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	Dynamic ISI #:	US-SKZG-240258	
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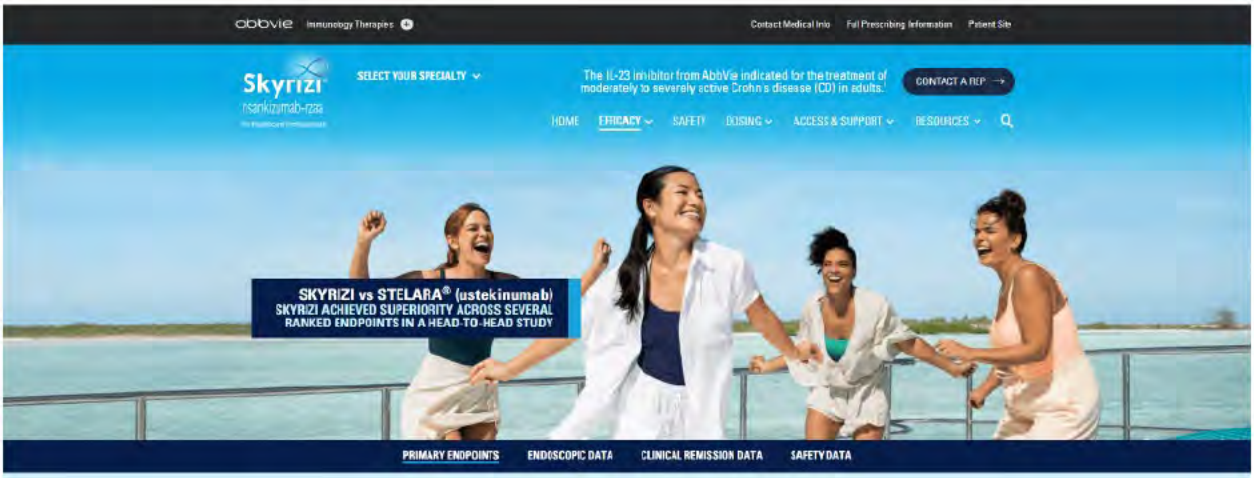


ENDPOINTS IN ADVANCE, MOTIVATE AND FORTIFY[1]

	ADVANCE Mixed Population*	MOTIVATE Biologic Failure Population†	FORTIFY Mixed Population*
	INDUCTION STUDIES (Week 12)		MAINTENANCE STUDY (Week 52)
CO-PRIMARY ENDPOINTS	p<0.001	p<0.001	p<0.05
Endoscopic Response (SES-CD)	SKYRIZI 600 mg IV 40% (135/338), Placebo 12% (21/175)	SKYRIZI 600 mg IV 25% (55/191), Placebo 11% (21/187)	SKYRIZI 360 mg SC 48% (56/117), SKYRIZI 180 mg SC 50% (67/135), Placebo (Induction Responders) 27% (28/130)
Clinical Remission (CDAI)	SKYRIZI 600 mg IV 45% (152/338), Placebo 25% (43/175)	SKYRIZI 600 mg IV 42% (80/191), Placebo 20% (37/187)	SKYRIZI 360 mg SC 57% (66/117), SKYRIZI 180 mg SC 61% (82/135), Placebo (Induction Responders) 45% (59/130)
SECONDARY ENDPOINT	p<0.001	p<0.001	
Endoscopic Remission	SKYRIZI 600 mg IV 24% (81/338), Placebo 9% (15/175)	SKYRIZI 600 mg IV 19% (37/191), Placebo 4% (8/187)	SKYRIZI 360 mg SC 41% (48/117), SKYRIZI 180 mg SC 33% (44/135), Placebo (Induction Responders) 13% (17/130) This endpoint was not statistically significant under the prespecified multiple testing procedure

All p-values are SKYRIZI treatment arms vs. placebo.

Placebo (Induction Responders): Patients who achieved CDAI clinical response (CR-100)[2] to SKYRIZI induction therapy and were randomized to receive placebo in the maintenance study.

