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Baseline and Early Predictors of Response to Risankizumab Induction and Maintenance Treatment in Patients with Moderate to Severe Crohn's Disease

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OBJECTIVE

To determine predictors of response to risankizumab induction and maintenance therapy

CONCLUSIONS

Colonic/ileal-colonic vs ileal disease at baseline was associated with a greater likelihood of achieving endoscopic endpoints; Corticosteroid use at baseline decreased the likelihood of achieving clinical endpoints at Week 12.

Although still effective, prior bio-failure was associated with a decreased likelihood of achieving endoscopic outcomes with risankizumab

Clinical or endoscopic response and remission after induction therapy was associated with a higher likelihood of achieving Week 52 clinical and endoscopic outcomes.

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INTRODUCTION

Pivotal phase 3 induction (ADVANCE and MOTIVATE) and maintenance (FORTIFY) studies established that treatment with risankizumab (RZB), a humanized monoclonal antibody with high specificity for the p19 subunit of interleukin-23, was superior to placebo for achieving clinical remission and endoscopic response in patients with moderate to severe Crohn's disease (CD).[1,2]

Identifying baseline‡ patient characteristics that may predict response to RZB would be of value.

METHODS

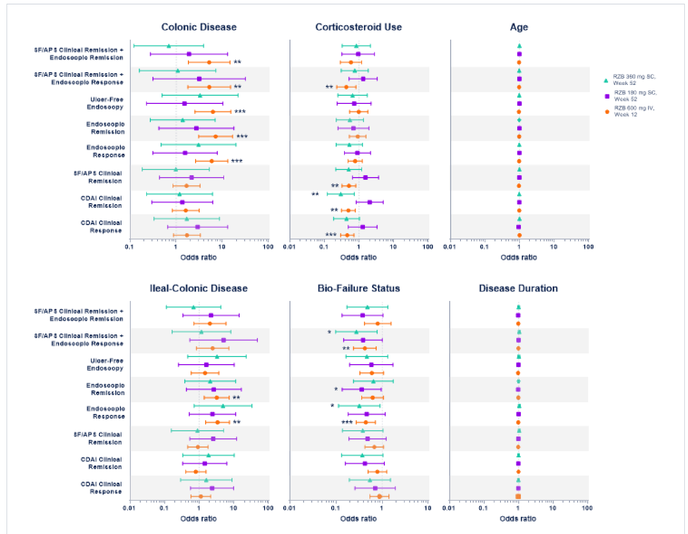
- **Pooled data from patients in the RZB 600 mg intravenous (IV) dosing groups in ADVANCE + MOTIVATE induction studies (n=527) and data from the RZB 180 mg and 360 mg subcutaneous (SC) dosing groups in the FORTIFY maintenance study (n=141) were evaluated.**
- **Separate multivariate logistic regression models were used to determine predictors of clinical and endoscopic outcomes at Weeks 12 and 52. For the maintenance population, additional logistic regression models were used to assess end-of-induction status with Week 52 outcomes.**

From multivariate logistic regression model with age, disease duration, baseline fecal calprotectin, baseline Hs-CRP, baseline corticosteroid use (yes/no), prior bio-failure, SES-CD total score, and disease location as dependent variables; forest plots depict odds ratios with 95% confidence intervals; **CDAI** = Crohn's Disease Activity Index; **SF/APS clinical remission** = average daily SF ≤2.8 and not worse than baseline of the induction study AND average daily AP score ≤1 and not worse than baseline of the induction study; **CDAI clinical remission** = CDAI < 150; **SF/APS clinical response** = ≥ 30% decrease in average daily SF and/or ≥ 30% decrease in average daily AP score and both not worse than baseline of the induction study; **CDAI clinical response** = reduction of CDAI ≥ 100 points from baseline of the induction study; **Endoscopic response** = decreasing in SES-CD > 50% from baseline of the induction study (or for subjects with isolated ileal disease and a baseline SES-CD of 4, at least a 2 point reduction from baseline of the induction study), as scored by central reviewer; **SES-CD** = Simple Endoscopic Score for Crohn's Disease; **Ulcer-free endoscopy** = SES-CD ulcerated surface subscore of 0 in subjects with SES-CD ulcerated surface subscore ≥1 at baseline of the induction study, as scored by a central reviewer; **Endoscopic remission** = SES-CD ≤4 and at least a 2 point reduction versus baseline of the induction study and no subscore greater than 1 in any individual variable, as scored by a central reviewer

RESULTS

Baseline characteristics associated with the achievement of clinical, endoscopic, and composite endpoints include:

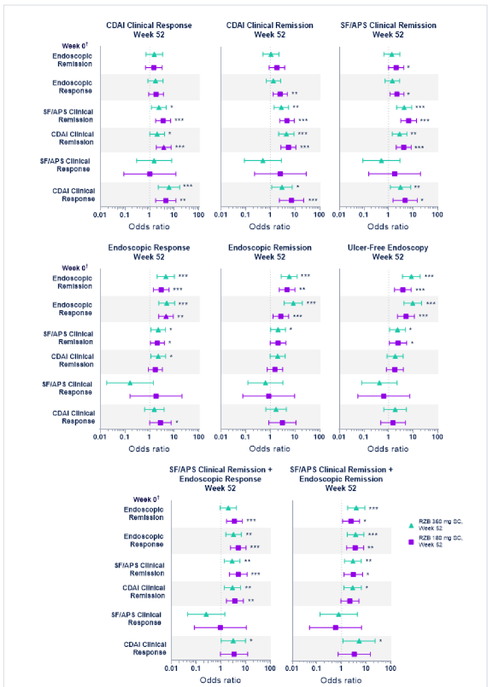
- **<u>Baseline disease location</u> – Colonic disease was associated with a greater likelihood of achieving endoscopic and composite (clinical and endoscopic) endpoints, and ileal-colonic disease was associated with a greater likelihood of achieving endoscopic endpoints, than ileal disease**
- **<u>Baseline corticosteroid use</u>§ – Corticosteroid use was associated with a decreased likelihood of achieving clinical endpoints at Weeks 12 and CDAI clinical remission at Week 52**
- **<u>Prior bio-failure</u> – Prior bio-failure was associated with a decreased likelihood of achieving**
  - **endoscopic response and the composite endpoint of SF/APS clinical remission + endoscopic response at Week 12 and Week 52 (with the 360 mg RZB SC dose)**
  - **endoscopic remission at Week 52 (with the 180 mg RZB SC dose)**
- **Neither age nor disease duration were predictive of achieving endpoints at Weeks 12 or 52**



‡Baseline of induction (ADVANCE, MOTIVATE)
§Patients taking corticosteroids at baseline continued their concomitant treatment at the baseline dose for the duration of the 12-week induction period.
P-value ≤ 0.05; ** P-value ≤ 0.01; *** P-value < 0.001

Patients achieving clinical endpoints at the end of induction (maintenance Week 0) are more likely to achieve clinical and endoscopic outcomes at Week 52

- **The achievement of SF/APS clinical remission, CDAI clinical remission, or CDAI clinical response after induction are all associated with a greater likelihood of achieving these same endpoints at Week 52 (180 mg and 360 mg RZB)**
- **The achievement of SF/APS clinical remission after induction is associated with a greater likelihood of achieving endoscopic and composite endpoints at Week 52**
- **The achievement of endoscopic response or endoscopic remission after induction is associated with a greater likelihood of achieving endoscopic and composite endpoints at Week 52**



†Week 0 of FORTIFY maintenance study