ONCE-DAILY

XELJANZ® XR
(tofacitinib)
extended release • 11 mg tablets

TEST YOUR KNOWLEDGE

This is intended for healthcare professionals.

XELJANZ UC EFFICACY DATA

XELJANZ SAFETY DATA

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with XELJANZ* are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

If a serious infection develops, interrupt XELJANZ until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

The most common serious infections reported with XELJANZ included pneumonia, cellulitis, herpes zoster, urinary tract infection, diverticulitis, and appendicitis. Avoid use of XELJANZ in patients with an active, serious infection, including localized infections.

In the UC population, XELJANZ 10 mg twice daily was associated with greater risk of serious infections compared to 5 mg twice daily. Opportunistic herpes zoster infections (including meningoencephalitis, ophthalmologic, and disseminated cutaneous) were seen in patients who were treated with XELJANZ 10 mg

STUDY DESIGNS, DEFINITIONS & ABBREVIATIONS
INDICATIONS & IMPORTANT SAFETY INFORMATION
REFERENCES
PRESCRIBING INFORMATION & MEDICATION GUIDE

INDICATION

Ulcerative Colitis

• XELJANZ©/XELJANZ© XR (tofacitinib) is indicated for the treatment of adult patients with moderately to severely active ulcerative colitis (UC), who have had an inadequate response or intolerance to
one or more TNF blockers.

Please see full Prescribing Information, including **BOXED WARNING** and Medication Guide, accessible from the navigation below or at XELJANZPI.com.

XELJANZ UC Efficacy Data

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Q1

5 Efficacy Questions Remaining

True or False? For patients with moderate to severe ulcerative colitis who have had an inadequate response or intolerance to 1 or more TNF blockers, XELJANZ recommended dosing includes a once-daily option.[1]

Select true or false

Help

- Each question is interactive
- Answer each question and enter your response using the touchscreen
- Press ‘View Answer’ to see the results
- Press ‘Additional Information’ to see more details regarding the question
- Press ‘Next Question’ to move to the next question
- Press the navigation buttons located above the question to see the correct answer to previous questions
- Press the gray buttons located on the bottom-right of the screen to view abbreviations and definitions, XELJANZ study designs, Important Safety Information and Indications, references, and full Prescribing Information including the **BOXED WARNING** and Medication Guide

TRUE FALSE

RESET VIEW ANSWER

Help Go to Safety

IMPORTANT SAFETY INFORMATION

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ADDITIONAL INFORMATION

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XELJANZ UC Efficacy Data

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[tofacitinib]

extended release • 11 mg tablets

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TRUE Correct answer

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ADDITIONAL INFORMATION

Help

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Recommended Dosing, Dosing Adjustments, and Important Administration

Recommended Adult Daily Dosage of XELJANZ/XELJANZ XR for Patients With Moderately to Severely Active Ulcerative Colitis Who Have Had an Inadequate Response or Are Intolerant to TNF Blockers[1]

XELJANZ	XELJANZ XR
 5 mg tofacitinib: White, round, immediate-release film-coated	 11 mg tofacitinib: Pink, oval, extended-release film-coated tablets
 10 mg tofacitinib: Blue, round, immediate-release film-coated	 22 mg tofacitinib: Beige, oval, extended-release film-coated
INDUCTION 10 mg twice daily for 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed, continue 10 mg twice daily for a maximum of 16 weeks. Discontinue 10 mg twice daily after 16 weeks if adequate therapeutic response is not achieved.	**INDUCTION** 22 mg once daily for 8 weeks; evaluate patients and transition to maintenance therapy depending on therapeutic response. If needed, continue 22 mg once daily for a maximum of 16 weeks. Discontinue 22 mg once daily after 16 weeks if adequate therapeutic response is not achieved.
MAINTENANCE 5 mg twice daily. For patients with loss of response during maintenance treatment, a dosage of 10 mg twice daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual	**MAINTENANCE** 11 mg once daily. For patients with loss of response during maintenance treatment, a dosage of 22 mg once daily may be considered and limited to the shortest duration, with careful consideration of the benefits and risks for the individual patient.

Patients treated with XELJANZ 5 mg twice daily may be switched to XELJANZ XR 11 mg once daily the day following the last dose of XELJANZ 5 mg.

Patients treated with XELJANZ 10 mg twice daily may be switched to XELJANZ XR 22 mg once daily the day following the last dose of XELJANZ 10 mg.

Changes between XELJANZ and XELJANZ XR should be made under the supervision of the healthcare provider.

Pills shown are not actual size.

NEXT QUESTION

ONCE-DAILY

XELJANZ® XR

[tofacitinib]

extended release • 11 mg tablets

IMPORTANT SAFETY INFORMATION

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	XELJANZ	XELJANZ XR
Patients receiving: • Strong CYP3A4 inhibitors (e.g., ketoconazole), • or A moderate CYP3A4 inhibitor(s) with a strong CYP2C19 inhibitor(s) (e.g., fluconazole)	If taking 10 mg twice daily, reduce to 5 mg twice daily. If taking 5 mg twice daily, reduce to 5 mg once daily.	If taking 22 mg once daily, reduce to 11 mg once daily. If taking 11 mg once daily, reduce to XELJANZ 5 mg once daily.
Patients with: • Moderate or severe renal impairment • Moderate hepatic impairment	If taking 10 mg twice daily, reduce to 5 mg twice daily. If taking 5 mg twice daily, reduce to 5 mg once daily.	If taking 22 mg once daily, reduce to 11 mg once daily. If taking 11 mg once daily, reduce to XELJANZ 5 mg once daily.
	For patients undergoing hemodialysis, dose should be administered after the dialysis session on dialysis days. If a dose was taken before the dialysis procedure, supplemental doses are not recommended in patients after dialysis	
Patients with severe hepatic impairment	Use is not recommended.	
Patients with lymphocyte count <500 cells/mm^3, confirmed by repeat testing	Discontinue dosing.	
Patients with ANC 500 cells/mm^3 to 1000 cells/mm^3	If taking 10 mg twice daily, reduce to 5 mg twice daily. When ANC is >1000 cells/mm^3, increase to 10 mg twice daily based on clinical response. If taking 5 mg twice daily, interrupt dosing. When ANC is >1000 cells/mm^3, resume 5 mg twice	If taking 22 mg once daily, reduce to 11 mg once daily. When ANC is >1000 cells/mm^3, increase to 22 mg once daily based on clinical response. If taking 11 mg once daily, interrupt dosing. When ANC is >1000 cells/mm^3, resume 11 mg once
Patients with ANC <500 cells/mm^3	Discontinue dosing.	
Patients with hemoglobin <8 g/dL, or a decrease of >2 g/dL	Interrupt dosing until hemoglobin values have normalized.	

NEXT QUESTION

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XELJANZ/XELJANZ XR Dosage and Administration Considerations[1]

IMPORTANT ADMINISTRATION

- XELJANZ XR is not interchangeable or substitutable with XELJANZ Oral Solution
- Changes between XELJANZ and XELJANZ XR should be made by the healthcare provider
- Dose interruption is recommended for management of lymphopenia, neutropenia, anemia, and if a patient develops a serious infection
- Take XELJANZ/XELJANZ XR with or without food

AVOID INITIATION IN PATIENTS WITH:

- ALC <500 cells/mm^3
- ANC <1000 cells/mm^3
- Active, serious infection
- Risk of thrombosis
- Hemoglobin levels <9 g/dL
- Severe hepatic impairment
- Concurrent live vaccine use

NEXT QUESTION

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UC EFFICACY QUESTION 1 – Correct Answer

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TRUE Correct answer

FALSE

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UC EFFICACY QUESTION 1 – Additional Information

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CLOSE

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XELJANZ/XELJANZ XR Dosage and Administration Considerations[1]

IMPORTANT ADMINISTRATION

- XELJANZ XR is not interchangeable or substitutable with XELJANZ Oral Solution
- Changes between XELJANZ and XELJANZ XR should be made by the healthcare provider
- Dose interruption is recommended for management of lymphopenia, neutropenia, anemia, and if a patient develops a serious infection
- Take XELJANZ/XELJANZ XR with or without food

AVOID INITIATION IN PATIENTS WITH:

- ALC <500 cells/mm^3
- ANC <1000 cells/mm^3
- Active, serious infection
- Risk of thrombosis
- Hemoglobin levels <9 g/dL
- Severe hepatic impairment
- Concurrent live vaccine use

CLOSE

IMPORTANT SAFETY INFORMATION

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TEST YOUR

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1139 patients with moderately to severely active UC were randomized to XELJANZ 10 mg twice daily or placebo (4:1 ratio).[1-3]

Which of the following were key eligibility criteria for OCTAVE Induction 1 and 2 (UC-I and UC-II)?

Select all that apply

- ☐ Total Mayo score ≥6
- ☐ Mayo endoscopic subscore ≥2
- ☐ Mayo rectal bleeding subscore of 0
- ☐ Clinical finding suggestive of Crohn's disease
- ☐ IV corticosteroids with concomitant immunosuppressant use
- ☐ Mayo rectal bleeding subscore ≥1
- ☐ History of failure or intolerance to TNF blockers, oral or IV corticosteroids, and/or azathioprine or 6-mercaptopurine
- ☐ Mayo stool frequency subscore of 0

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4 Efficacy Questions Remaining

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TEST YOUR

OCTAVE Induction (UC-I and UC-II) Clinical Trial Design[1-3]

Key eligibility criteria[1,2]

Adults with moderately to severely active UC for ≥4 months:
Total Mayo score ≥6
Mayo endoscopic subscore ≥2
Mayo rectal bleeding subscore ≥1

History of failure or intolerance to ≥1 of the following:
Oral or IV corticosteroids
Azathioprine or 6-mercaptopurine
TNF blocker

Permitted concomitant medications included stable doses of:
Oral 5-ASA or sulfasalazine
Oral corticosteroid (prednisone daily dose ≤25 mg equivalent)

Prohibited concomitant medications:
Immunosuppressants
(immunomodulators or biological therapies)

OCTAVE Induction 1 and 2
(UC-I and UC-II)

Randomization

XELJANZ 10 mg BID (N=905)
Placebo (N=234)

Assessment at week 8[a]

8 weeks

Primary endpoint[1]

Remission at week 8
Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore 0

Secondary endpoints[1,2]

Clinical response at week 8
Definition: Total Mayo score decrease ≥3 points and ≥30% from BL
Mayo rectal bleeding subscore decrease ≥1 point from BL or absolute score ≤1

Improvement of endoscopic appearance of the mucosa at week 8:
Definition: Mayo endoscopic subscore ≤1

[a]The total number of patients does not include those who received XELJANZ 15 mg BID (n=22).[3] **XELJANZ 15 mg twice daily is not an approved dose.[1]**

NEXT QUESTION

UC EFFICACY QUESTION 2 – Correct Answer

The OCTAVE clinical program included 2 identical 8-week induction studies, OCTAVE Induction 1 and 2 (UC-I and UC-II), in which 1139 patients with moderately to severely active UC were randomized to XELJANZ 10 mg twice daily or placebo (4:1 ratio).

Which of the following were key eligibility criteria for OCTAVE Induction 1 and 2 (UC-I and UC-II)?[1-3]

- [x] Total Mayo score ≥6 — Correct answer
- [x] Mayo endoscopic subscore ≥2 — Correct answer
- [ ] Mayo rectal bleeding subscore of 0
- [ ] Clinical finding suggestive of Crohn's disease
- [ ] IV corticosteroids with concomitant immunosuppressant use
- [x] Mayo rectal bleeding subscore ≥1 — Correct answer
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ADDITIONAL INFORMATION

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TEST YOUR UC EFFICACY QUESTION 2 – Additional Information

OCTAVE Induction (UC-I and UC-II) Clinical Trial Design[1-3]

Key eligibility criteria[1,2]

Adults with moderately to severely active UC for ≥4 months:
Total Mayo score ≥6
Mayo endoscopic subscore ≥2
Mayo rectal bleeding subscore ≥1

History of failure or intolerance to ≥1 of the following:
Oral or IV corticosteroids
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TNF blocker

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OCTAVE Induction 1 and 2
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Randomization

XELJANZ 10 mg BID (N=905)
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Assessment at week 8[a]

8 weeks

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Definition: Total Mayo score ≤2
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3 Efficacy Questions Remaining

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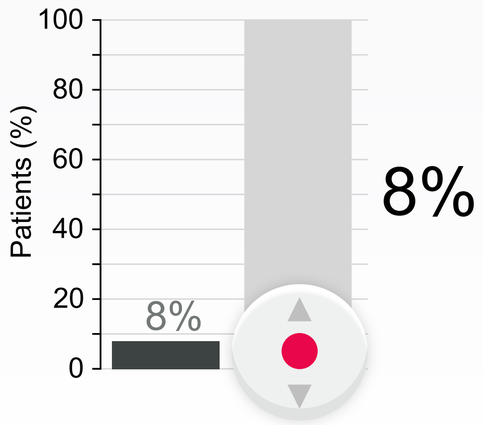
In the OCTAVE Induction 1 and 2 (UC-I and UC-II) clinical trials, what percentage of the total patient populations[a] and

Drag the slider to select your answer

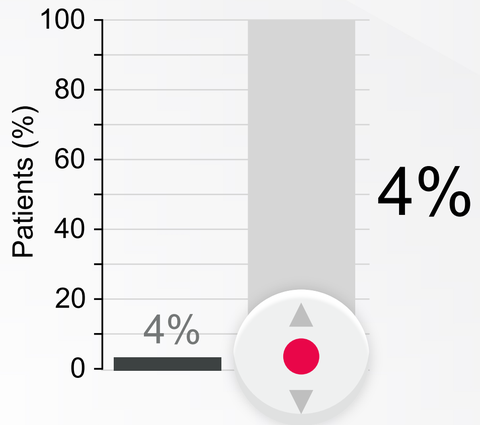
Total Patient Population[a] (Primary Endpoint)

OCTAVE Induction 1



PLACEBO (n/N=10/122) XELJANZ 10 mg BID (N=476)

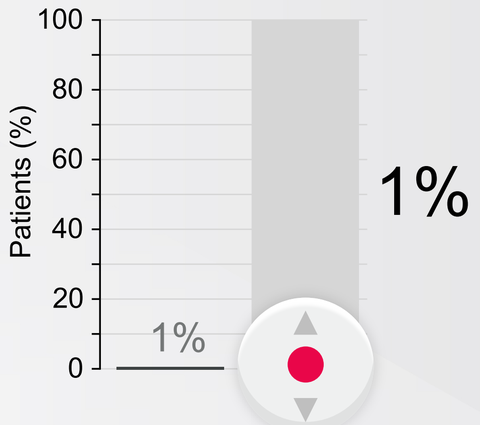
OCTAVE Induction 2



PLACEBO (n/N=4/112) XELJANZ 10 mg BID (N=429)

Percentage of Patients in Remission at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]

OCTAVE Induction 1 and 2



PLACEBO (n/N=1/124) XELJANZ 10 mg BID (N=465)

- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.

