

# **Disease Clearance: A Comprehensive Treatment Target in UC**

Presented by Dr. David T. Rubin

Storyboard



# Final Storyboard

This storyboard presents (as relevant):

- Indication of visuals in the video
- The transcript indicated at the top of each slide
- Timecode indicated at the top of each slide
- Accessibility language describing the video and animations indicated in a text box at the bottom of each slide; including text on screen

# Final Storyboard

[00:00-00:07]

**Disease Clearance:  
A Comprehensive Treatment Target in UC**  
*Dr. David T. Rubin*

## **Visual description/accessibility transcript:**

Background music plays as title “Disease Clearance: A Comprehensive Treatment Target in UC” appears onscreen.

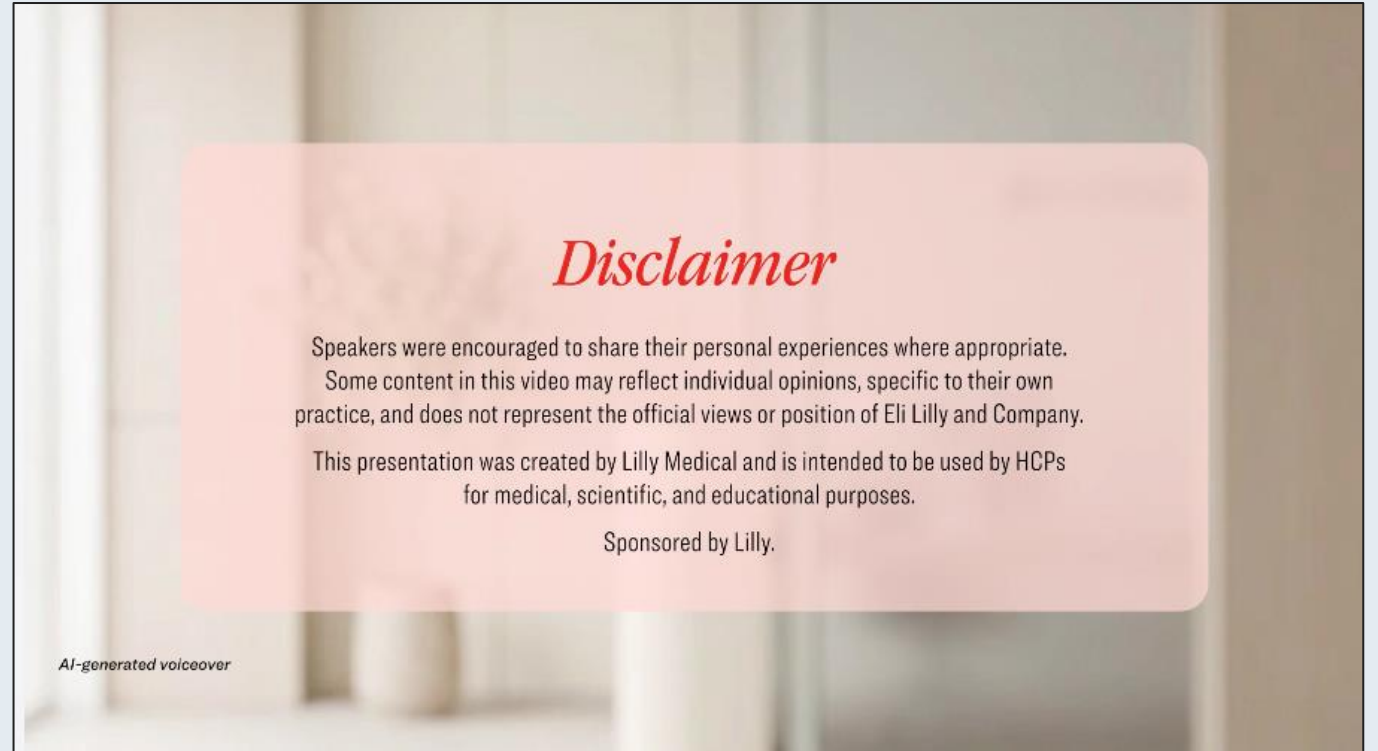
# Final Storyboard

[00:07-00:33]

## AI voiceover transcript:

Speakers were encouraged to share their personal experiences where appropriate. Some content in this video may reflect individual opinions, specific to their own practice, and does not represent the official views or position of Eli Lilly and Company

This presentation was created by Lilly Medical and is intended to be used by HCPs for medical, scientific, and educational purposes. Sponsored by Lilly Medical.



## Visual description/accessibility transcript:

Background music plays as disclaimer appears, stating: Speakers were encouraged to share their personal experiences where appropriate. Some content in this video may reflect individual opinions, specific to their own practice, and does not represent the official views or position of Eli Lilly and Company. This presentation was commissioned by Lilly Medical and is intended for use by healthcare professionals (HCPs) for medical, scientific, and educational purposes. Sponsored by Lilly Medical. Background music fades.

# Final Storyboard

[00:33-00:39]

**Speaker transcript:**

My name is Doctor David Rubin. I'm a professor of medicine at the University of Chicago.



**Visual description/accessibility transcript:**

Doctor Rubin appears on screen speaking to the camera. Affiliations: Joseph B. Kirsner Professor of Medicine; Chief, Section of Gastroenterology, Hepatology and Nutrition; Director, Inflammatory Bowel Disease Center; University of Chicago Medicine.

# Final Storyboard

[00:39-00:44]

## AI voiceover transcript:

Doctor. Rubin is speaking on behalf of Lilly.