STUDY DESIGNS:

ADVANCE (N=850) and MOTIVATE (N=569) induction studies were 12-week, randomized, double-blind, placebo-controlled studies that evaluated the efficacy and safety of SKYRIZI in patients with moderately to severely active Crohn's disease[3] who demonstrated prior treatment failure to conventional and/or biologic treatment.[1] Patients received an IV infusion of SKYRIZI 600 mg (recommended dose), risankizumab-rzaa 1200 mg[1] or placebo at Weeks 0, 4, and 8.[1]

FORTIFY (N=382) Maintenance study was a 52-week study that evaluated the efficacy and safety of SKYRIZI in patients who achieved clinical response (decrease in CDAI ≥100)[2] from SKYRIZI induction in the ADVANCE and MOTIVATE studies. Patients were randomized to SKYRIZI 180 mg SC, SKYRIZI 360 mg SC, or placebo at Week 12 and every 8 weeks thereafter.[1]

Definition of Endoscopic Response + Definition of Clinical Remission + Definition of Endoscopic Remission + Footnotes and Definitions +

STUDY DESIGN & BASELINE CHARACTERISTICS +

FIRST APPROVED CROHN'S DISEASE THERAPY THAT MET ENDOSCOPIC SUPERIORITY ENDPOINTS IN A HEAD-TO-HEAD TRIAL[2,3]

Skyrizi® risankizumab-rzaa VS STELARA® ustekinumab

PRIMARY ENDPOINTS EVALUATED:

- Non-Inferiority Endpoint: CLINICAL REMISSION (CDAI <150) AT WEEK 24*, Endpoint Met
- Superiority Endpoint: ENDOSCOPIC REMISSION† (SES-CD ≤4) AT WEEK 48‡, Endpoint Met

*The percentage of subjects who met clinical remission at Week 24. Statistical requirement for non-inferiority achieved with ~50% of study population.

†Endoscopic remission: SES-CD ≤4 and at least a 2-point reduction versus baseline and no subscore greater than 1 in any individual variable, as scored by a central reviewer.

‡The percentage of subjects who met endoscopic remission at Week 48.

Study Design Intro: SEQUENCE was a Phase 3, multicenter, randomized, open-label, efficacy assessment-blinded[§] study of SKYRIZI (n=255) compared to STELARA (ustekinumab)[‖] (n=265) for the treatment of adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy. Eligible patients were randomized (1:1) to receive either SKYRIZI (600 mg IV to 360 mg SC) or STELARA (weight-based[¶] IV to 90 mg SC). After induction dosing was completed, patients remained on their respective therapy throughout the duration of the maintenance period (treat-through study design). No dose escalation allowed throughout the trial.

DOSING: The lowest effective dosage for SKYRIZI should be used to maintain therapeutic response. The comparative effectiveness of SKYRIZI 180 mg is unknown, as it was not evaluated in this study.

§The investigator and site personnel were blinded to the results of the clinical outcomes (CDAI) and endoscopies were centrally read with assessors blinded to study drug.

‖**Active Comparator:** 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.

¶Baseline Stelara IV dose is weight based: ≤55 kg: 260 mg; >55 kg to 85 kg: 390 mg; or >85 kg: 520 mg.

#STELARA is a registered trademark of Johnson & Johnson. See US Prescribing Information for further information.

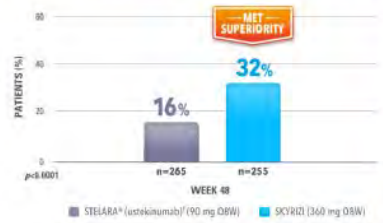
Definition of Non-Inferiority + Definition of Superiority + Footnotes and Definitions +

STUDY DESIGN & BASELINE CHARACTERISTICS +

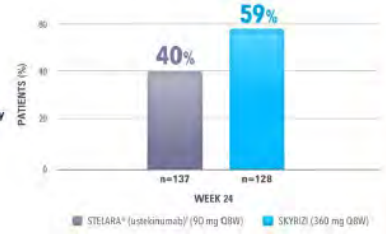
HEAD-TO-HEAD TRIAL: PRIMARY ENDPOINTS (NRI-MI)[2,3]