[a]Total population includes patients without prior TNF blocker failure.[1] [b]Limitations: While these subgroup analyses were predefined, the pooled data are post hoc analyses.[2] [c]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to TNF blocker therapy.[1]

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3 Efficacy Questions Remaining

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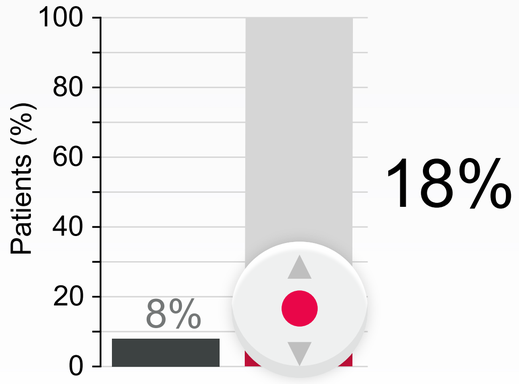
Drag the slider to select your answer

Total Patient Population[a] (Primary Endpoint)

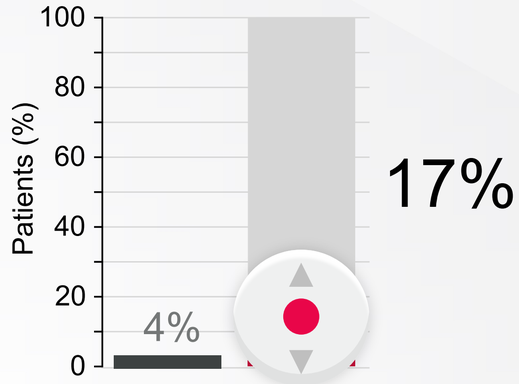
Percentage of Patients in Remission at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]

OCTAVE Induction 1



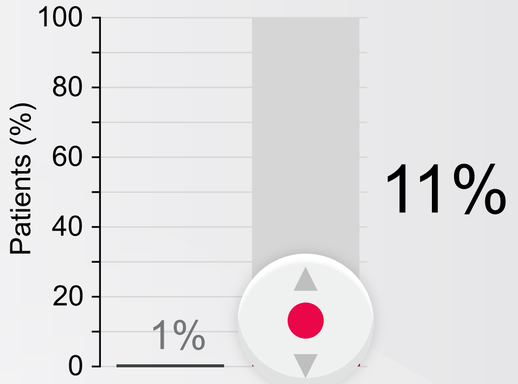
PLACEBO (n/N=10/122) | XELJANZ 10 mg BID (N=476)

OCTAVE Induction 2



PLACEBO (n/N=4/112) | XELJANZ 10 mg BID (N=429)

OCTAVE Induction 1 and 2



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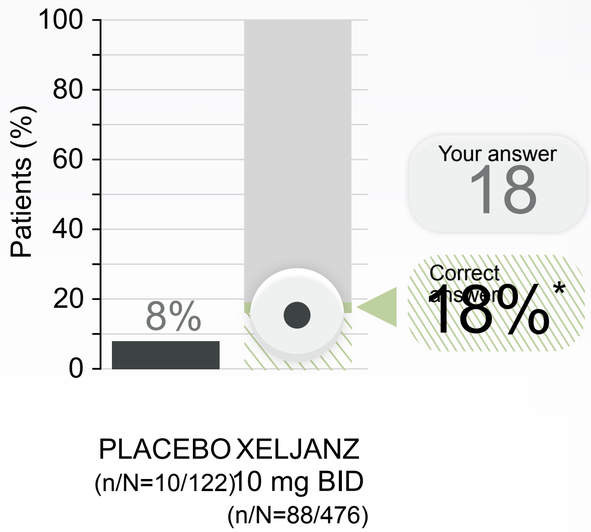
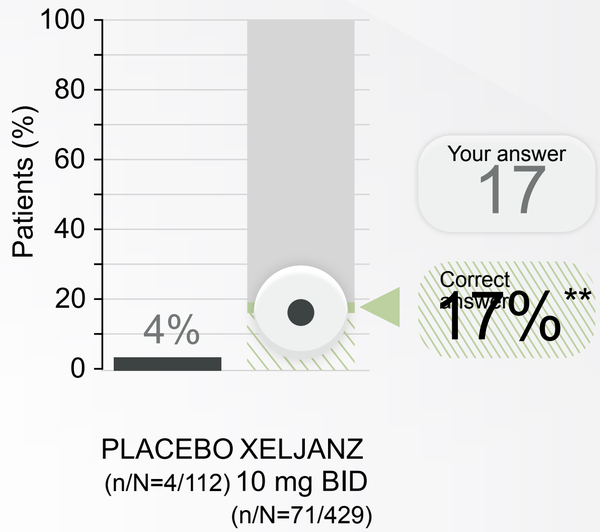
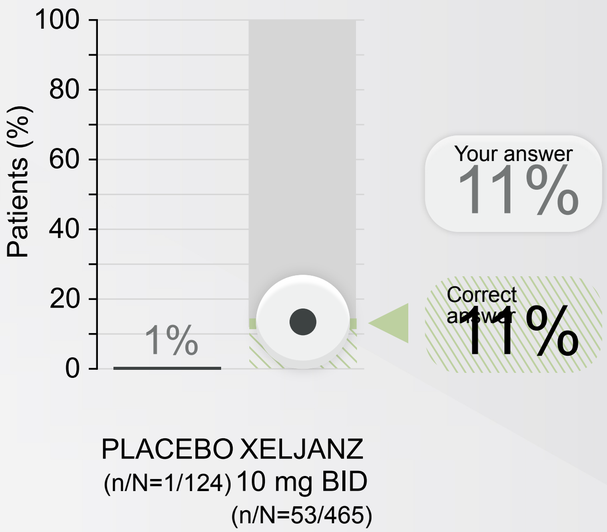


OCTAVE Induction 2



Percentage of Patients in Remission at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]

OCTAVE Induction 1 and 2



XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.

*P<0.01, **P<0.001 vs placebo.

[a]Total population includes patients without prior TNF blocker failure.[1] [b]Limitations: While these subgroup analyses were predefined, the pooled data are post hoc analyses.[2] [c]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to TNF

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SERIOUS INFECTIONS

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If a serious infection develops, interrupt XELJANZ until the infection is controlled.

Reported infections include:

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3 Efficacy Questions Remaining

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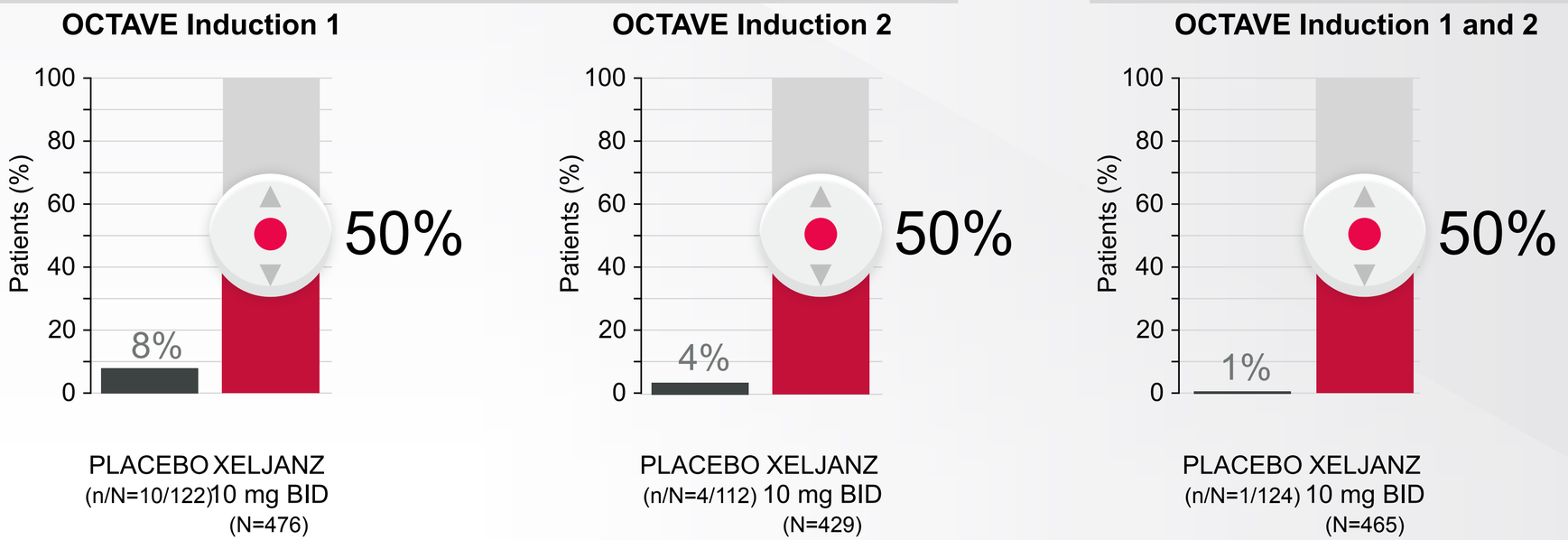
In the OCTAVE Induction 1 and 2 (UC-I and UC-II) clinical trials, what percentage of the total patient populations[a] and

Drag the slider to select your answer

Total Patient Population[a] (Primary Endpoint)

Percentage of Patients in Remission at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]



- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

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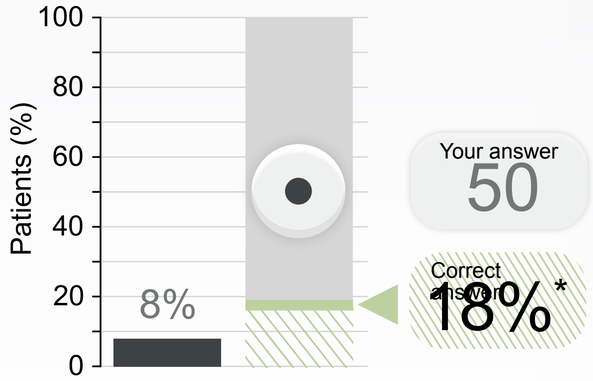
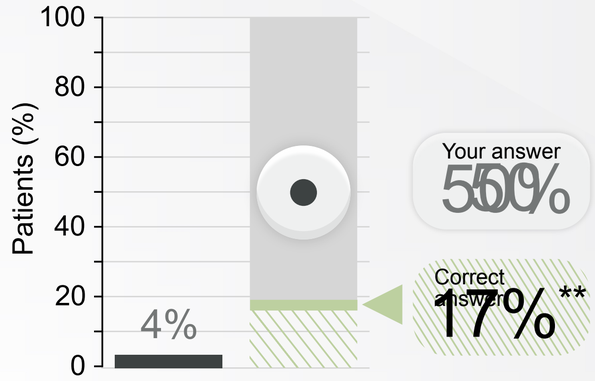
OCTAVE Induction 1



PLACEBO (n/N=10/122) XELJANZ 10 mg BID (n/N=88/476)

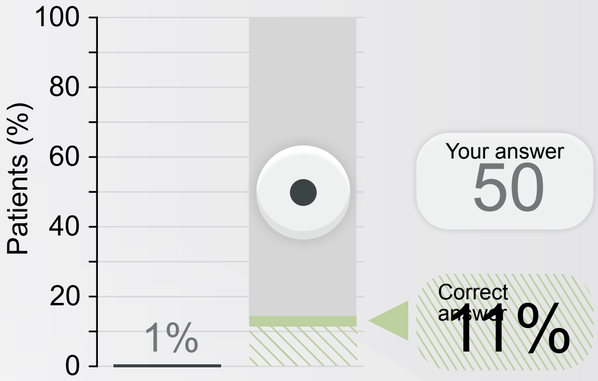
OCTAVE Induction 2



PLACEBO (n/N=4/112) XELJANZ 10 mg BID (n/N=71/429)

Percentage of Patients in Remission at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]

OCTAVE Induction 1 and 2



PLACEBO (n/N=1/124) XELJANZ 10 mg BID (n/N=53/465)

- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

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*P<0.01, **P<0.001 vs placebo.