## Visual description/accessibility transcript:

Doctor Rubin's disclosures are shown: Professor Rubin is a consultant for Lilly and is also a consultant for: AbbVie, Abivax, AltruBio, Athos Therapeutics, Bristol Myers Squibb, Celltrion, Connect BioPharma, Genentech (Roche), Iterative Health, Janssen Pharmaceuticals, Johnson & Johnson, Merck & Company, Mirador, Odyssey Therapeutics, Pfizer, Sanofi, Spyre, Takeda, Vedanta Biosciences, and Ventyx Biosciences. He has investigator-initiated research grants from Pfizer and Takeda. Content accurate as of May 2026.

# Final Storyboard

[00:44-00:47]

**Speaker transcript:**

In ulcerative colitis, specifically...



In ulcerative colitis, specifically,

**Visual description/accessibility transcript:**

Doctor Rubin speaks to the camera.

# Final Storyboard

[00:47-00:54]

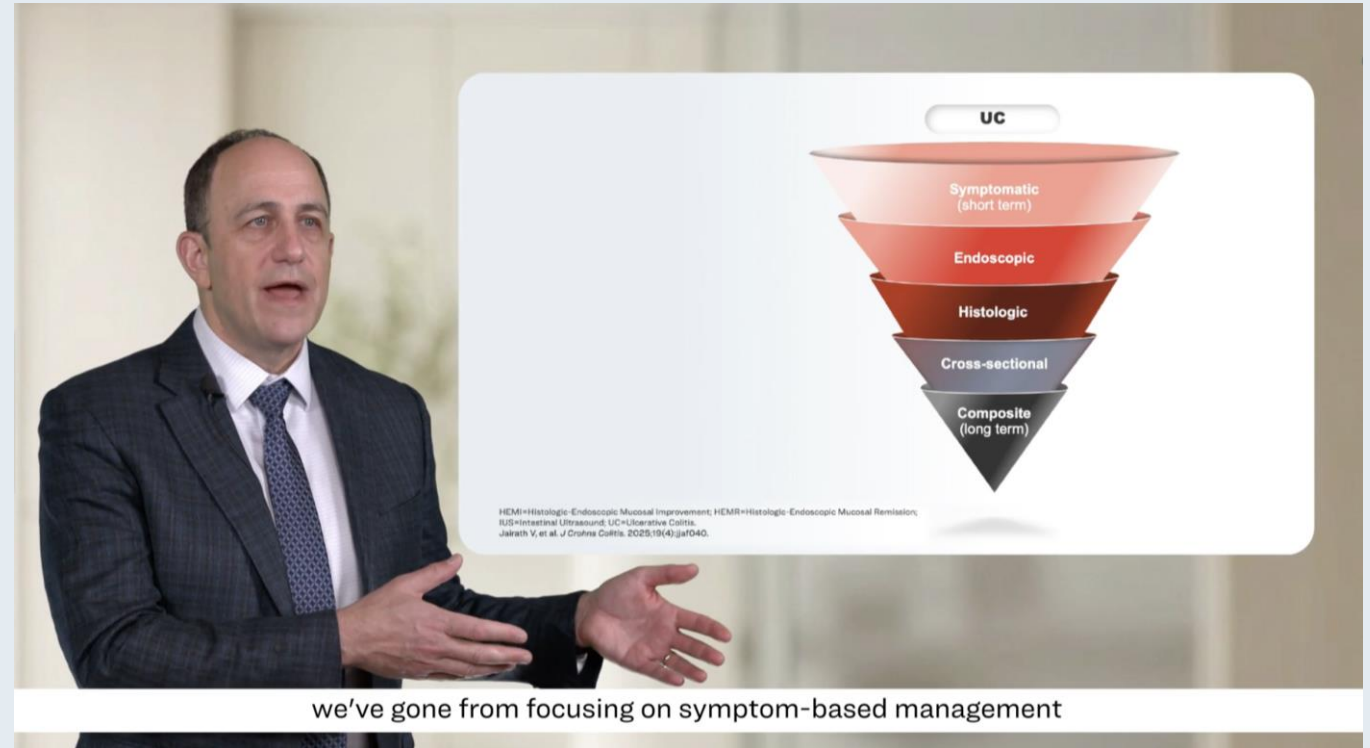
## Speaker transcript:

...we've gone from focusing on symptom-based management to recognizing the importance of endoscopic healing...<sup>1</sup>

## Reference(s):

Script and animation:

1. Jairath V, et al. *J Crohns Colitis*. 2025;19(4):jjaf040.



## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Graphic summarizing treatment targets in ulcerative colitis, including symptomatic (short-term), endoscopic, histologic, cross-sectional, and composite (long-term) outcomes.

# Final Storyboard

[00:54-01:03]