SEQUENCE was a Phase 3, multicenter, randomized, open-label, efficacy assessment-blinded* head-to-head study comparing SKYRIZI and STELARA (ustekinumab) in **adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy.**

Endoscopic Remission (SES-CD ≤4) (Superiority Endpoint)



Clinical Remission (CDAI <150) (Non-inferiority Endpoint)



~2X MORE PATIENTS ON SKYRIZI DEMONSTRATED ENDOSCOPIC REMISSION VS STELARA AT WEEK 48

PATIENTS AT BASELINE HAD AN AVERAGE DISEASE DURATION OF ~9 YEARS AND AVERAGE SES-CD SCORE OF 14

SKYRIZI DEMONSTRATED SYMPTOM RELIEF AS MEASURED BY CLINICAL REMISSION AT WEEK 24

DATA LIMITATION: The open-label nature of this study may have influenced these results.

DOSING: The lowest effective dosage for SKYRIZI should be used to maintain therapeutic response. The comparative effectiveness of SKYRIZI 180 mg is unknown, as it was not evaluated in this study.

*The investigator and site personnel were blinded to the results of the clinical outcomes (CDAI) and endoscopies were centrally read with assessors blinded to study drug.

†**Active Comparator:** 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.

‡STELARA is a registered trademark of Johnson & Johnson. See US Prescribing Information for further information.

Definition of Non-Inferiority + Definition of Superiority + Definition of Endoscopic Remission + Definition of Clinical Remission + Footnotes and Definitions +

STUDY DESIGN & BASELINE CHARACTERISTICS +

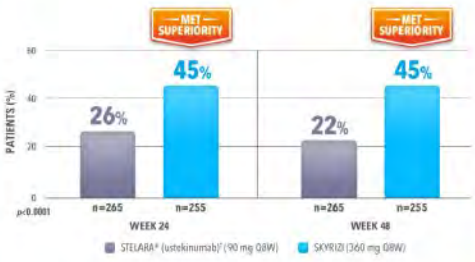
ENDOSCOPIC DATA

ENDOSCOPIC RESPONSE | ENDOSCOPIC REMISSION | STEROID-FREE ENDOSCOPIC REMISSION

SUPERIORITY MET ACROSS ENDOSCOPIC OUTCOMES[2,3]

Endoscopic Response at Week 24 and Week 48 (Ranked Secondary Endpoints, NRI-MI)

SEQUENCE was a Phase 3, multicenter, randomized, open-label, efficacy assessment-blinded* head-to-head study comparing SKYRIZI and STELARA (ustekinumab) in **adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy.**



MORE PATIENTS ON SKYRIZI EXPERIENCED ENDOSCOPIC RESPONSE VS STELARA AT WEEKS 24 AND 48

DATA LIMITATION: The open-label nature of this study may have influenced these results.

DOSING: The lowest effective dosage for SKYRIZI should be used to maintain therapeutic response. The comparative effectiveness of SKYRIZI 180 mg is unknown, as it was not evaluated in this study.

*Endoscopies were centrally read with assessors blinded to study drug.
†**Active Comparator:** 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.
‡STELARA is a registered trademark of Johnson & Johnson. See US Prescribing Information for further information.