[a]Total population includes patients without prior TNF blocker failure.[1] [b]Limitations: While these subgroup analyses were predefined, the pooled data are post hoc analyses.[2] Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to TNF

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OCTAVE Induction (UC-I and UC-II) Clinical Trial Design[1-3]

Key eligibility criteria[1,2]

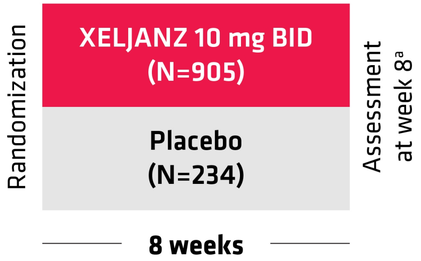
Adults with moderately to severely active UC for ≥4 months:
Total Mayo score ≥6
Mayo endoscopic subscore ≥2
Mayo rectal bleeding subscore ≥1

History of failure or intolerance to ≥1 of the following:
Oral or IV corticosteroids
Azathioprine or 6-mercaptopurine
TNF blocker

Permitted concomitant medications included stable doses of:
Oral 5-ASA or sulfasalazine
Oral corticosteroid (prednisone daily dose ≤25 mg equivalent)

Prohibited concomitant medications:
Immunosuppressants
(immunomodulators or biological therapies)

OCTAVE Induction 1 and 2
(UC-I and UC-II)



Primary endpoint[1]

Remission at week 8
Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore 0

Secondary endpoints[1,2]

Clinical response at week 8
Definition: Total Mayo score decrease ≥3 points and ≥30% from BL
Mayo rectal bleeding subscore decrease ≥1 point from BL or absolute score ≤1

Improvement of endoscopic appearance of the mucosa at week 8:
Definition: Mayo endoscopic subscore ≤1

[a]The total number of patients does not include those who received XELJANZ 15 mg BID (n=22).[3] **XELJANZ 15 mg twice daily is not an approved dose.[1]**

NEXT QUESTION

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS
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UC EFFICACY QUESTION 3 – Correct Answer

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In the OCTAVE Induction 1 and 2 (UC-I and UC-II) clinical trials, what percentage of the total patient populations[a] and

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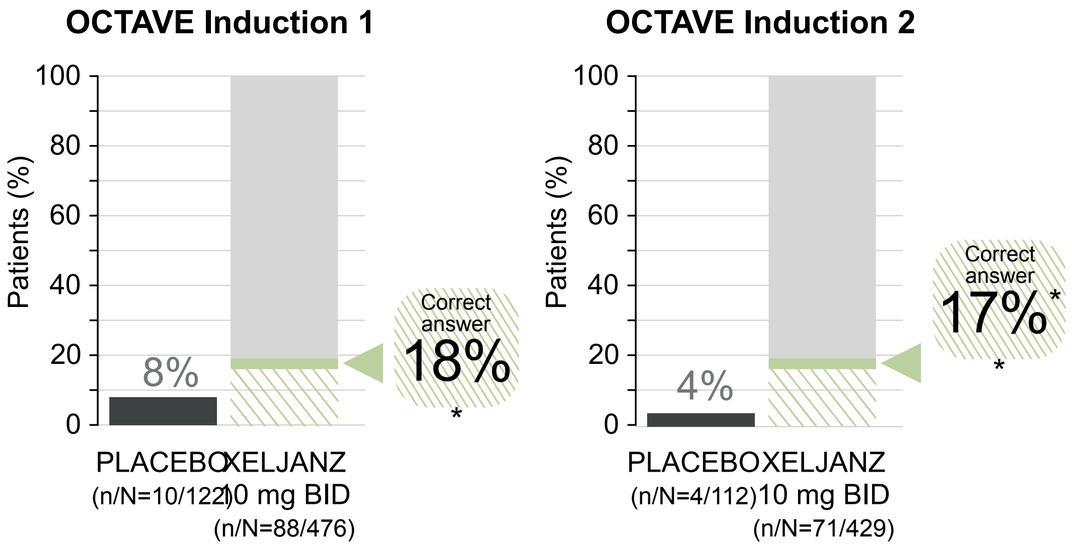
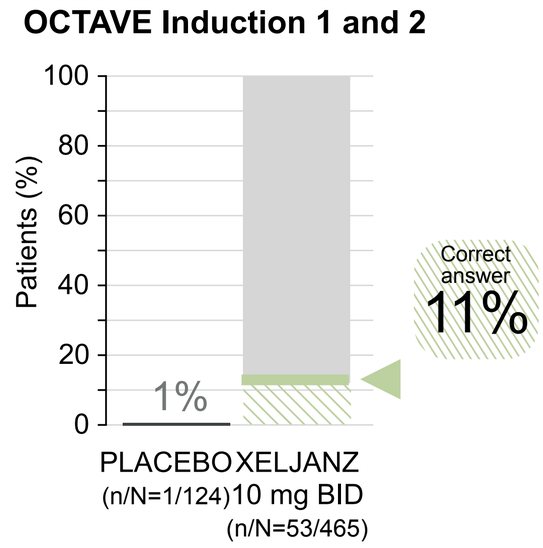


Percentage of Patients in Remission at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]



- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

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*P<0.01, **P<0.001 vs placebo.
[a]Total population includes patients without prior TNF blocker failure.[1]
[b]Limitations: While these subgroup analyses were predefined, the pooled data are post hoc analyses.[2]
[c]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to TNF blocker therapy.[1]

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UC EFFICACY QUESTION 3 – Additional Information

OCTAVE Induction (UC-I and UC-II) Clinical Trial Design[1-3]

Key eligibility criteria[1,2]

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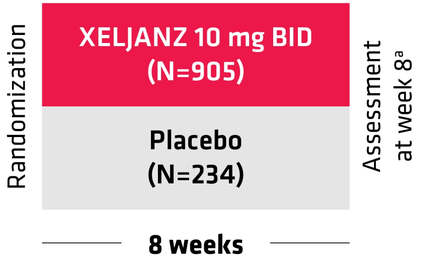
OCTAVE Induction 1 and 2
(UC-I and UC-II)



Primary endpoint[1]

Remission at week 8
Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore 0

Secondary endpoints[1,2]

Clinical response at week 8
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Mayo rectal bleeding subscore decrease ≥1 point from BL or absolute score ≤1

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Definition: Mayo endoscopic subscore ≤1

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2 Efficacy Questions Remaining

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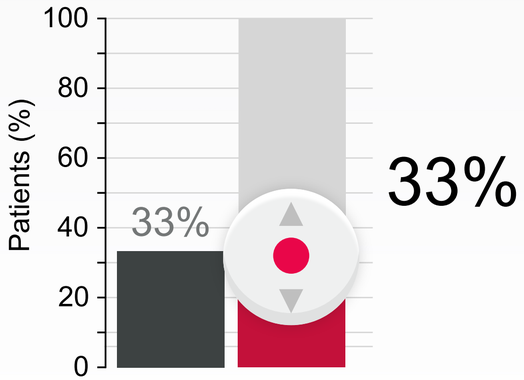
Drag the slider to select your answer

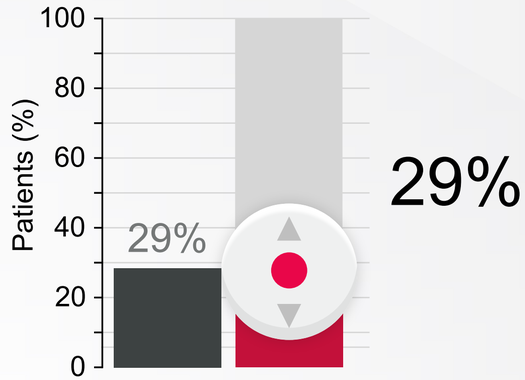
Total Patient Population[a] (Key Secondary Endpoint)

OCTAVE Induction 1



PLACEBO (n/N=40/122) | XELJANZ 10 mg BID (N=476)

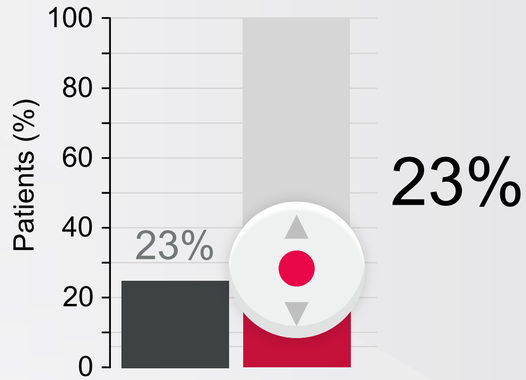
OCTAVE Induction 2



PLACEBO (n/N=32/112) | XELJANZ 10 mg BID (N=429)

Percentage of Patients With Clinical Response at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]

OCTAVE Induction 1 and 2



PLACEBO (n/N=29/124) | XELJANZ 10 mg BID (N=465)

- Clinical response was defined as a decrease from baseline in the total Mayo score of ≥3 points and ≥30%, with an accompanying decrease in the subscore for rectal bleeding of ≥1 point or an absolute subscore for rectal bleeding of 0 or 1[1]

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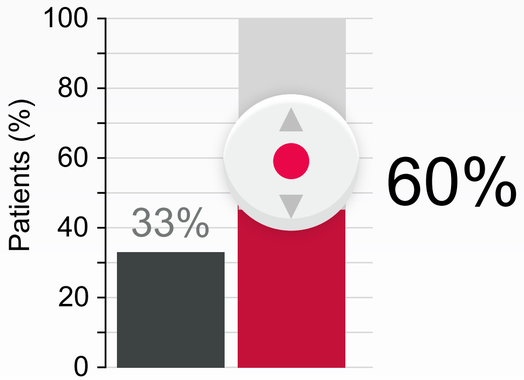

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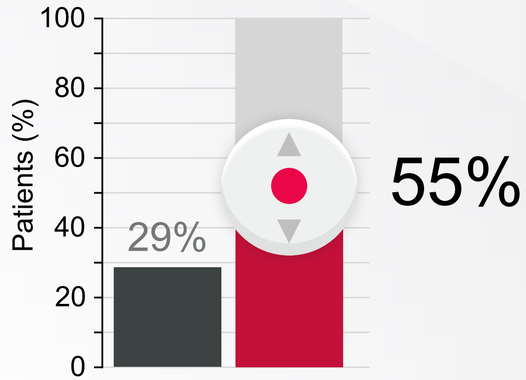
OCTAVE Induction 2



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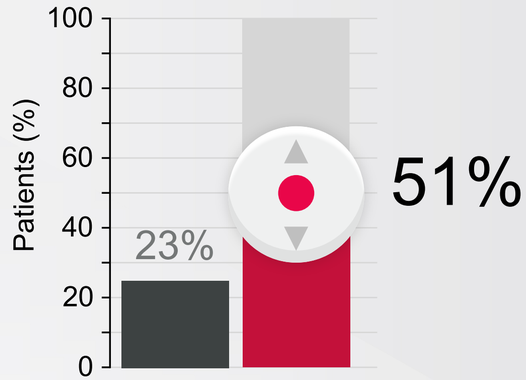

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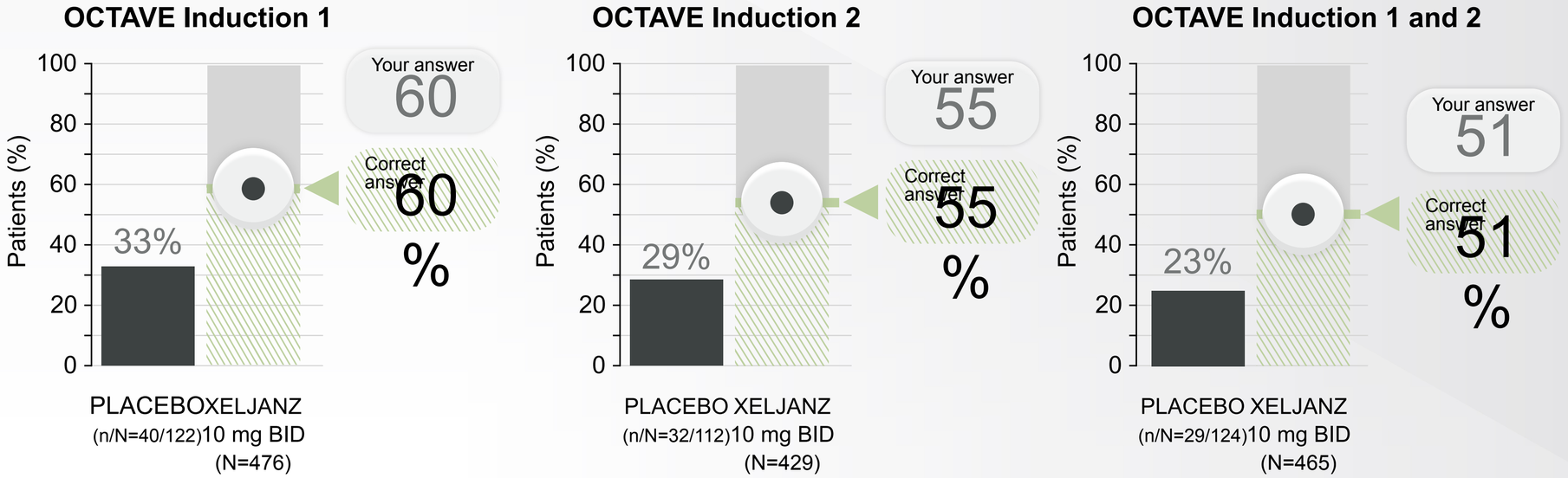

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SERIOUS INFECTIONS

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If a serious infection develops, interrupt XELJANZ until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

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In the UC population, XELJANZ 10 mg twice daily was associated with greater risk of serious infections compared to 5 mg twice daily. Opportunistic herpes zoster infections (including meningoencephalitis, ophthalmologic, and disseminated cutaneous) were seen in patients who were treated with XELJANZ 10 mg

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2 Efficacy Questions Remaining

The OCTAVE clinical program included 2 identical 8-week induction studies, OCTAVE Induction 1 and 2 (UC-I and UC-II), in which

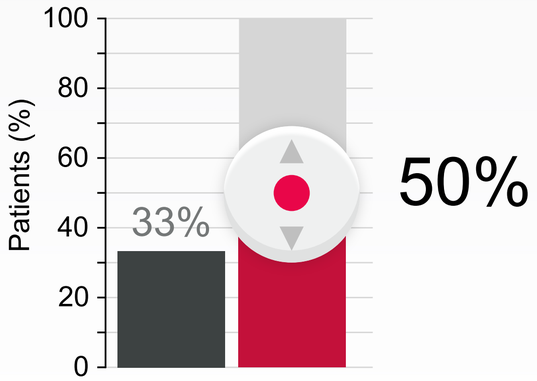
1139 patients with moderately to severely active UC were randomized to XELJANZ 10 mg twice daily or placebo (4:1 ratio).