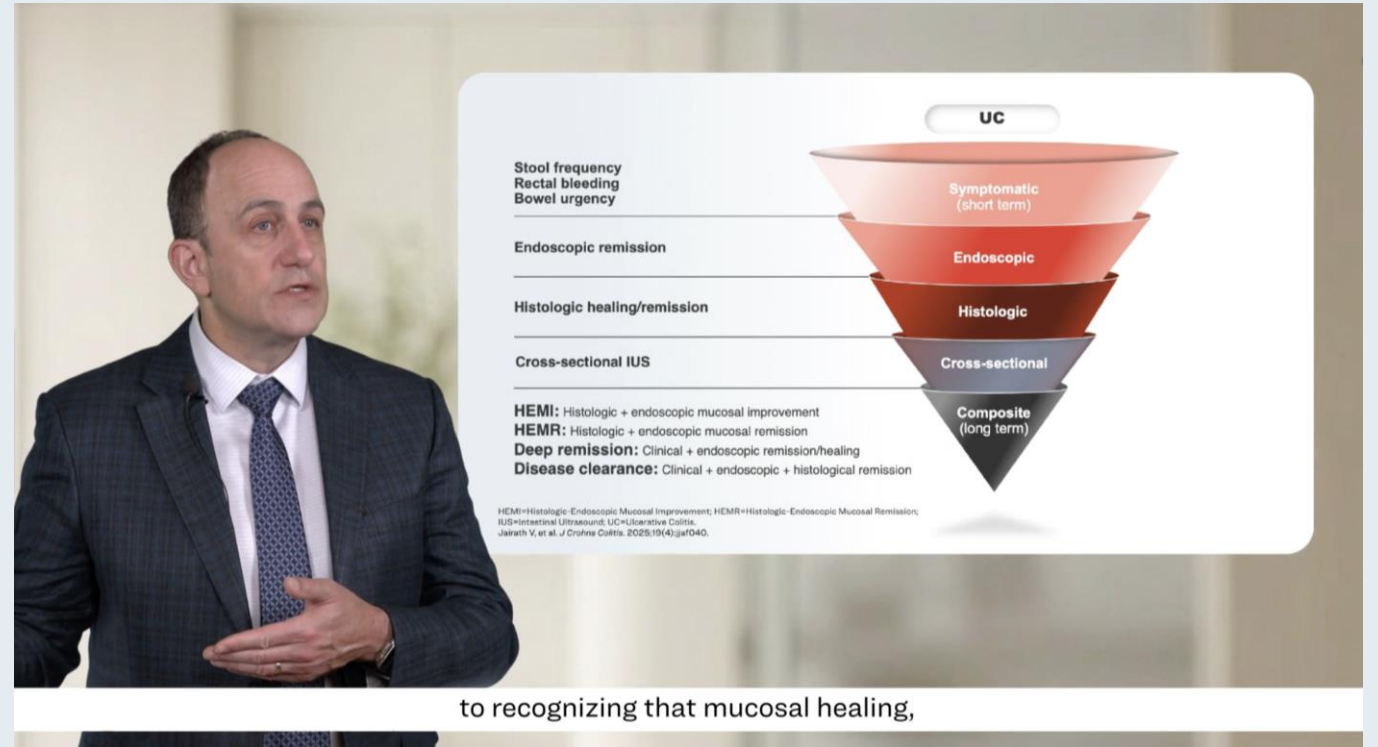
## Speaker transcript:

...to recognizing that mucosal healing, which may include histology, actually adds another level of depth and predictability to all of this...<sup>1</sup>

## Reference(s):

Script and animation:

1. Jairath V, et al. *J Crohns Colitis*. 2025;19(4):jjaf040.



to recognizing that mucosal healing,

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Graphic summarizing treatment targets remains on screen. Additional details appear alongside. 1. Example of symptomatic targets, including stool frequency, rectal bleeding, and bowel urgency; 2. Endoscopic remission; 3. Histologic healing/remission; 4. Cross-sectional intestinal ultrasound; 5. List of composite outcomes, including HEMI, HEMR, deep remission, and disease clearance.

# Final Storyboard

[01:03-01:15]

## Speaker transcript:

...and, increasingly, combining symptoms with endoscopy and histology, to something that we're now calling disease clearance, may in fact provide even better outcomes.<sup>1</sup>

## Reference(s):

Script and animation:

1. Jairath V, et al. *J Crohns Colitis*. 2025;19(4):jjaf040.

UC

Stool frequency  
Rectal bleeding  
Bowel urgency

Symptomatic  
(short term)

Endoscopic remission

Endoscopic

Histologic healing/remission

Histologic

Cross-sectional IUS

Cross-sectional

Composite  
(long term)

**HEMI:** Histologic + endoscopic mucosal improvement  
**HEMR:** Histologic + endoscopic mucosal remission  
**Deep remission:** Clinical + endoscopic remission/healing  
**Disease clearance:** Clinical + endoscopic + histological remission

HEMI=Histologic-Endoscopic Mucosal Improvement; HEMR=Histologic-Endoscopic Mucosal Remission;  
IUS=Intestinal Ultrasound; UC=Ulcerative Colitis.  
Jairath V, et al. *J Crohns Colitis*. 2025;19(4):jjaf040.

And, increasingly, combining symptoms

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Graphic summarizing treatment targets remains on screen; composite outcomes are highlighted and defined: HEMI=histologic plus endoscopic mucosal improvement; HEMR=histologic plus endoscopic mucosal remission; Deep remission=clinical plus endoscopic remission/healing; Disease clearance=clinical plus endoscopic plus histologic remission.

# Final Storyboard

[01:15-01:30]

## Speaker transcript:

As we've treated people beyond symptoms to deeper levels of disease control, we've been able to show that that correlates with stability over time and, increasingly, we've learned that that changes natural history of the disease.<sup>1</sup>

## Reference(s):

Script:

1. Danese S, et al. *United European Gastroenterol J.* 2025;13(6):902-910.



As we've treated people beyond symptoms

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

# Final Storyboard

[01:30-02:15]

## Speaker transcript:

You can combine symptoms, endoscopy, and histology in some of these analyses, and this was done with the mirikizumab data and the mirikizumab study in ulcerative colitis all the way out to 4 years.<sup>1,2</sup> And so what we've called disease clearance in these analyses means the patients in symptomatic remission, in endoscopic remission, and histologic remission.<sup>2</sup> And when you combine all of this to what we would think would be the patient doing as well as we could hope, they do extremely well the longer you follow them out.<sup>3</sup> The loss of response that we've described and that we know is a feature of many of our therapies, and it's a consequence of these conditions, seems to be better controlled the deeper the endpoint we get.<sup>3</sup>

