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| 1 | 18 Aug 2023 | Initial copy development | TS |
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[PAGE 1 – FRONT COVER]

[Headline]
Risankizumab as induction therapy for Crohn's disease: results from the Phase 3 ADVANCE and MOTIVATE induction trials

[Subhead]
By D'Haens G, Panaccione R, Baert F, et al.
Lancet 2022; 399: 2015–30. doi:10.1016/S0140-6736(22)00467-6

[Flash]
Key Messages

[Body]
In both ADVANCE and MOTIVATE randomised, placebo-controlled trials:

- Risankizumab was generally well tolerated and effective in patients with previous bio-failure and those without previous bio-failure [p2B]
- Significant clinical remission and endoscopic response were achieved at week 12 with both 600 mg and 1200 mg doses compared to placebo group (p values ≤0·0001) [p6A; 8B; 9A]
- Significant clinical remission was demonstrated as early as 4 weeks after a single dose (p value range: 0.0072 to 0.023) [p9A]
- 1200 mg risankizumab yielded no better efficacy than the 600 mg dose [p12A, B]

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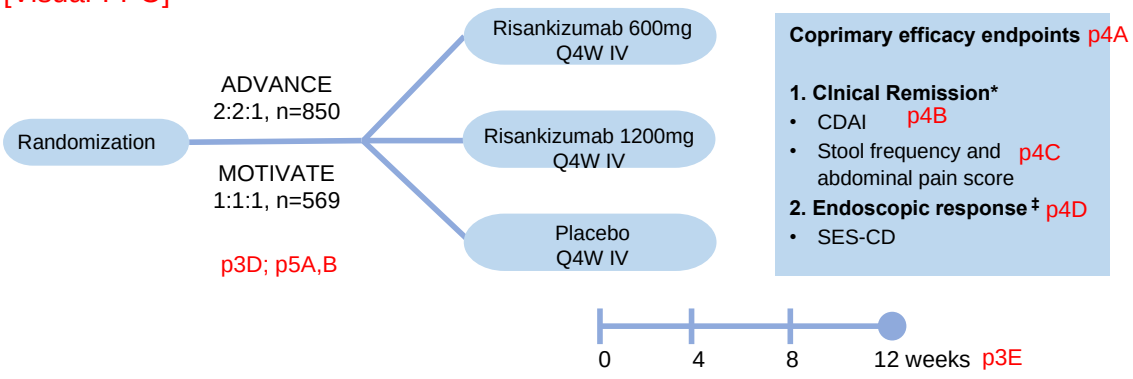
[PAGE 2 – INSIDE LEFT]

[Eyebrow/Tab]
Study Design

[Copy]
Inclusion criteria:

- 16 - 80 years of age [p3A]
- Moderate-to-severe Crohn's disease for at least 3 months before baseline§ [p3B]
- Intolerance to inadequate response to previous therapies† [p3C]

[Visual-FPO]




[Copy near graph]
Adapted from D'Haens G, Panaccione R, Baert F, et al.

[Copy for visual-left to right]
Randomization

ADVANCE
2:2:1, n=850

MOTIVATE
1:1:1, n=569

Risankizumab 600mg
Q4W IV

Risankizumab 1200mg
Q4W IV

Placebo
Q4W IV

0 4 8 12 weeks

Coprimary efficacy endpoints
1. Clnical Remission*

- CDAI

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- Stool frequency and abdominal pain score

2. Endoscopic response‡
   - SES-CD

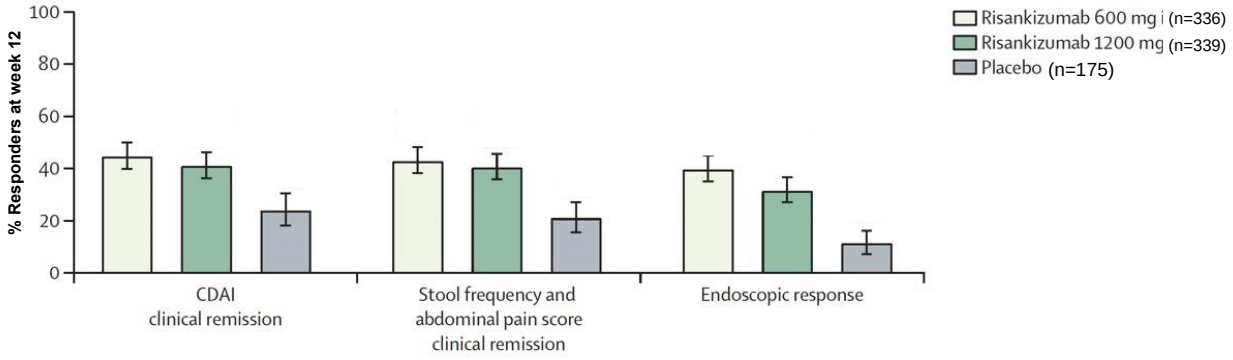
[Eyebrow/Tab]
Efficacy Data

[Headline]
Symptomatic and endoscopic improvement was observed at week 12 [p2A; p12C]

[Body]