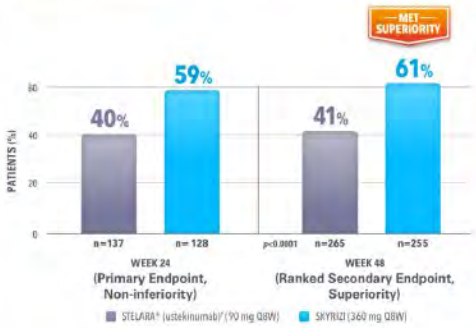
Definition of Superiority | Definition of Endoscopic Response | Footnotes and Definitions

STUDY DESIGN & BASELINE CHARACTERISTICS +

DEMONSTRATED SYMPTOM RELIEF DATA[2,3]

Clinical Remission at Week 24 and Week 48 (NRI-MI)

SEQUENCE was a Phase 3, multicenter, randomized, open-label, efficacy assessment-blinded* head-to-head study comparing SKYRIZI and STELARA (ustekinumab) in **adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy.**



SKYRIZI DEMONSTRATED SYMPTOM RELIEF AS MEASURED BY CLINICAL REMISSION AT WEEK 24 AND WEEK 48

DATA LIMITATION: **The open-label nature of this study may have influenced these results.**

DOSING: **The lowest effective dosage for SKYRIZI should be used to maintain therapeutic response. The comparative effectiveness of SKYRIZI 180 mg is unknown, as it was not evaluated in this study.**

*The investigator and site personnel were blinded to the results of the clinical outcomes (CDAI).
‡**Active Comparator:** 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.
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Definition of Superiority ⊕ Definition of Non-Inferiority ⊕ Definition of Clinical Remission ⊕ Footnotes and Definitions ⊕

STUDY DESIGN & BASELINE CHARACTERISTICS +

SAFETY PROFILE: EVALUATION THROUGH WEEK 48[2,3]

SEQUENCE was a Phase 3, multicenter, randomized, open-label, study of SKYRIZI and STELARA (ustekinumab) in **adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy.**

TREATMENT EMERGENT ADVERSE EVENTS THROUGH WEEK 48	STELARA® (ustekinumab)* (N=265, PYs=269.9) % (E/100 PYs)	SKYRIZI (N=262, PYs=257.6) % (E/100 PYs)
Any AE	82.6 (282.7)	85.1 (341.2)
Serious AE	17.4 (23.7)	10.3 (14.0)
AE leading to discontinuation of study drug	4.9 (5.2)	3.8 (3.9)
Death	0	0
Infections	44.5 (62.6)	53.8 (90.4)
Serious infection	4.2 (5.2)	3.1 (3.9)
Opportunistic infection (excluding TB/Herpes Zoster)	0	0.4 (0.4)
Malignant tumors	0.4 (0.4)	0.4 (0.4)
Adjudicated MACE‡	0.4 (0.4)	0
Active TB	0	0
Herpes Zoster	0.4 (0.4)	0.4 (0.4)
Serious hypersensitivity	0	0
Adjudicated anaphylactic reaction	0	0
Hepatic events	5.3 (8.5)	6.9 (10.1)
Injection site reactions	2.3 (3.0)	1.9 (1.9)

For the safety population, 7 patients randomized to SKYRIZI received 1200 mg IV and/or 180 mg SC and were included only in the safety analysis. Safety Data presented includes all patients who received at least 1 dose of study drug.

*__Active Comparator:__ 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.
†STELARA is a registered trademark of Johnson & Johnson. See US Prescribing Information for further information.

CLICK TO VIEW TEAES REPORTED BY ≥5%

THE SAFETY PROFILE OF SKYRIZI WAS GENERALLY CONSISTENT WITH PREVIOUSLY REPORTED STUDIES AND AS DESCRIBED IN THE FULL PRESCRIBING INFORMATION.

THE SAFETY RATES OBSERVED IN CLINICAL TRIALS MAY NOT REFLECT CLINICAL PRACTICE.

Footnotes and Definitions

STUDY DESIGN & BASELINE CHARACTERISTICS +

HAVE YOU SEEN THE PATIENT CASE STUDIES?

DISCOVER PATIENT CASES →

DO YOU KNOW ABOUT SKYRIZI'S ESTABLISHED SAFETY PROFILE?

EXPLORE SAFETY →

INDICATIONS AND IMPORTANT SAFETY INFORMATION FOR SKYRIZI® (risankizumab-rzaa)[1]

Indications

Plaque Psoriasis: SKYRIZI is indicated for the treatment of moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.