## Reference(s):

Script and animation:

1. Data on file, Eli Lilly and Company.
2. Magro F, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.157.
3. Speaker's professional opinion



Ulcerative Colitis  
**Mirikizumab:**  
**Disease Clearance Over 4 Years**

Year	Response Rate (%)	Nx
Year 1 <sup>1</sup>	75.6	164
Year 2 <sup>1</sup>	70.7	133
Year 3 <sup>1</sup>	74.0	123
Year 4 <sup>1</sup>	65.6	90

**Disease Clearance, OC<sup>2</sup>**  
Symptomatic remission (SF=0 or 1 with ≥1-point decrease from baseline, RB=0)  
+ Endoscopic improvement (ES=0 or 1)  
+ Histologic remission (Geboes score ≤2B.0)

**No published data for other IL-23p19 inhibitors available**

Note: Disease clearance data are in Week 52 LUCENT-2 maintenance remitters and are reported as OC.  
ES=Endoscopic Subscore; IL=Interleukin; MIR=Mirikizumab; OC=Observed Case; Nx=Number of Patients With Nonmissing Values; Q4W=Every 4 Weeks; RB=Rectal Bleeding Subscore; SD=Subcutaneous; SF=Stool Frequency Score. 1. Data on file, Eli Lilly and Company. 2. Magro F, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.157.

You can combine symptoms,

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Line graph showing disease clearance response rate with mirikizumab at Year 1 (75.6%), Year 2 (70.7%), Year 3 (74%), and Year 4 (65.6%). Data reported as observed case in Week 52 LUCENT-2 maintenance remitters. Disease clearance defined as: Symptomatic remission (SF=0 or 1 with ≥1-point decrease from baseline, RB=0); endoscopic improvement (ES=0 or 1); histologic remission (Geboes score ≤2B.0). A banner states that no published data for other IL-23p19 inhibitors are available.

# Final Storyboard

[02:15-02:46]

## Speaker transcript:

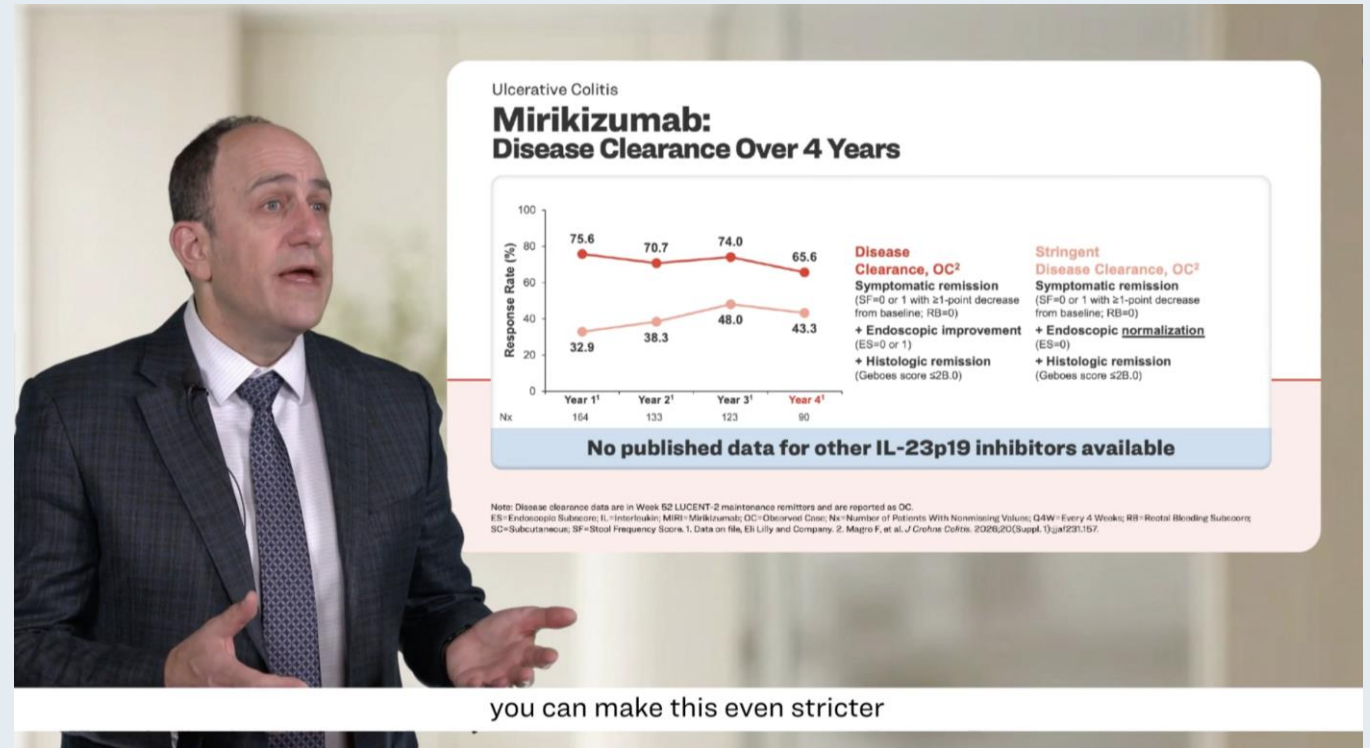
Furthermore, you can make this even stricter if you define disease clearance by a stringent definition, which means both symptomatic remission, endoscopic normalization, which here would be a Mayo endoscopic score of 0, and histologic remission with the same definition.<sup>2</sup> You see that over time, not only does it remain stable, but it even increases a bit over the years.<sup>1</sup>