[Graph title]
At week 12, significantly higher patient proportions in ADVANCE achieved clinical remission and endoscopic response in both risankizumab group vs. placebo (p ≤0·0001)# [p6A; 8B]

[Visual-FPO] [p8C]




[Copy for graph]
[y-axis label] %Responders at week 12
[y-axis range] 0 20 40 60 80 100
[x-axis labels] CDAI clinical remission Stool frequency and abdominal pain score clinical remission endoscopic response
[x-axis data labels] 45.2 41.6 24.5 43.5 41.0 21.7 40.2 32.1 12.0 [p8A]
[Label at the right]
Risankizumab 600 mg (n=336) Risankizumab 1200 mg (n=339) Placebo (n=175)

[Eyebrow/Tab]
Safety Profile

[Chart title]
Treatment-emergent AEs and AEs of safety interest were similar in all treatment groups# [p10A; p11A]

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[Visual-FPO] [p13A, B]

| N (%) in ADVANCE trial | Risankizumab 600 mg (n=373) | Risankizumab 1200 mg (n=372) | Placebo (n=186) |
|---|---|---|---|
| AEs | 210 (56%) | 191 (51%) | 105 (56%) |
| Severe AEs | 22 (6%) | 18 (5%) | 18 (10%) |
| Serious AEs | 27 (7%) | 14 (4%) | 28 (15%) |
| AEs leading to discontinuation | 9 (2%) | 7 (2%) | 14 (8%) |
| **AEs of safety interest: serious infections** | 3 (1%) | 2 (1%) | 7 (4%) |

[Abbreviations]
Q4W, every 4 weeks; IV, intravenous; CDAI, Crohn's disease activity index; SES-CD, Simple Endoscopic Score for Crohn's disease; AE, adverse events

[Footnotes]
§ Moderate to severe Crohn's disease was defined by: 1) CDAI score of 220–450 at baseline, 2) average daily stool frequency ≥4 and/or average daily abdominal pain score ≥2, 3) SES-CD ≥6, or ≥4 for isolated ileal disease [p3B]
† ADVANCE included patients who failed prior biologic or conventional therapy, MOTIVATE included patients who failed prior biotherapy [p3C]
* Defined by CDAI <150 or daily liquid or very soft stool frequency ≤2·8 and abdominal pain score ≤1 and both not worse than baseline [p4B, C]
‡ Defined as >50% SES-CD decrease from baseline, or at least a 2-point reduction for isolated ileal disease and when baseline score was 4 [p4D]
# MOTIVATE demonstrated similar results for efficacy [p6A; 9A], treatment-emergent AEs [p10A] and AEs of safety interest [p11A]

[Logos]
<AbbVie logo>

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## Visualizing Copy

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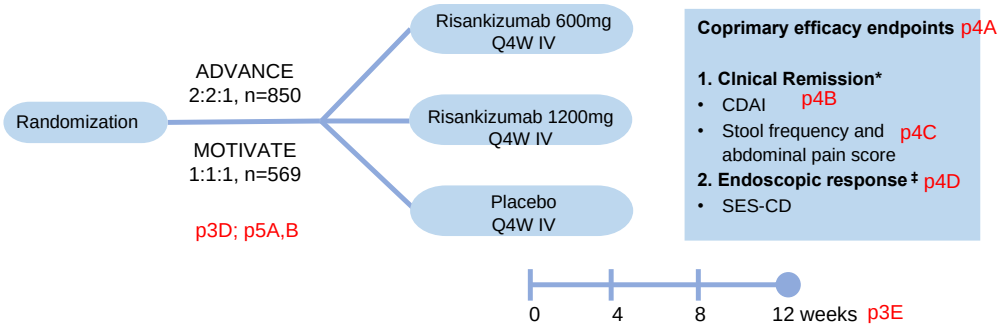


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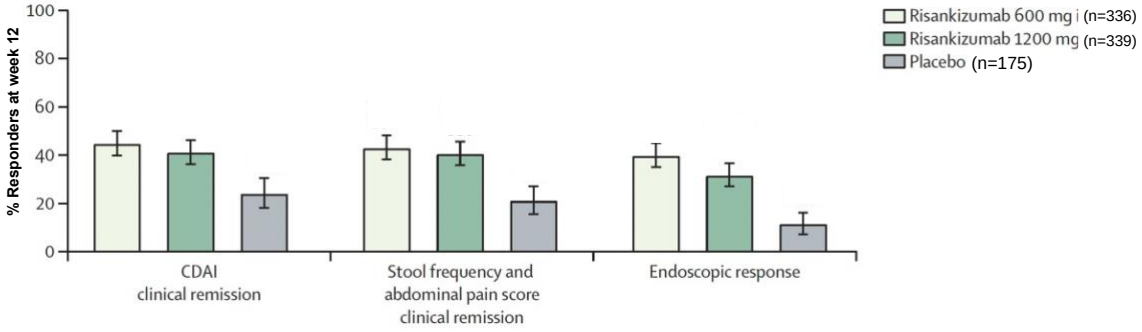


## Safety Profile

Treatment-emergent AEs and AEs of safety interest were similar in all treatment groups#

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