Psoriatic Arthritis: SKYRIZI is indicated for the treatment of active psoriatic arthritis in adults.

Crohn's Disease: SKYRIZI is indicated for the treatment of moderately to severely active Crohn's disease in adults.

Ulcerative Colitis: SKYRIZI is indicated for the treatment of moderately to severely active ulcerative colitis in adults.

Important Safety Information

<INSERT DYNAMIC ISI>

REFERENCES

1. SKYRIZI [package insert]. North Chicago, IL: AbbVie Inc.
2. Peyrin-Biroulet L, Chapman JC, Colombel J-F, et al. Risankizumab Versus Ustekinumab for Patients With Moderate to Severe Crohn's Disease: Results From the Phase 3b SEQUENCE Study. Presented at United European Gastroenterology Week (UEGW 2023), October 14-17, 2023, Copenhagen, Denmark.
3. Data on File, AbbVie Inc. ABVRRTI76928.
4. Olivera P, Sandborn WJ, Panés J, et al. Physicians' Perspective on the Clinical Meaningfulness of Inflammatory Bowel Disease Trial Results: An International Organization for the Study of Inflammatory Bowel Disease (IOIBD) Survey. *Aliment Pharmacol Ther*. 2018;47(6):773-83.

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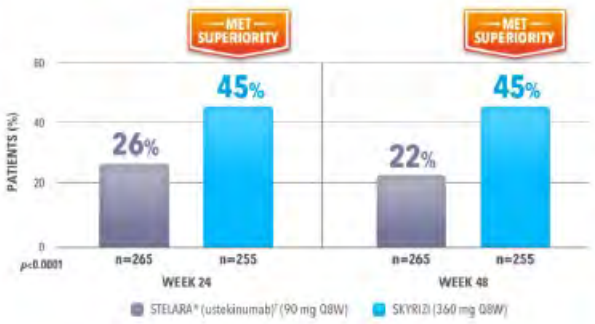
ENDOSCOPIC DATA

ENDOSCOPIC RESPONSE | ENDOSCOPIC REMISSION | STEROID-FREE ENDOSCOPIC REMISSION

SUPERIORITY MET ACROSS ENDOSCOPIC OUTCOMES[2,3]

Endoscopic Response at Week 24 and Week 48 (Ranked Secondary Endpoints, NRI-MI)

SEQUENCE was a Phase 3, multicenter, randomized, open-label, efficacy assessment-blinded* head-to-head study comparing SKYRIZI and STELARA (ustekinumab) in **adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy.**



MORE PATIENTS ON SKYRIZI EXPERIENCED ENDOSCOPIC RESPONSE VS STELARA AT WEEKS 24 AND 48

DATA LIMITATION: The open-label nature of this study may have influenced these results.

DOSING: The lowest effective dosage for SKYRIZI should be used to maintain therapeutic response. The comparative effectiveness of SKYRIZI 180 mg is unknown, as it was not evaluated in this study.

*Endoscopies were centrally read with assessors blinded to study drug.
†**Active Comparator:** 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.

‡STELARA is a registered trademark of Johnson & Johnson. See US Prescribing Information for further information.

Definition of Superiority | Definition of Endoscopic Response | Footnotes and Definitions

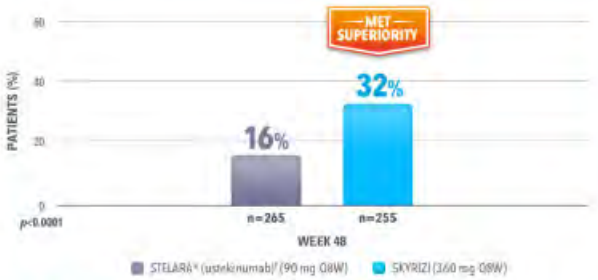
STUDY DESIGN & BASELINE CHARACTERISTICS +