In the OCTAVE Induction 1 and 2 (UC-I and UC-II) clinical trials, what percentage of the total patient populations[a] and the

Drag the slider to select your answer

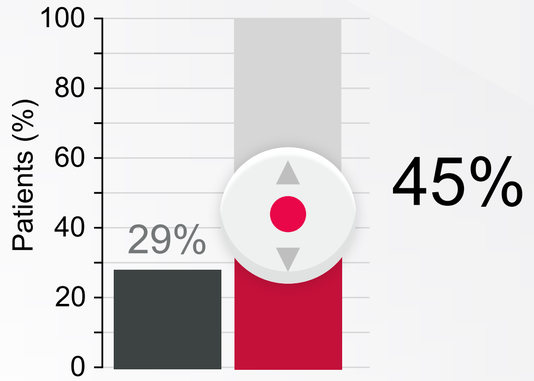
Total Patient Population[a] (Key Secondary Endpoint)

OCTAVE Induction 1



PLACEBO (n/N=40/122) | XELJANZ 10 mg BID (N=476)

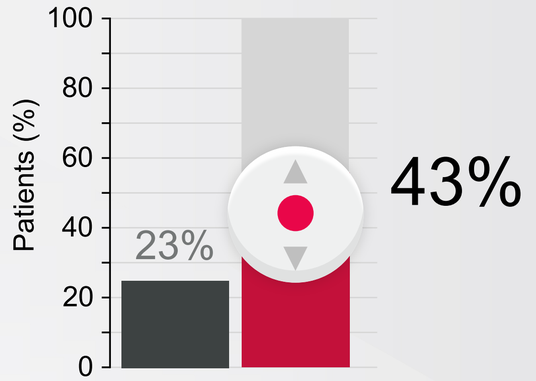
OCTAVE Induction 2



PLACEBO (n/N=32/112) | XELJANZ 10 mg BID (N=429)

Percentage of Patients With Clinical Response at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]

OCTAVE Induction 1 and 2



PLACEBO (n/N=29/124) | XELJANZ 10 mg BID (N=465)

- Clinical response was defined as a decrease from baseline in the total Mayo score of ≥3 points and ≥30%, with an accompanying decrease in the subscore for rectal bleeding of ≥1 point or an absolute subscore for rectal bleeding of 0 or 1[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.

[a]Total population includes patients without prior TNF blocker failure.[1]

[b]Limitations: While these subgroup analyses were predefined, the pooled data are post hoc analyses.[2]

[c]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to TNF blocker

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IMPORTANT SAFETY INFORMATION

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Q1 | Q2 | Q3 | Q4

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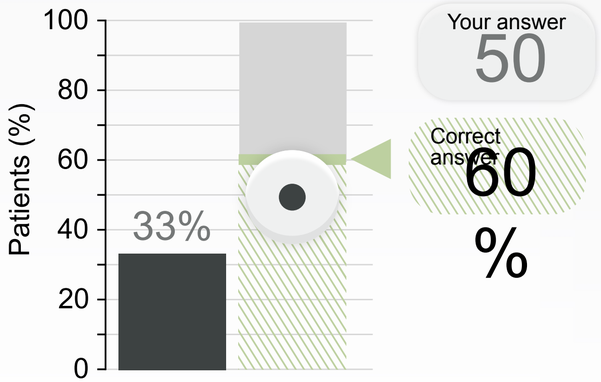
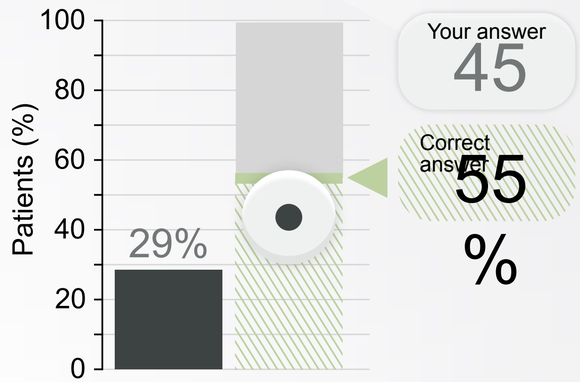
Percentage of Patients With Clinical Response at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]

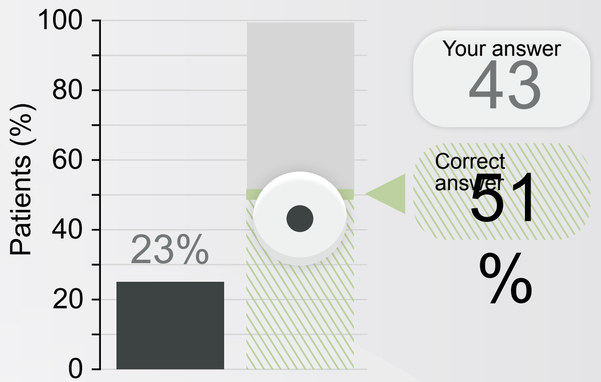
OCTAVE Induction 1



OCTAVE Induction 2



OCTAVE Induction 1 and 2



- Clinical response was defined as a decrease from baseline in the total Mayo score of ≥3 points and ≥30%, with an accompanying decrease in the subscore for rectal bleeding of ≥1 point or an absolute subscore for rectal bleeding of 0 or 1[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.

[a]Total population includes patients without prior TNF blocker failure.[1]

[b]Limitations: While these subgroup analyses were predefined, the pooled data are post hoc analyses.[2]

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OCTAVE Induction (UC-I and UC-II) Clinical Trial Design[1-3]

Key eligibility criteria[1,2]

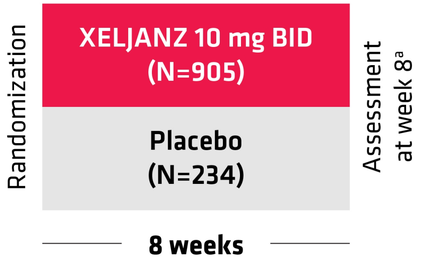
Adults with moderately to severely active UC for ≥4 months:
Total Mayo score ≥6
Mayo endoscopic subscore ≥2
Mayo rectal bleeding subscore ≥1

History of failure or intolerance to ≥1 of the following:
Oral or IV corticosteroids
Azathioprine or 6-mercaptopurine
TNF blocker

Permitted concomitant medications included stable doses of:
Oral 5-ASA or sulfasalazine
Oral corticosteroid (prednisone daily dose ≤25 mg equivalent)

Prohibited concomitant medications:
Immunosuppressants
(immunomodulators or biological therapies)

OCTAVE Induction 1 and 2
(UC-I and UC-II)



Primary endpoint[1]

Remission at week 8
Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore 0

Secondary endpoints[1,2]

Clinical response at week 8
Definition: Total Mayo score decrease ≥3 points and ≥30% from BL
Mayo rectal bleeding subscore decrease ≥1 point from BL or absolute score ≤1

Improvement of endoscopic appearance of the mucosa at week 8:
Definition: Mayo endoscopic subscore ≤1

[a]The total number of patients does not include those who received XELJANZ 15 mg BID (n=22).[3] **XELJANZ 15 mg twice daily is not an approved dose.**[1]

NEXT QUESTION

UC EFFICACY QUESTION 4 – Correct Answer

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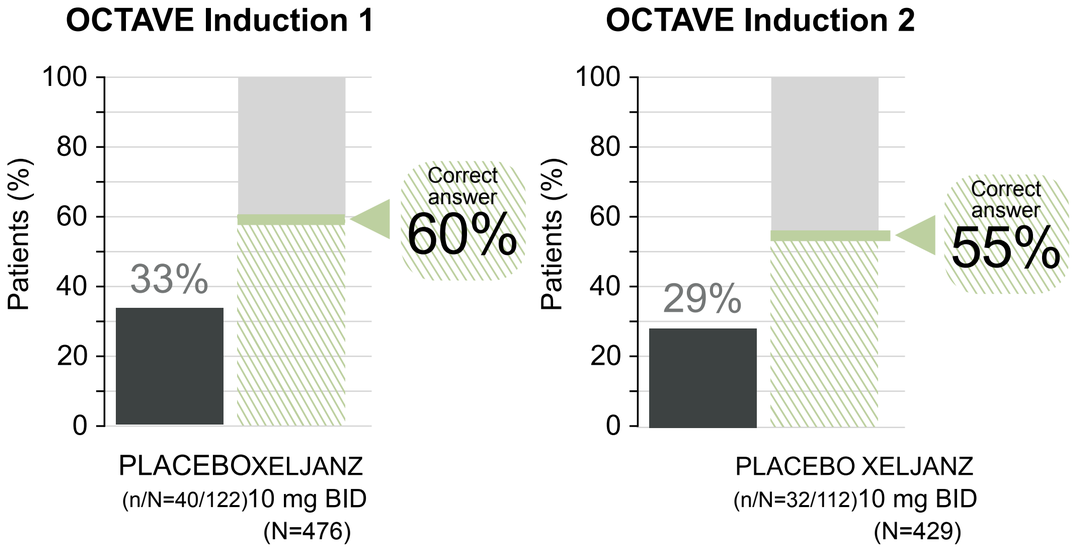
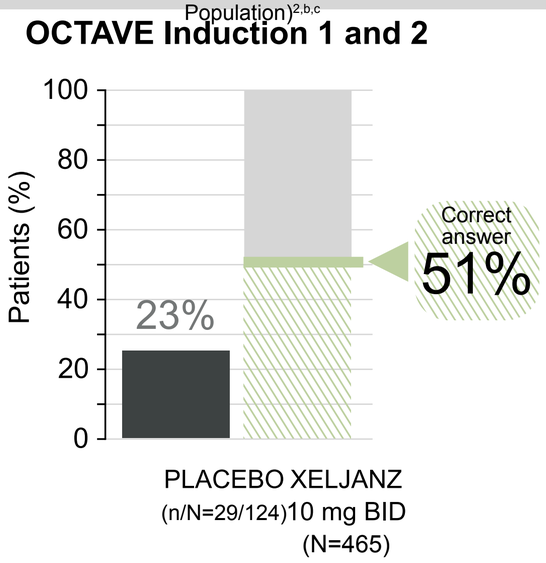
In the OCTAVE Induction 1 and 2 (UC-I and UC-II) clinical trials, what percentage of the total patient populations[a] and the

Drag the slider to select your answer

Total Patient Population[a] (Key Secondary Endpoint)



Percentage of Patients With Clinical Response at Week 8 With Prior TNF Blocker Failure (Pooled Data of Subgroup Population)[2,b,c]



- Clinical response was defined as a decrease from baseline in the total Mayo score of ≥3 points and ≥30%, with an accompanying decrease in the subscore for rectal bleeding of ≥1 point or an absolute subscore for rectal bleeding of 0 or 1[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.