We're looking forward to other data with other drugs and other studies. But for now, this is all we have and it's with mirikizumab.<sup>3</sup> But for now, this is all we have and it's with mirikizumab.<sup>3</sup>

## Reference(s):

Script and animation:

1. Data on file, Eli Lilly and Company.
2. Magro F, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.157.
3. Speaker's professional opinion.



you can make this even stricter

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Line graph showing disease clearance over 4 years remains on screen. A second line is added with data for stringent disease clearance at Year 1 (32.9%), Year 2 (38.3%), Year 3 (48%), and Year 4 (43.3%). Stringent disease clearance defined as: Symptomatic remission (SF=0 or 1 with  $\geq 1$ -point decrease from baseline, RB=0); endoscopic normalization (ES=0); histologic remission (Geboes score  $\leq 2B.0$ ).

# Final Storyboard

[02:46-03:01]

## Speaker transcript:

The way I translate this in clinical practice is I say to my patients who are doing really well that “the longer they're in remission, the better they're going to feel in general, because their body will adjust to being healthy again.” I think that's really important.<sup>1</sup>

## Reference(s):

Script:

1. Speaker's professional opinion.



## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

# Final Storyboard

[03:01-03:34]

## Speaker transcript:

So, one of the messages for you when you take care of a patient with ulcerative colitis, is to acknowledge that symptom improvement is directly related to improved quality of life.<sup>1,2</sup> But disease management means that you're pairing symptom improvement with objective measures, like endoscopy and increasingly histology, as ways to know that you're controlling the disease process, which will predict stability of those symptom improvements.<sup>2</sup> And what we hope, and we expect, long-term disease modification.<sup>2</sup>

## Reference(s):

Script:

1. D'Amico F, et al. *United European Gastroenterol J.* 2022;10(7):775-782.
2. Danese S, et al. *United European Gastroenterol J.* 2025;13(6):902-910.

Animation:

1. D'Amico F, et al. *United European Gastroenterol J.* 2022;10(7):775-782.



	0	1	2	3	4	5	6
Achieved	109	96	75	49	30	15	2
Not Achieved	385	297	178	91	55	26	9

So, one of the messages for you

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Graphic showing components of disease clearance: Symptomatic remission, endoscopic remission, histologic remission. To the right, a Kaplan-Meier graph shows the probability of remaining free from negative outcomes (such as escalation of therapy, UC-related hospitalization/surgery) over 6 years. Separate curves show patients achieving disease clearance have a higher probability of remaining free from negative outcomes versus patient not achieving disease clearance.

# Final Storyboard

[03:34-03:46]

## Speaker transcript:

What we see across the class of these therapies is a very nice safety profile.<sup>1</sup> This is in part due to what we've come to understand regarding the immunology of interleukin-23 inhibition.<sup>1</sup>

## Reference(s):

Script:

1. Speaker's professional opinion.



## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

# Final Storyboard

[03:46-03:53]

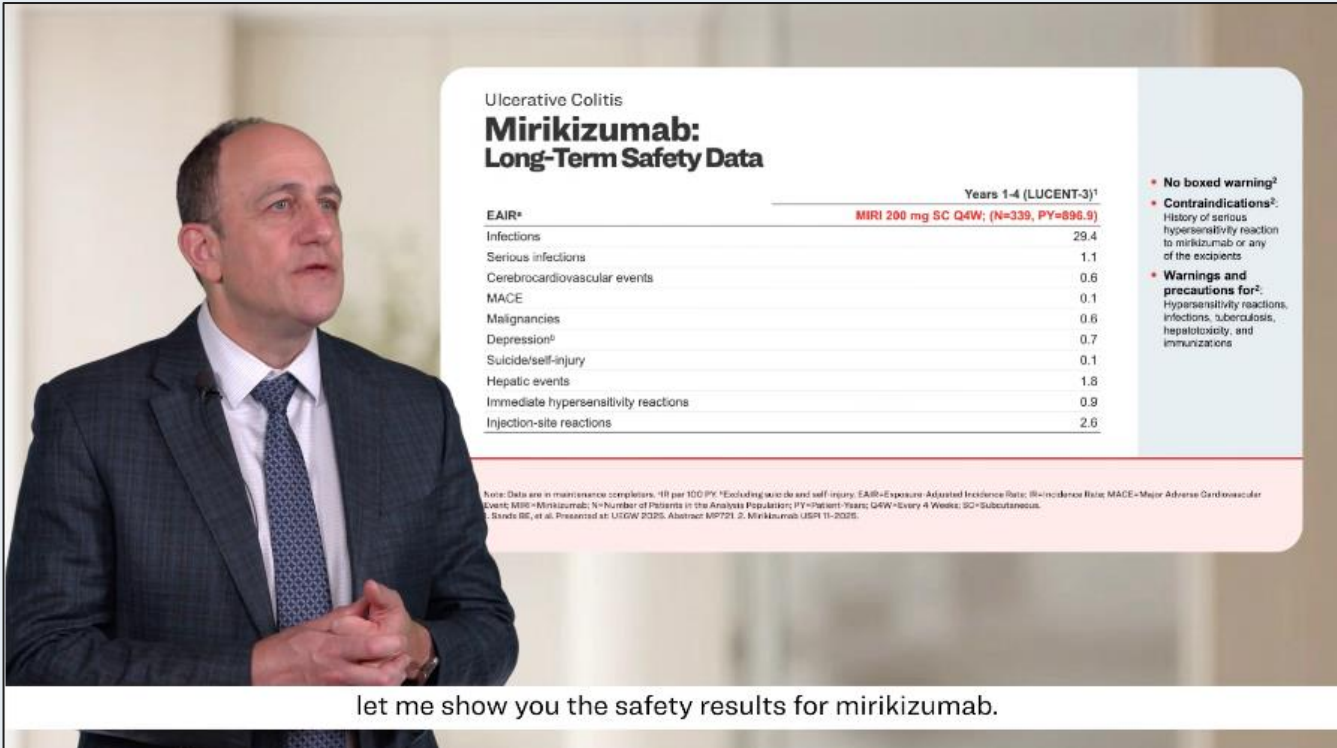
## Speaker transcript:

More specifically, let me show you the safety results for mirikizumab.<sup>1,2</sup>

## Reference(s):

Script and animation:

1. Sands BE, et al. Presented at: UEGW 2025. Abstract MP721.
2. Mirikizumab USPI 11-2025.



The storyboard frame shows a man in a suit speaking to the camera. An on-screen figure displays safety data for mirikizumab in ulcerative colitis patients. The figure includes a table of adverse events and their incidence rates, along with a list of warnings and contraindications.

EAIR*	Years 1-4 (LUCENT-3) <sup>1</sup>
Infections	29.4
Serious infections	1.1
Cerebrocardiovascular events	0.6
MACE	0.1
Malignancies	0.6
Depression <sup>b</sup>	0.7
Suicide/self-injury	0.1
Hepatic events	1.8
Immediate hypersensitivity reactions	0.9
Injection-site reactions	2.6

**EAIR\*** MIRI 200 mg SC Q4W; (N=339, PY=896.9)

- **No boxed warning<sup>2</sup>**
- **Contraindications<sup>2</sup>:** History of serious hypersensitivity reaction to mirikizumab or any of the excipients
- **Warnings and precautions for<sup>2</sup>:** Hypersensitivity reactions, infections, tuberculosis, hepatotoxicity, and immunizations

Note: Data are in maintenance completers. \*IR per 100 PY. <sup>1</sup>Excluding suicide and self-injury. EAIR=Exposure-Adjusted Incidence Rate; IR=Incidence Rate; MACE=Major Adverse Cardiovascular Events; MIRI=Mirikizumab; N=Number of Patients in the Analysis Population; PY=Patient-Years; Q4W=Every 4 Weeks; SC=Subcutaneous.  
Sands BE, et al. Presented at: UEGW 2025. Abstract MP721. 2. Mirikizumab USPI 11-2025.

let me show you the safety results for mirikizumab.

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Table of long-term mirikizumab safety data from Years 1-4 of LUCENT-3.

Analysis includes 339 patients with 896.9 patient-years of exposure. Exposure-adjusted incidence rates (incidence rate per 100 patient years) are shown for: Infections (29.4); serious infections (1.1); cerebrocardiovascular events (0.6); major adverse cardiovascular event (0.1); malignancies (0.6); depression (excluding suicide and self-injury) (0.7); suicide/self-injury (0.1); hepatic events (1.8); immediate hypersensitivity reactions (0.9); injection-site reactions (2.6).

Data are in maintenance completers.

# Final Storyboard

[03:53-03:59]

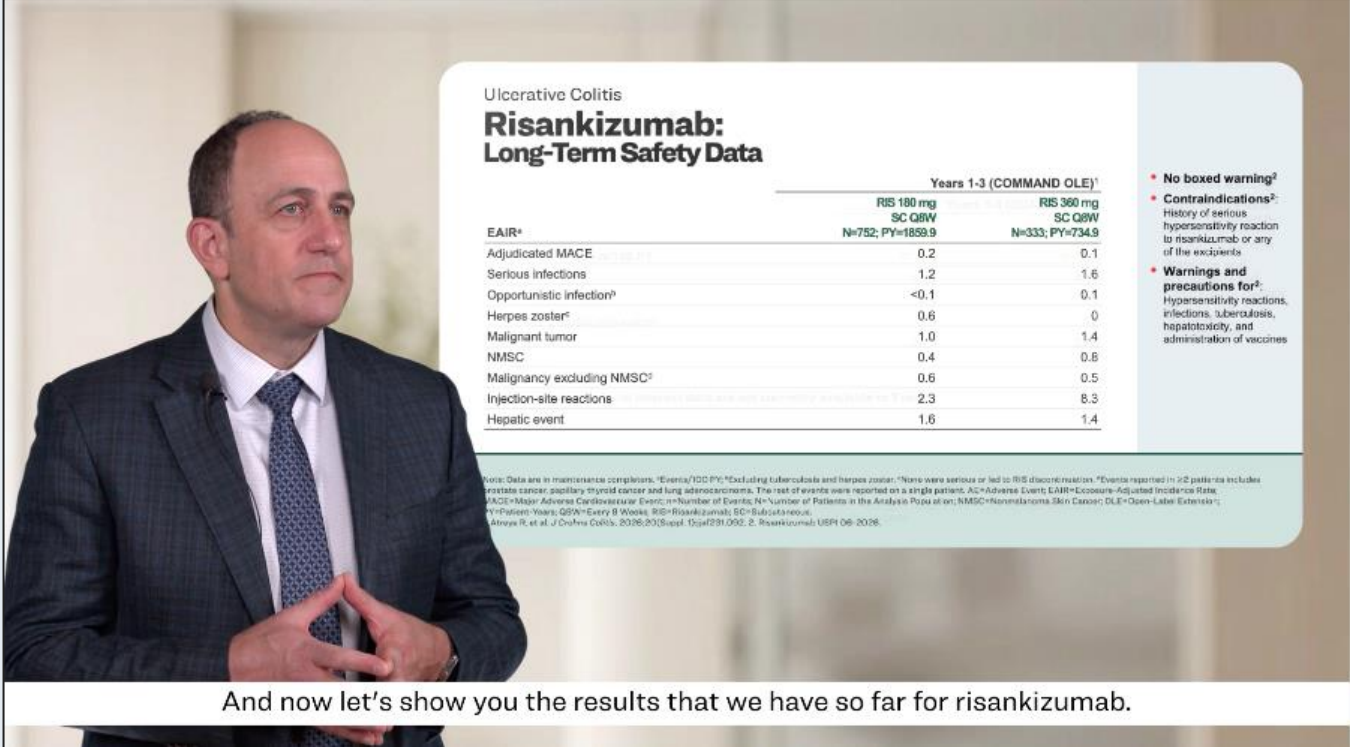
## Speaker transcript:

And now let's show you the results that we have so far for risankizumab.<sup>1,2</sup>

## Reference(s):

Script and animation:

1. Atreya R, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.092.
2. Risankizumab 06-2026.



Ulcerative Colitis  
**Risankizumab:  
Long-Term Safety Data**

	Years 1-3 (COMMAND OLE) <sup>1</sup>	
	RIS 180 mg SC Q8W N=752; PY=1859.9	RIS 360 mg SC Q8W N=333; PY=734.9
EAIR <sup>a</sup>		
Adjudicated MACE	0.2	0.1
Serious infections	1.2	1.6
Opportunistic infection <sup>b</sup>	<0.1	0.1
Herpes zoster <sup>c</sup>	0.6	0
Malignant tumor	1.0	1.4
NMSC	0.4	0.8
Malignancy excluding NMSC <sup>d</sup>	0.6	0.5
Injection-site reactions	2.3	8.3
Hepatic event	1.6	1.4

**\* No boxed warning<sup>2</sup>**  
**\* Contraindications<sup>2</sup>:** History of serious hypersensitivity reaction to risankizumab or any of the excipients  
**\* Warnings and precautions for<sup>2</sup>:** Hypersensitivity reactions, infections, tuberculosis, hepatotoxicity, and administration of vaccines

Footnote: Data are in maintenance completers. <sup>a</sup>Events/100 PY; <sup>b</sup>Excluding tuberculosis and herpes zoster; <sup>c</sup>None were serious or led to RIS discontinuation; <sup>d</sup>Events reported in ≥2 patients includes prostate cancer, papillary thyroid cancer and lung adenocarcinoma. The rest of events were reported on a single patient. AC=Adverse Event; EAIR=Exposure-Adjusted Incidence Rate; MACE=Major Adverse Cardiovascular Event; N=Number of Patients in the Analysis; PY=Patient-Years; Q8W=Every 8 Weeks; RIS=Risankizumab; SC=Subcutaneous; Atreya R, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.092. 2. Risankizumab; USP 06-2026.

And now let's show you the results that we have so far for risankizumab.

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Table of long-term risankizumab safety data from Years 1-3 of COMMAND OLE. Analysis includes 752 patients who received 180 mg (1859.9 patient-years of exposure), and 333 who received 360 mg (734.9 patient-years of exposure). Exposure-adjusted incidence rates (events per 100 patient years) are shown for: adjusted major adverse cardiovascular event (0.2 and 0.1); serious infections (1.2 and 1.6); opportunistic infection (excluding tuberculosis and herpes zoster) (<0.1 and 0.1); herpes zoster (none were serious or led to risankizumab discontinuation) (0.6 and 0); malignant tumor (1.0 and 1.4); nonmelanoma skin cancer (0.4 and 0.8); malignancy excluding nonmelanoma skin cancer (events reported in ≥2 patients includes prostate cancer, papillary thyroid cancer, and lung adenocarcinoma) (0.6 and 0.5); injection-site reactions (2.3 and 8.3); hepatic event (1.6 and 1.4). Data are in maintenance completers.

# Final Storyboard

[03:59-04:04]