ENDOSCOPIC RESPONSE | **ENDOSCOPIC REMISSION** | STEROID-FREE ENDOSCOPIC REMISSION

SUPERIORITY MET ACROSS ENDOSCOPIC OUTCOMES[2,3]

Endoscopic Remission at Week 48 (Primary Endpoint, NRI-MI)

SEQUENCE was a Phase 3, multicenter, randomized, open-label, efficacy assessment-blinded* head-to-head study comparing SKYRIZI and STELARA (ustekinumab) in **adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy.**



~2X MORE PATIENTS ON SKYRIZI DEMONSTRATED ENDOSCOPIC REMISSION VS STELARA AT WEEK 48

PATIENTS AT BASELINE HAD AN AVERAGE DISEASE DURATION OF ~9 YEARS AND AVERAGE SES-CD SCORE OF 14

DATA LIMITATION: The open-label nature of this study may have influenced these results.

DOSING: The lowest effective dosage for SKYRIZI should be used to maintain therapeutic response. The comparative effectiveness of SKYRIZI 180 mg is unknown, as it was not evaluated in this study.

*Endoscopies were centrally read with assessors blinded to study drug.
†**Active Comparator:** 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.
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Definition of Superiority | Definition of Endoscopic Remission | Footnotes and Definitions

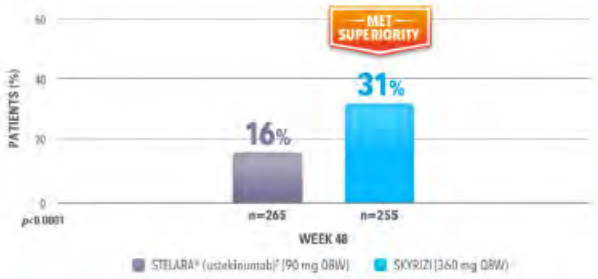
STUDY DESIGN & BASELINE CHARACTERISTICS +

ENDOSCOPIC RESPONSE | ENDOSCOPIC REMISSION | **STEROID-FREE ENDOSCOPIC REMISSION**

SUPERIORITY MET ACROSS ENDOSCOPIC OUTCOMES[2,3]

Steroid-Free Endoscopic Remission at Week 48 (Ranked Secondary Endpoint, NRI-MI)

SEQUENCE was a Phase 3, multicenter, randomized, open-label, efficacy assessment-blinded* head-to-head study comparing SKYRIZI and STELARA (ustekinumab) in **adult patients with moderate to severe Crohn's disease who have failed anti-TNF therapy.**



~2X MORE PATIENTS ON SKYRIZI WERE IN ENDOSCOPIC REMISSION WITHOUT STEROIDS (STEROID-FREE ENDOSCOPIC REMISSION) VS STELARA AT WEEK 48

IN THE SEQUENCE TRIAL, 71 (27%) AND 58 (23%) PATIENTS WERE TAKING CORTICOSTEROID AT BASELINE IN THE STELARA AND SKYRIZI ARMS, RESPECTIVELY.

DATA LIMITATION: **The open-label nature of this study may have influenced these results.**

DOSING: **The lowest effective dosage for SKYRIZI should be used to maintain therapeutic response. The comparative effectiveness of SKYRIZI 180 mg is unknown, as it was not evaluated in this study.**

Steroid-free clinical remission in the FORTIFY trial was not statistically significant under the pre-specified multiple testing procedure.

Steroid-free Endoscopic Remission: Total population of patients who achieved endoscopic remission, defined as SES-CD ≤4 and at least a 2-point reduction versus baseline and no subscore greater than 1 in any individual variable, as scored by a central reviewer, who also did not receive a steroid at Week 48.

*Endoscopies were centrally read with assessors blinded to study drug.
†**Active Comparator:** 31 patients received US approved ustekinumab. All other patients received European Union approved ustekinumab. The comparability between US and Non US approved ustekinumab has not been established.
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Definition of Superiority | Definition of Steroid-Free Clinical Remission (in FORTIFY) | Footnotes and Definitions

STUDY DESIGN & BASELINE CHARACTERISTICS +