[a]Total population includes patients without prior TNF blocker failure.[1]

[b]Limitations: While these subgroup analyses were predefined, the pooled data are post hoc analyses.[2]

[c]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to TNF

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SERIOUS INFECTIONS

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UC EFFICACY QUESTION 4 – Additional Information

OCTAVE Induction (UC-I and UC-II) Clinical Trial Design[1-3]

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Mayo endoscopic subscore ≥2
Mayo rectal bleeding subscore ≥1

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Azathioprine or 6-mercaptopurine
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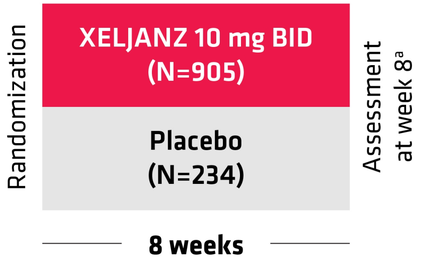
Oral corticosteroid (prednisone daily dose ≤25 mg equivalent)

Prohibited concomitant medications:
Immunosuppressants
(immunomodulators or biological therapies)

OCTAVE Induction 1 and 2
(UC-I and UC-II)



Primary endpoint[1]

Remission at week 8
Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore 0

Secondary endpoints[1,2]

Clinical response at week 8
Definition: Total Mayo score decrease ≥3 points and ≥30% from BL
Mayo rectal bleeding subscore decrease ≥1 point from BL or absolute score ≤1

Improvement of endoscopic appearance of the mucosa at week 8:
Definition: Mayo endoscopic subscore ≤1

[a]The total number of patients does not include those who received XELJANZ 15 mg BID (n=22).[3] **XELJANZ 15 mg twice daily is not an approved dose.[1]**

CLOSE

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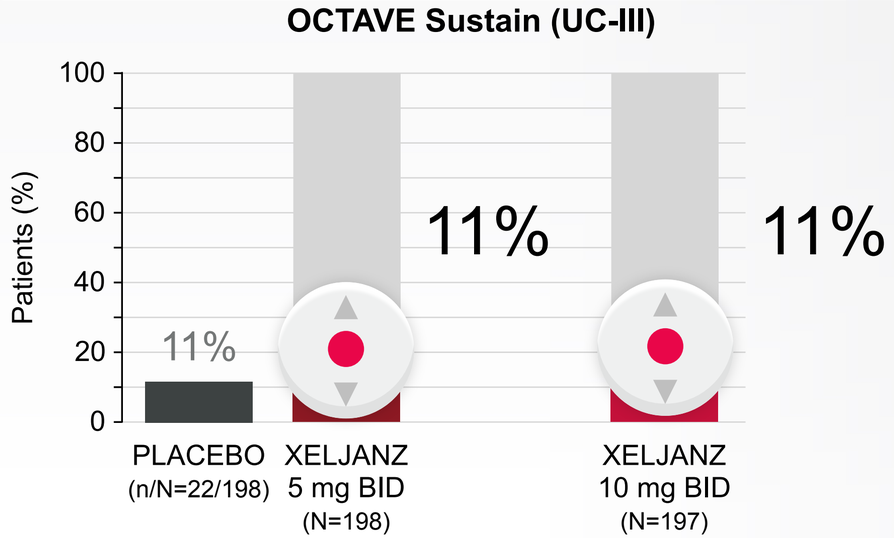
1 Efficacy Question Remaining

The OCTAVE clinical program included a 52-week maintenance study, OCTAVE Sustain (UC-III), of 593 patients who completed the induction trials (UC-I or UC-II) and achieved clinical response. These patients were re-randomized to XELJANZ 5 mg twice daily,
XELJANZ 10 mg twice daily, or placebo (1:1:1 ratio).

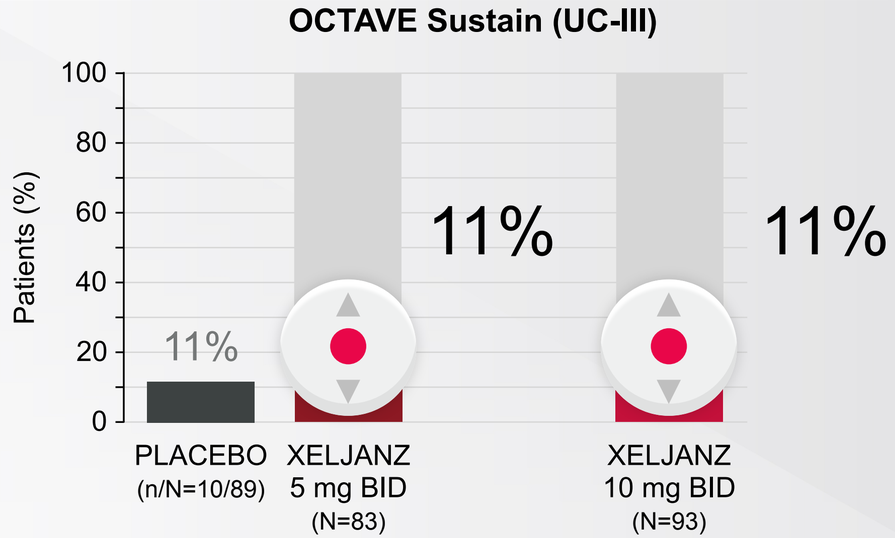
In OCTAVE Sustain (UC-III), what percentage of the total patient population[a] and the subgroup of patients with prior TNF

Drag the slider to select your answer

Total Patient Population[a] (Primary Endpoint)[1,2]



Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.[1]

[a]Total population includes patients without prior TNF blocker failure.[1]
[b]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to a TNF blocker therapy.[1]

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IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

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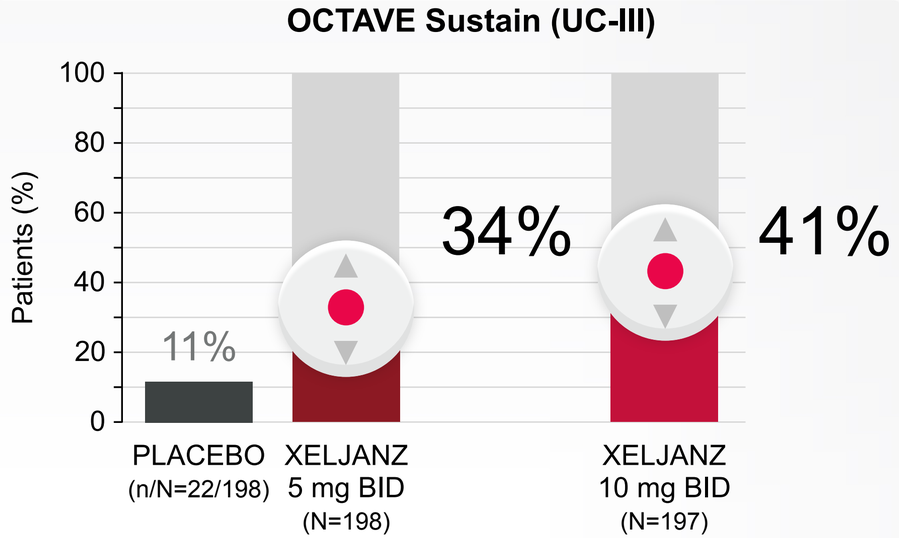
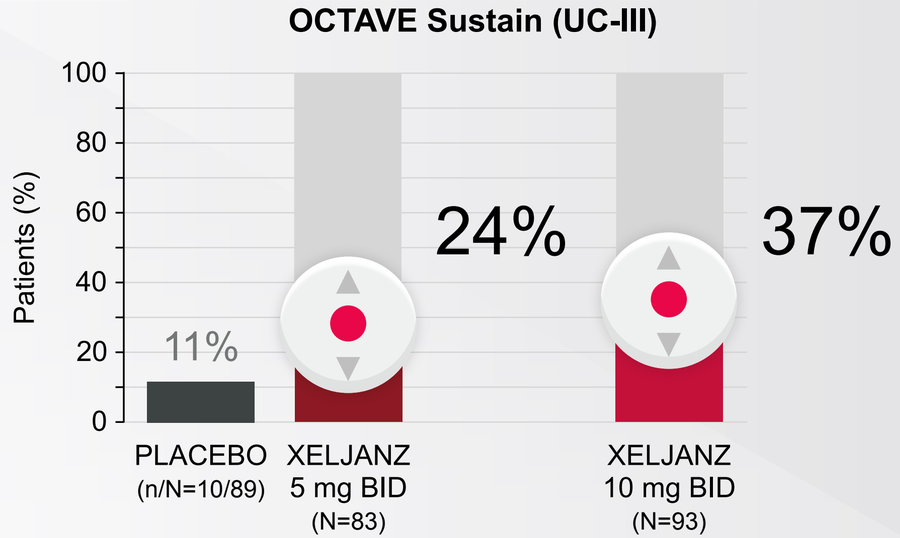
Drag the slider to select your answer

Total Patient Population[a] (Primary Endpoint)[1,2]



Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

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[a]Total population includes patients without prior TNF blocker failure.[1]
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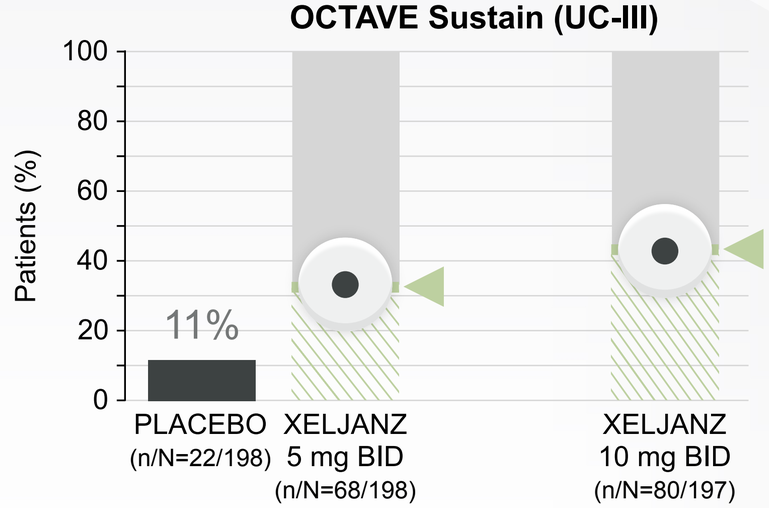
Total Patient Population[a] (Primary Endpoint)[1,2]



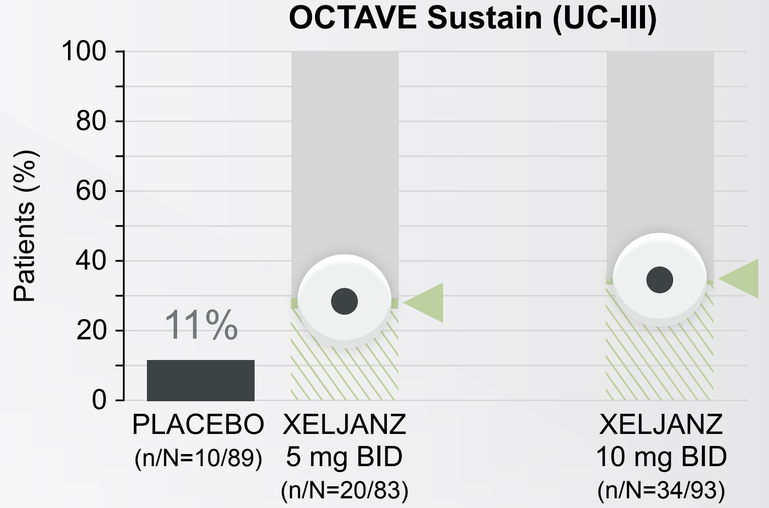
Correct answer: 34 *** %

Your answer: 34

Correct answer: 41 *** %

Your answer: 41

Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



Correct answer: 24 %

Your answer: 24

Correct answer: 37 %

Your answer: 37

- Remission (primary endpoint at week 8 [UC-I and UC-II] and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

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***P<0.0001

[a]Total population includes patients without prior TNF blocker failure.[1]

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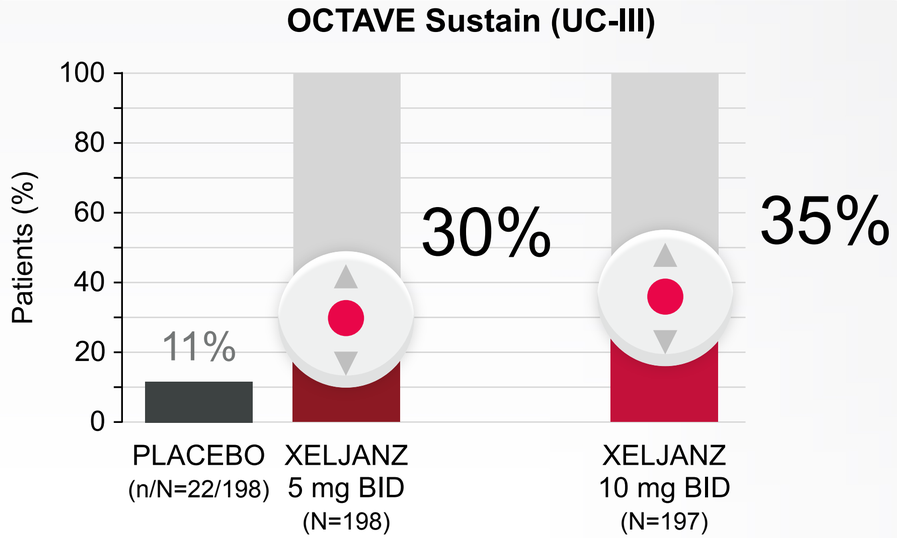
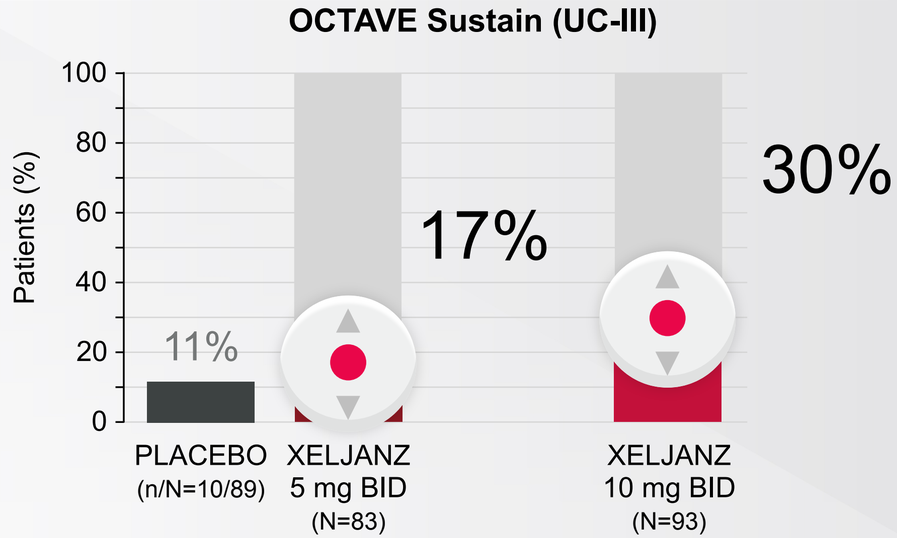
Drag the slider to select your answer

Total Patient Population[a] (Primary Endpoint)[1,2]



Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.[1]

[a]Total population includes patients without prior TNF blocker failure.[1]
[b]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to a TNF blocker therapy.[1]

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IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with XELJANZ* are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

If a serious infection develops, interrupt XELJANZ until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

The most common serious infections reported with XELJANZ included pneumonia, cellulitis, herpes zoster, urinary tract infection, diverticulitis, and appendicitis. Avoid use of XELJANZ in patients with an active, serious infection, including localized infections.

