at Induction Baseline and at end of Maintenance



Mean CDAI, SF, AP, and SES-CD scores over time

	Baseline of Induction			Week 0 Maintenance			Week 24 Maintenance			Week 52 Maintenance			Week 52 Mean Change from Baseline		
	Withdrawal (PBO SC)	RZB 180 mg SC	RZB 360 mg SC	Withdrawal (PBO SC)	RZB 180 mg SC	RZB 360 mg SC	Withdrawal (PBO SC)	RZB 180 mg SC	RZB 360 mg SC	Withdrawal (PBO SC)	RZB 180 mg SC	RZB 360 mg SC	Withdrawal (PBO SC)	RZB 180 mg SC	RZB 360 mg SC
CDAI	307.4 N=164	323.2 N=157	308.9 N=141	133.6 N=163	132.8 N=157	137.2 N=138	145.1 N= 149	135.9 N=144	146.1 N=130	120.6 N = 98	99.4 N = 112	101.6 N=96	-186.8	-223.8	-207.3
SF	5.7 N=164	6.0 N=157	5.9 N=141	1.8 N=163	2.2 N=157	2.1 N=139	2.0 N=134	1.8 N=129	1.8 N=119	1.5 N=89	1.5 N=104	1.4 N=94	-4.2	-4.5	-4.5
APS	1.9 N=164	2.0 N=157	1.8 N=141	0.7 N=163	0.7 N=157	0.7 N=139	0.7 N=134	0.6 N=129	0.6 N=119	0.6 N=89	0.5 N=104	0.5 N=94	-1.3	-1.5	-1.3
SES-CD	14 N=164	14.7 N=157	14.3 N=141	7.6 N=162	7.9 N=151	8.5 N=136	not assessed	not assessed	not assessed	7.8 N=90	5.5 N=113	4.4 N=96	-6.2	-9.2	-9.9

For APS and SF: Week 8: Withdrawal (PBO SC), N = 155; 180 mg SC, N = 147; 360 mg SC, N = 136; Week 16: Withdrawal (PBO SC), N = 155; 180 mg SC, N = 145; 360 mg SC, N = 135; Week 32: Withdrawal (PBO SC), N = 116; 180 mg SC, N = 122; 360 mg SC, N = 107; Week 40: Withdrawal (PBO SC), N = 104; 180 mg SC, N = 113; 360 mg SC, N = 100; Week 48: Withdrawal (PBO SC), N = 96; 180 mg SC, N = 107; 360 mg SC, N = 96