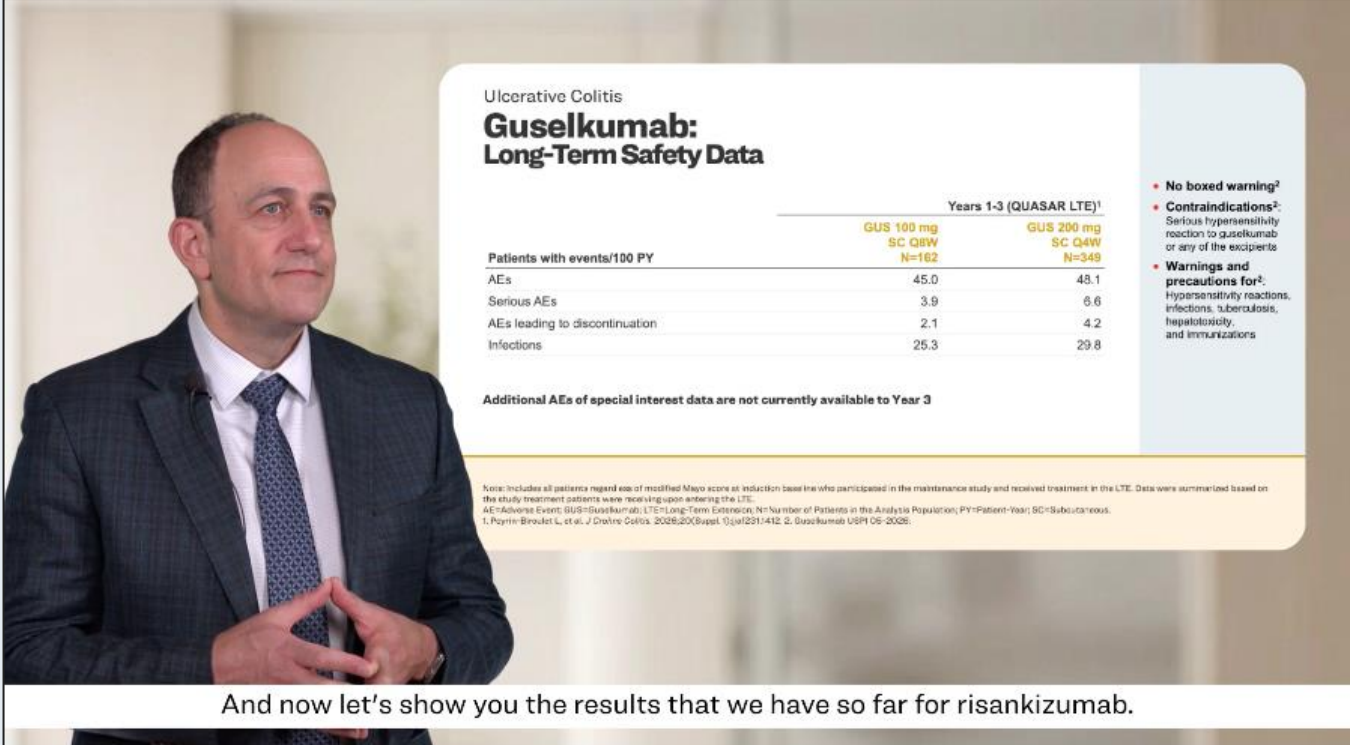
## Speaker transcript:

And now here are the results for guselkumab.<sup>1,2</sup>

## Reference(s):

Script and animation:

1. Peyrin-Biroulet L, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.1412.
2. Guselkumab USPI 05-2026.



Ulcerative Colitis  
**Guselkumab:  
Long-Term Safety Data**

	Years 1-3 (QUASAR LTE) <sup>1</sup>	
	GUS 100 mg SC Q8W N=162	GUS 200 mg SC Q4W N=349
Patients with events/100 PY		
AEs	45.0	48.1
Serious AEs	3.9	6.6
AEs leading to discontinuation	2.1	4.2
Infections	25.3	29.8

Additional AEs of special interest data are not currently available to Year 3

- **No boxed warning<sup>2</sup>**
- **Contraindications<sup>2</sup>:** Serious hypersensitivity reaction to guselkumab or any of the excipients
- **Warnings and precautions for<sup>2</sup>:** Hypersensitivity reactions, infections, tuberculosis, hepatotoxicity, and immunizations

Note: Includes all patients regardless of modified Mayo score at induction baseline who participated in the maintenance study and received treatment in the LTE. Data were summarized based on the study treatment patients were receiving upon entering the LTE.  
AE=Adverse Event; GUS=Guselkumab; LTE=Long-Term Extension; N=Number of Patients in the Analysis Population; PY=Patient-Year; SC=Subcutaneous.  
1. Peyrin-Biroulet L, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.1412. 2. Guselkumab USPI 05-2026.

And now let's show you the results that we have so far for risankizumab.

## Visual description/accessibility transcript:

Doctor Rubin speaks to the camera.

On-screen figure: Table of long-term guselkumab safety data from Years 1-3 of QUASAR LTE. Analysis includes 162 patients who received 100 mg, and 349 patients who received 200 mg. Number of patients with events/100 patient years are shown for: Adverse events (45.0 and 48.1); serious adverse events (3.9 and 6.6); adverse events leading to discontinuation (2.1 and 4.2); infections (25.3 and 29.8). Additional adverse events of special interest data are not currently available to Year 3. Data include all patients regardless of modified Mayo score at induction baseline who participated in the maintenance study and received treatment in the long-term extension. Data were summarized based on what the study treatment patients were receiving upon entering the long-term extension.

# Final Storyboard

[04:04-04:11]

**Speaker transcript:**

And as you can appreciate these three therapies in their long-term follow-up look very similar in their overall safety profile.<sup>1</sup>

**Reference(s):**

Script:

1. Speaker's professional opinion.



**Visual description/accessibility transcript:**

Doctor Rubin speaks to the camera.

# Final Storyboard

[04:11-04:18]

## *References*

Atreya R, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.092.  
D'Amico F, et al. *United European Gastroenterol J*. 2022;10(7):775-782.  
Data on file, Eli Lilly and Company.  
Guselkumab USPI 05-2026.  
Jairath V, et al. *J Crohns Colitis*. 2025;19(4):jjaf040.  
Magro F, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.157.  
Mirikizumab USPI 11-2025.  
Peyrin-Biroulet L, et al. *J Crohns Colitis*. 2026;20(Suppl. 1):jjaf231.412.  
Risankizumab USPI 06-2026.  
Sands BE, et al. Presented at: UEGW 2025. Abstract MP721.

Screen transitions to show the reference list and music starts to play.

# Final Storyboard

[04:18-04:23]

## *US Full Prescribing Information*



Risankizumab-rzaa



Guselkumab



Mirikizumab-mrkz

Screen transitions to QR codes to the US prescribing information for risankizumab, guselkumab, and mirikizumab. Music continues to play.

# Final Storyboard

[04:23-04:28]



Lilly logo appears and music fades.