In the UC population, XELJANZ 10 mg twice daily was associated with greater risk of serious infections compared to 5 mg twice daily. Opportunistic herpes zoster infections (including meningoencephalitis, ophthalmologic, and disseminated cutaneous) were seen in patients who were treated with XELJANZ 10 mg

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1 Efficacy Question Remaining

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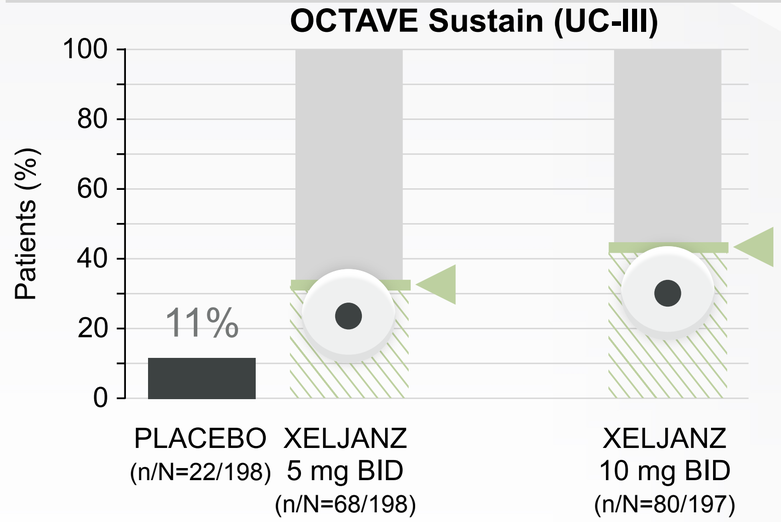
In OCTAVE Sustain (UC-III), what percentage of the total patient population[a] and the subgroup of patients with prior TNF blocker

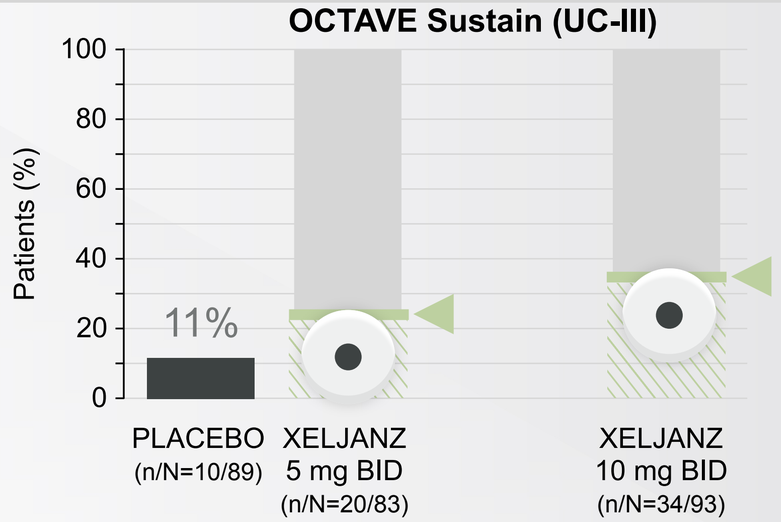
Total Patient Population[a] (Primary Endpoint)[1,2]



Correct answer 34%*** | Your answer 30

Correct answer 41%*** | Your answer 35

Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



Correct answer 24% | Your answer 17

Correct answer 37% | Your answer 30

- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.[1]

***P<0.0001

[a]Total population includes patients without prior TNF blocker failure.[1]

[b]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to a TNF blocker therapy.[1]

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IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

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If a serious infection develops, interrupt XELJANZ until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ use.**
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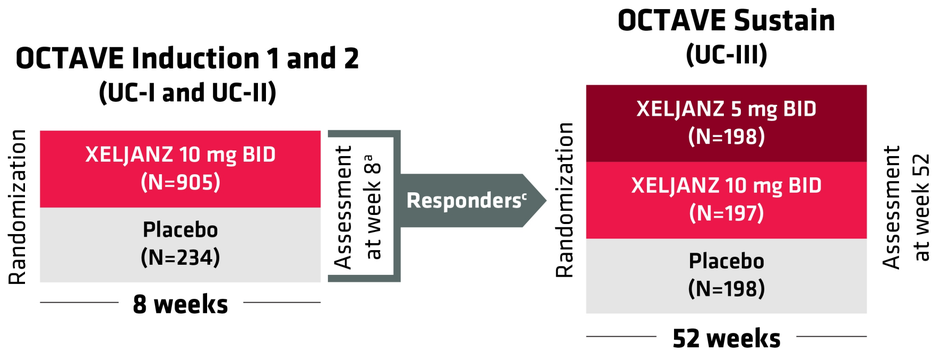
OCTAVE Sustain (UC-III) Clinical Trial Design[1-3]



Key eligibility criteria[1,3,b]

Response at week 8 of OCTAVE Induction trials

Tapering of corticosteroids was required at baseline of OCTAVE Sustain
Stable-dose corticosteroid use was allowed during induction

Primary endpoint[1]

Remission at week 52
Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore of 0

Key secondary endpoints[1]

Improvement of endoscopic appearance of the mucosa at week 52
Definition: Mayo endoscopic subscore ≤1

Sustained corticosteroid-free remission
Definition: Remission at BL and weeks 24 and 52, and no corticosteroids for ≥4 weeks prior to weeks 24 and 52

[a]The total number of patients does not include those who received XELJANZ 15 mg BID (n=22).[3] **XELJANZ 15 mg twice daily is not an approved dose.**[1]
[b]Key eligibility criteria regarding use of concomitant medications from OCTAVE Induction studies were retained in OCTAVE Sustain except for corticosteroid use.
[c]Total Mayo score decrease ≥3 points and ≥30% from baseline, plus Mayo rectal bleeding subscore decrease ≥1 point from baseline or absolute score ≤1.

NEXT QUESTION

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS
Patients treated with XELJANZ* are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

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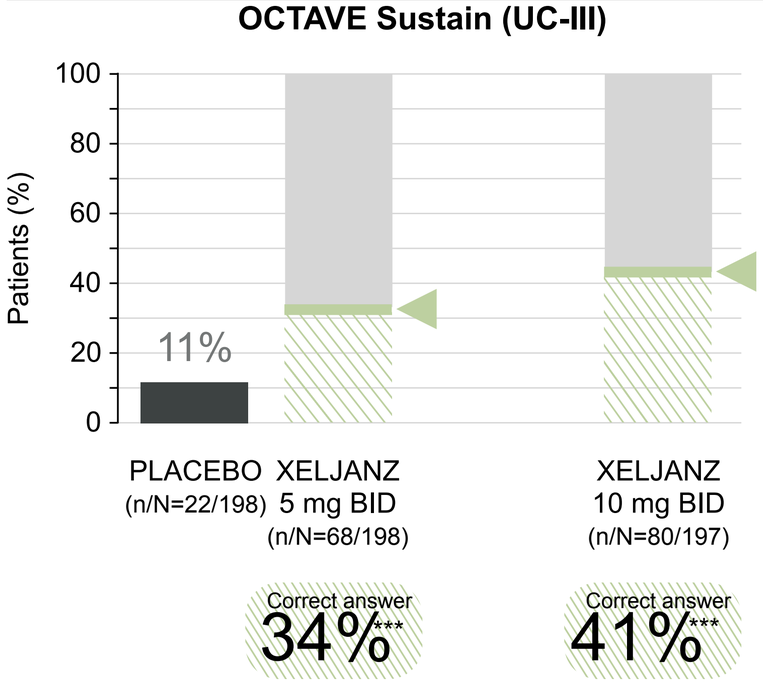
UC EFFICACY QUESTION 5 – Correct Answer

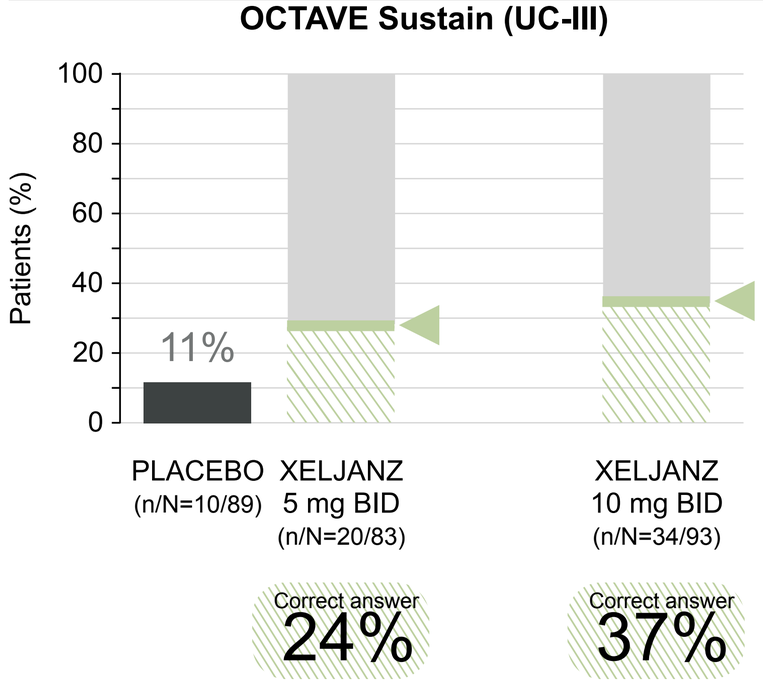
The OCTAVE clinical program included a 52-week maintenance study, OCTAVE Sustain (UC-III), of 593 patients who completed the induction trials (UC-I or UC-II) and achieved clinical response. These patients were re-randomized to XELJANZ 5 mg twice daily, XELJANZ 10 mg twice daily, or placebo (1:1:1 ratio).

In OCTAVE Sustain (UC-III), what percentage of the total patient population[a] and the subgroup of patients with prior TNF blocker

Total Patient Population[a] (Primary Endpoint)[1,2]



Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



- Remission (primary endpoint at week 8 [UC-I and UC-II], and primary endpoint at week 52 [UC-III]) was defined as Mayo score ≤2 with no individual subscore >1 **and** rectal bleeding subscore = 0[1]

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***P<0.0001

[a]Total population includes patients without prior TNF blocker failure.[1]

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ADDITIONAL INFORMATION

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

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Reported infections include:

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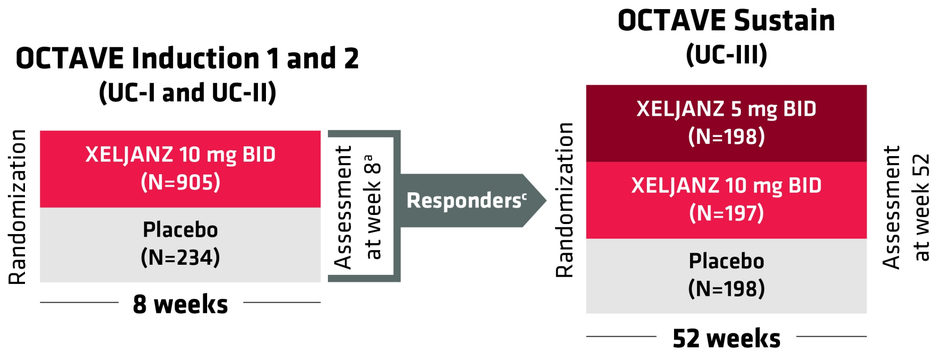
UC EFFICACY QUESTION 5 – Additional Information

OCTAVE Sustain (UC-III) Clinical Trial Design[1-3]



Key eligibility criteria[1,3,b]

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Stable-dose corticosteroid use was allowed during induction

Primary endpoint[1]

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Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore of 0

Key secondary endpoints[1]

Improvement of endoscopic appearance of the mucosa at week 52
Definition: Mayo endoscopic subscore ≤1

Sustained corticosteroid-free remission
Definition: Remission at BL and weeks 24 and 52, and no corticosteroids for ≥4 weeks prior to weeks 24 and 52

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0 Efficacy Questions Remaining

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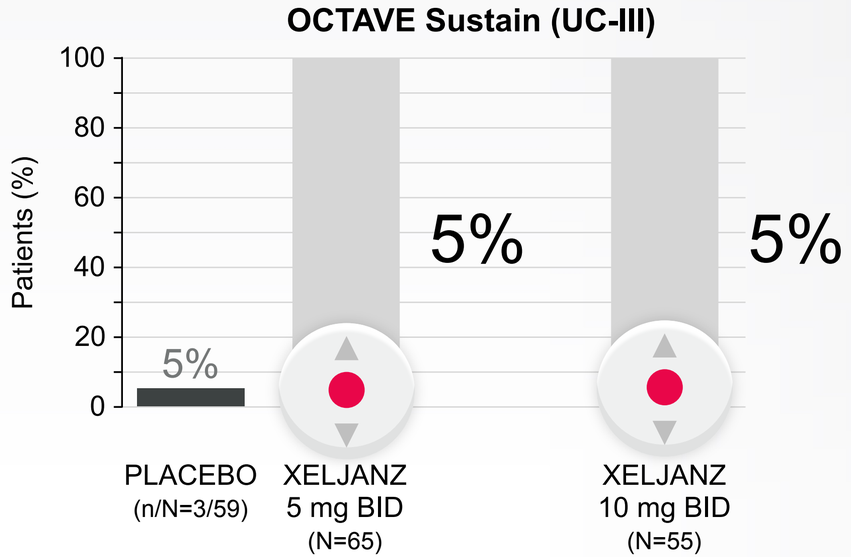
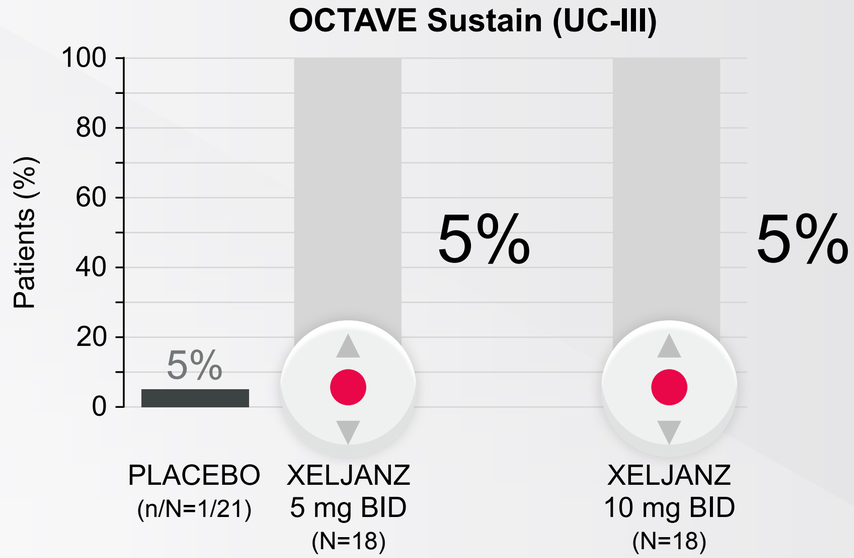
In OCTAVE Sustain (UC-III), what percentage of the total patient population[a] and the subgroup of patients with prior TNF blocker inadequate response or intolerance had sustained corticosteroid-free remission through week 52?[1-3]

Drag the slider to select your answer

Total Patient Population[a] (Key Secondary Endpoint)[1,2]



Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



- Sustained corticosteroid-free remission was defined as remission (a total Mayo score ≤2, with no individual subscore >1 **and** a rectal bleeding subscore of 0) and not taking corticosteroids for at least 4 weeks prior to the visit at both week 24 and week 52 among patients in remission at baseline[1]

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[a]Total population includes patients without prior TNF blocker failure.[1]

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SERIOUS INFECTIONS

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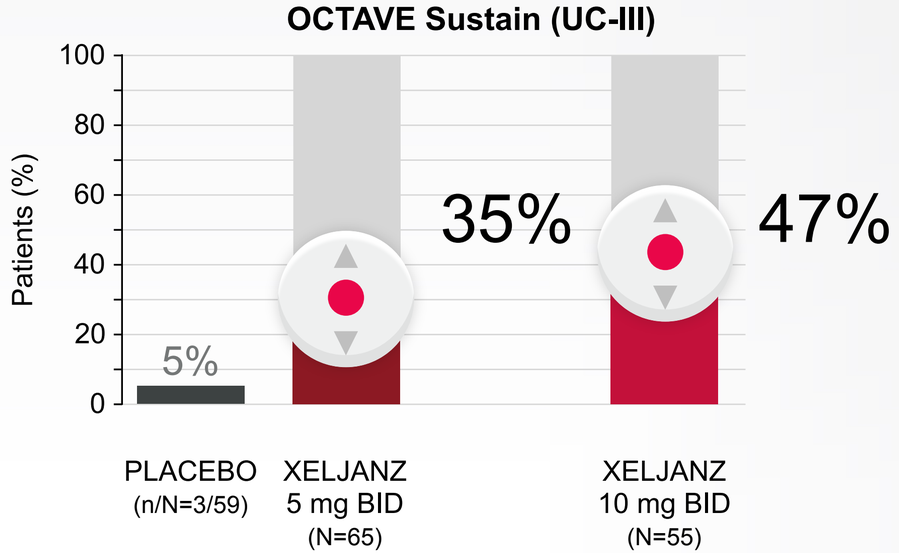
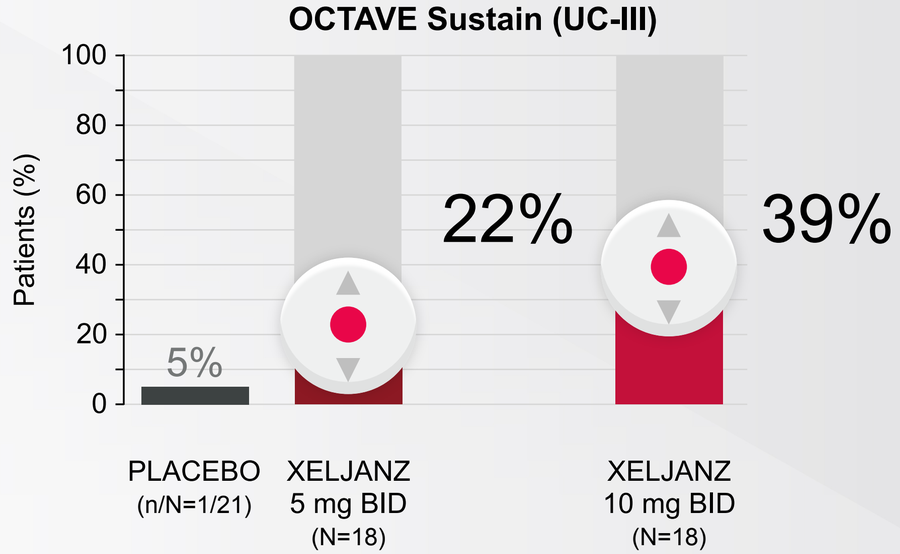
In OCTAVE Sustain (UC-III), what percentage of the total patient population[a] and the subgroup of patients with prior TNF blocker inadequate response or intolerance had sustained corticosteroid-free remission through week 52?[1-3]

Drag the slider to select your answer

Total Patient Population[a] (Key Secondary Endpoint)[1,2]



Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



- Sustained corticosteroid-free remission was defined as remission (a total Mayo score ≤2, with no individual subscore >1 **and** a rectal bleeding subscore of 0) and not taking corticosteroids for at least 4 weeks prior to the visit at both week 24 and week 52 among patients in remission at baseline[1]

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[a]Total population includes patients without prior TNF blocker failure.[1]

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Drag the slider to select your answer

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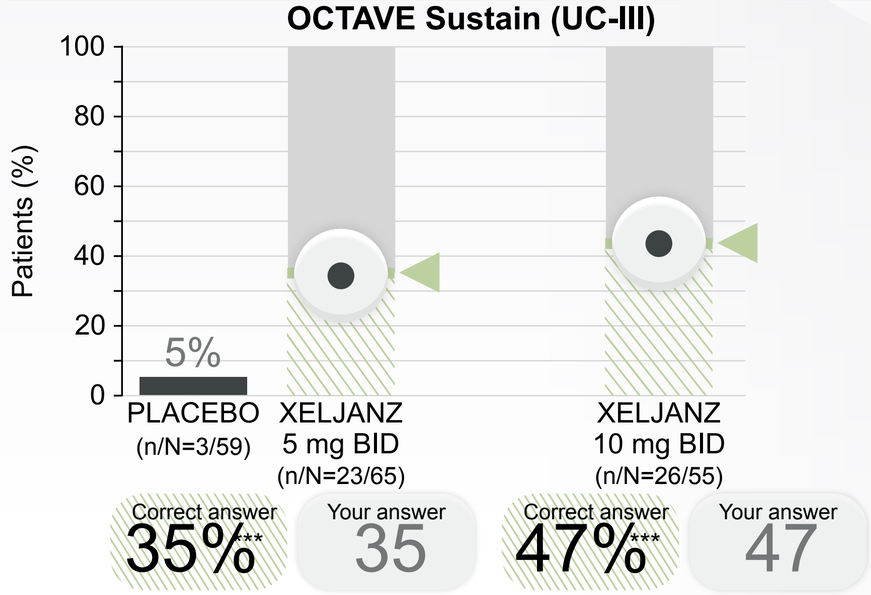
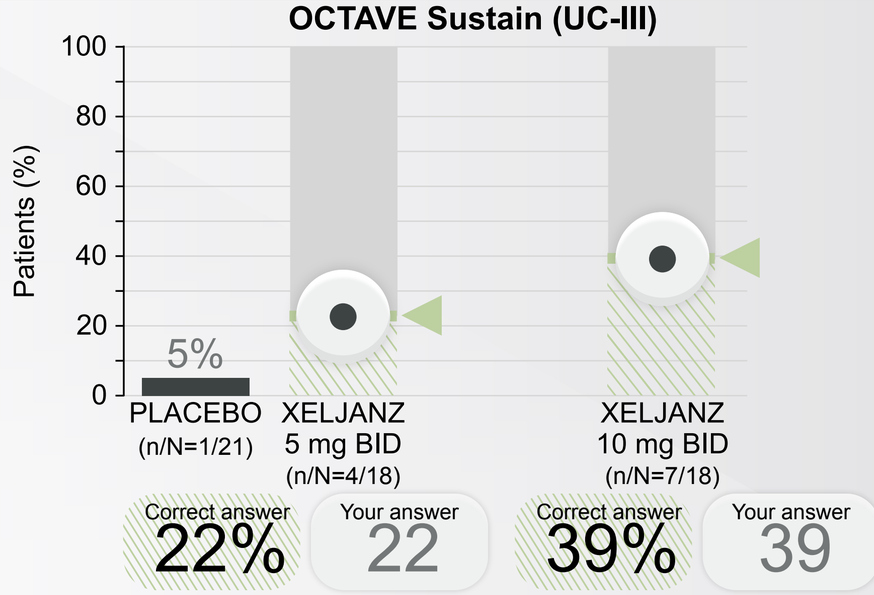


Correct answer	Your answer	Correct answer	Your answer
35%***	35	47%***	47

Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



Correct answer	Your answer	Correct answer	Your answer
22%	22	39%	39

- Sustained corticosteroid-free remission was defined as remission (a total Mayo score ≤2, with no individual subscore >1 **and** a rectal bleeding subscore of 0) and not taking corticosteroids for at least 4 weeks prior to the visit at both week 24 and week 52 among patients in remission at baseline[1]

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***P<0.0001

[a]Total population includes patients without prior TNF blocker failure.[1] [b]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to a TNF blocker therapy.[1]

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Drag the slider to select your answer

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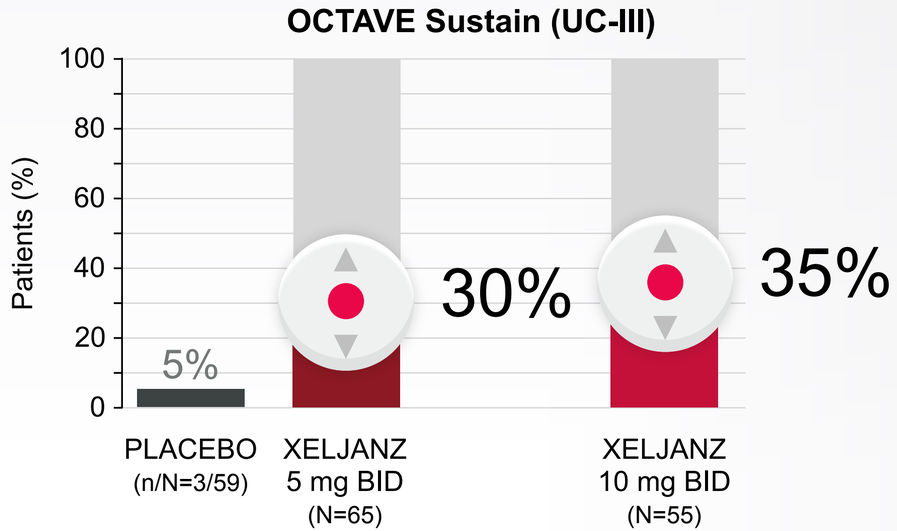
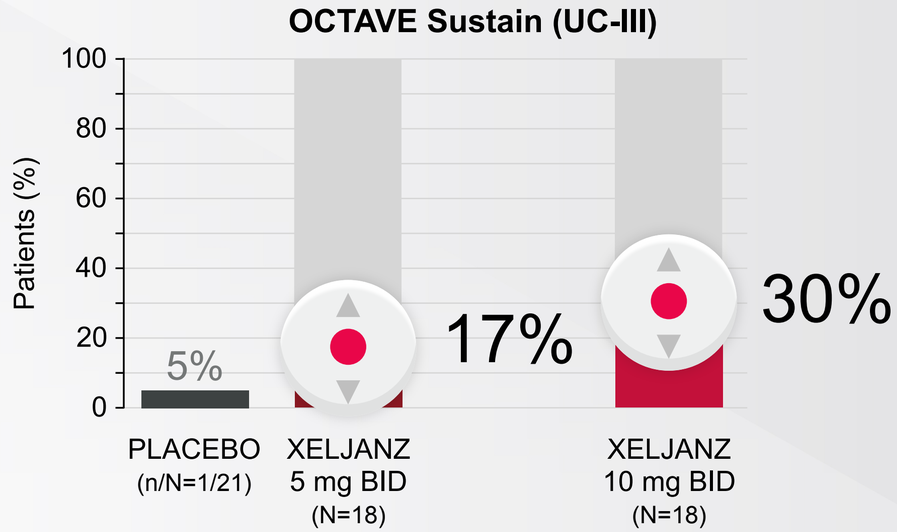


Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



- Sustained corticosteroid-free remission was defined as remission (a total Mayo score ≤2, with no individual subscore >1 **and** a rectal bleeding subscore of 0) and not taking corticosteroids for at least 4 weeks prior to the visit at both week 24 and week 52 among patients in remission at baseline[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.[1]

[a]Total population includes patients without prior TNF blocker failure.[1]

[b]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to a TNF blocker therapy.[1]

RESET

VIEW ANSWER

Help

Go to Safety

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

Patients treated with XELJANZ* are at increased risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants, such as methotrexate or corticosteroids.

If a serious infection develops, interrupt XELJANZ until the infection is controlled.

Reported infections include:

- **Active tuberculosis, which may present with pulmonary or extrapulmonary disease. Patients should be tested for latent tuberculosis before XELJANZ use and during therapy. Treatment for latent infection should be initiated prior to XELJANZ use.**
- **Invasive fungal infections, including cryptococcosis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, including herpes zoster, and other infections due to opportunistic pathogens.**

The most common serious infections reported with XELJANZ included pneumonia, cellulitis, herpes zoster, urinary tract infection, diverticulitis, and appendicitis. Avoid use of XELJANZ in patients with an active, serious infection, including localized infections.

In the UC population, XELJANZ 10 mg twice daily was associated with greater risk of serious infections compared to 5 mg twice daily. Opportunistic herpes zoster infections (including meningoencephalitis, ophthalmologic, and disseminated cutaneous) were seen in patients who were treated with XELJANZ 10 mg

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Q1 | Q2 | Q3 | Q4 | Q5 | Q6

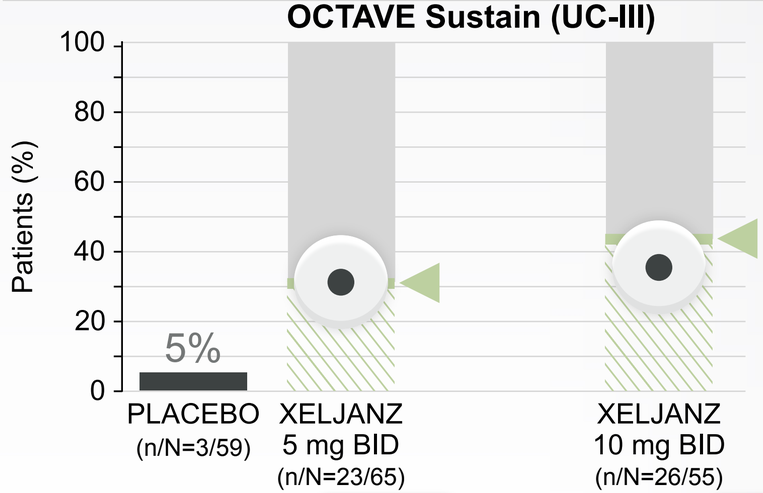
0 Efficacy Questions Remaining

The OCTAVE clinical program included a 52-week maintenance study, OCTAVE Sustain (UC-III), of 593 patients who completed the induction trials (UC-I or UC-II) and achieved clinical response. These patients were re-randomized to XELJANZ 5 mg twice daily, XELJANZ 10 mg twice daily, or placebo (1:1:1 ratio).

In OCTAVE Sustain (UC-III), what percentage of the total patient population[a] and the subgroup of patients with prior TNF blocker inadequate response or intolerance had sustained corticosteroid-free remission through week 52?[1-3]

Drag the slider to select your answer

Total Patient Population[a] (Key Secondary Endpoint)[1,2]



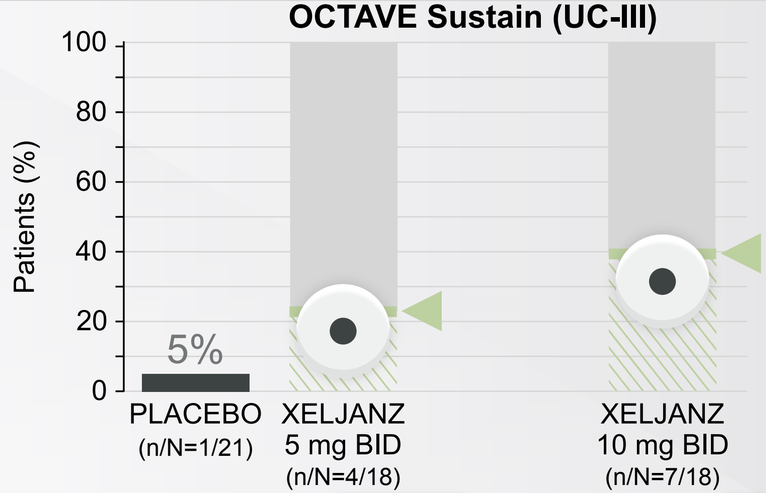
Correct answer: 35 *** %

Your answer: 30

Correct answer: 47 *** %

Your answer: 35

Percentage of Patients in Remission at Week 52 With Prior TNF Blocker Failure (Subgroup Population)[1,2,b]



Correct answer: 22 %

Your answer: 17

Correct answer: 39 %

Your answer: 30

- Sustained corticosteroid-free remission was defined as remission (a total Mayo score ≤2, with no individual subscore >1 **and** a rectal bleeding subscore of 0) and not taking corticosteroids for at least 4 weeks prior to the visit at both week 24 and week 52 among patients in remission at baseline[1]

XELJANZ is approved for use in patients with inadequate response or intolerance to TNF blockers.[1]

***P<0.0001

[a]Total population includes patients without prior TNF blocker failure.[1]

[b]Prior TNF blocker failure was defined as inadequate response, loss of response, or intolerance to a TNF blocker therapy.[1]

ADDITIONAL INFORMATION

Help

Go to Safety

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

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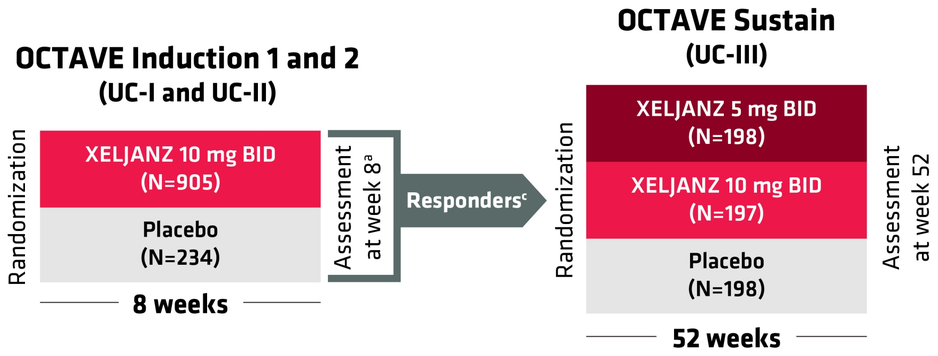
OCTAVE Sustain (UC-III) Clinical Trial Design[1-3]



Key eligibility criteria[1,3,b]

Response at week 8 of OCTAVE Induction trials

Tapering of corticosteroids was required at baseline of OCTAVE Sustain
Stable-dose corticosteroid use was allowed during induction

Primary endpoint[1]

Remission at week 52
Definition: Total Mayo score ≤2
No individual Mayo subscore >1
Mayo rectal bleeding subscore of 0

Key secondary endpoints[1]

Improvement of endoscopic appearance of the mucosa at week 52
Definition: Mayo endoscopic subscore ≤1

Sustained corticosteroid-free remission
Definition: Remission at BL and weeks 24 and 52, and no corticosteroids for ≥4 weeks prior to weeks 24 and 52

[a]The total number of patients does not include those who received XELJANZ 15 mg BID (n=22).[3] **XELJANZ 15 mg twice daily is not an approved dose.**[1]
[b]Key eligibility criteria regarding use of concomitant medications from OCTAVE Induction studies were retained in OCTAVE Sustain except for corticosteroid use.
[c]Total Mayo score decrease ≥3 points and ≥30% from baseline, plus Mayo rectal bleeding subscore decrease ≥1 point from baseline or absolute score ≤1.

COMPLETE

IMPORTANT SAFETY INFORMATION

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UC EFFICACY QUESTION 6 – Correct Answer

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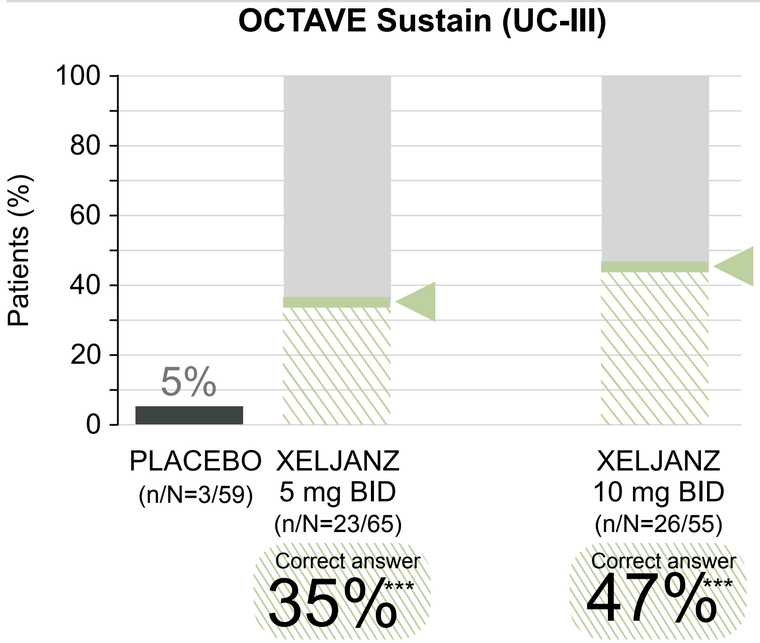

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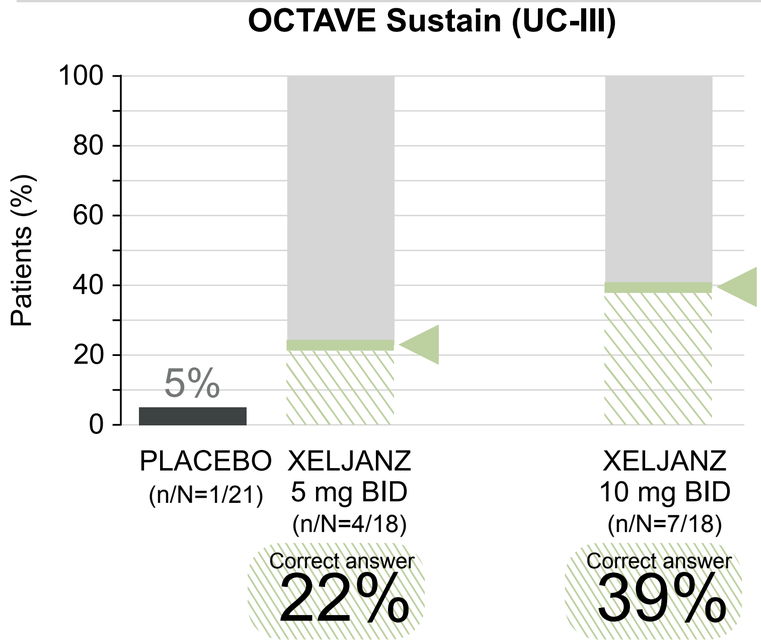

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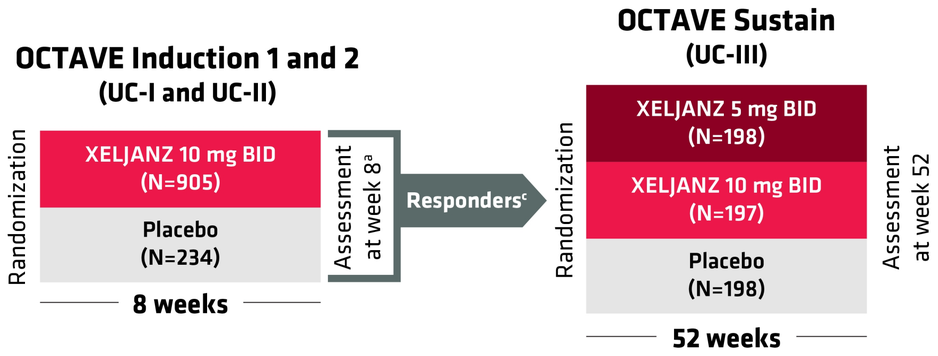
UC EFFICACY QUESTION 6 – Additional Information

OCTAVE Sustain (UC-III) Clinical Trial Design[1-3]



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CLOSE

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You have successfully tested your knowledge of select XELJANZ UC Efficacy Data!

Now, let's test your knowledge of select **XELJANZ Safety Data**.

START

IMPORTANT SAFETY INFORMATION

SERIOUS INFECTIONS

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