Transcript Details
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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

Long-Term Efficacy and Safety Data in Ulcerative Colitis

Dr. Cohen:
Hi. My name is Erica Cohen. I'm a gastroenterologist at Capital Digestive Care℠ in Chevy Chase, Maryland, and my focus is on management of Crohn's disease and ulcerative colitis.

In my clinical practice, treatment decisions are guided by the patient's needs at every stage of their journey. For patients with moderate to severe ulcerative colitis, or UC, achieving and maintaining long-term remission is a key treatment goal.

In this video, we'll review Omvoh's 4-year clinical data in UC and explore how Omvoh may be able to help patients reach their long-term treatment goals.

Let's start by reviewing Omvoh's indications and contraindications.

Omvoh is an interleukin-23 antagonist indicated for adults with moderately to severely active ulcerative colitis, or UC, or moderately to severely active Crohn's disease, or CD.[1]

It is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

This is not the complete Important Safety Information for Omvoh, so please see additional Important Safety Information at the end of this video.

Onscreen Text:
INDICATIONS[1]

Omvoh is an interleukin-23 antagonist indicated for adults with:

- moderately to severely active ulcerative colitis
- moderately to severely active Crohn's disease

CONTRAINDICATIONS

Omvoh is contraindicated in patients with a history of serious hypersensitivity reaction to mirikizumab-mrkz or any of the excipients.

This is not the complete Important Safety Information for Omvoh. Please see additional Important Safety Information at the end of this video.

Dr. Cohen:
Omvoh's efficacy and safety were evaluated in adults with moderately to severely active UC in the LUCENT trials.

LUCENT-1 was a double-blind, placebo-controlled induction study. Omvoh responders entered LUCENT-2 for maintenance and were re-randomized to Omvoh or placebo.

LUCENT-3 is the open-label extension trial in which adult patients who completed LUCENT-2 on Omvoh were assessed for long-term efficacy and those patients who received at least one dose of Omvoh from the LUCENT trial program were assessed for long-term safety.

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Onscreen Text:
The Efficacy and Safety of Omvoh Were Studied in Adult Patients With Moderately to Severely Active UC in the LUCENT Clinical Trials[1,2]

The schematic shows the induction, maintenance, and extension study designs.

UC-1 (LUCENT-1): Blinded Induction

Randomized 3:1

N=1279[a]

The two arms of the trial were Omvoh 300 mg IV (Week 0, 4 and 8) and placebo IV (Week 0, 4, and 8).

LUCENT-1 lasted from Week 0 to Week 12 of treatment.

Primary endpoint: clinical remission at Week 12

UC-2 (LUCENT-2): Blinded Maintenance

Responders from LUCENT-1 (Re-randomized 2:1)

N=581[a]

The two arms of the trial were Omvoh 200 mg SC Q4W and placebo SC Q4W.

Lucent 2 lasted from Week 12 to Week 52 (40 weeks).

Primary endpoint: clinical remission at Week 40

UC-3 (LUCENT-3): Single-arm, Open-label, Long-term Extension

Completers from LUCENT-2[b] (2nd interim analysis at Week 212)[b]

This was a single arm trial with Omvoh 200 mg SC Q4W.

LUCENT-3 lasted from Week 52 to Week 212 (160 weeks).

At baseline of LUCENT-1, all patients had inadequate response, loss of response, or intolerance to at least one corticosteroid, immunomodulator, biologic treatment (TNF blocker, vedolizumab), or tofacitinib.[1]

In LUCENT-2, patients who were on concomitant UC therapies during LUCENT-1 were required to continue on stable doses of oral aminosalicylates and immunomodulator agents. Corticosteroid tapering was required for patients who were receiving oral corticosteroids at baseline and achieved clinical response in LUCENT-1.[1,]

In LUCENT-3, adult patients who completed LUCENT-2 on Omvoh were assessed for long-term efficacy and adult patients who received at least one dose of Omvoh from the UC trial program were assessed for long-term safety.[2]

[a]Patients with a mMS of 5 to 9 at baseline in LUCENT-1 were included in the efficacy analyses of LUCENT-1 (N=1062) and LUCENT-2 (N=506).[1]

[b]The analysis was completed at Week 212 or after 4 years of continuous treatment with Omvoh.

IV=intravenous; mMS=modified Mayo Score; Q4W=every 4 weeks; SC=subcutaneous; TNF=tumor necrosis factor; UC=ulcerative colitis.

Dr. Cohen:
The LUCENT trials included adult patients who had been treated with a prior biologic treatment and those who were bio-naive.

Onscreen Text:
LUCENT-1 CLINICAL TRIAL: BASELINE CHARACTERISTICS

The Omvoh Trials Included Adult Patients Who Had Been Treated With a Prior Biologic[a] and Those Who Were Bio-naive[1]

AT BASELINE IN LUCENT-1[1] Patients had an mMS of 5 to 9, including a centrally read endoscopic subscore (ES) of 2 or 3 Patients had a median mMS of 7

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58% had severely active disease (mMS of 7 to 9)

BASELINE THERAPIES[1] 41% of patients were receiving oral corticosteroids

24% were receiving immunomodulators

75% were receiving aminosalicylates

PRIOR THERAPIES[1] 57% were biologic- and Janus kinase inhibitor (JAKi)- naïve

41% had failed at least one biologic (TNF blocker vedolizumab)

3% had failed a JAKi

2% had previously received but had not failed a biologic or JAKi

[a]Prior biologic or JAKi failure includes loss of response, inadequate response, or intolerance to one or more biology therapy (TNF blocker or vedolizumab), or tofacitinib

ES=endoscopic subscore ; JAKi=Janus kinase inhibitor ; mMS=modified Mayo score; TNF=tumor necrosis factor.

Dr. Cohen:
By Week 12 in LUCENT-1, patients on Omvoh showed meaningful improvements compared to placebo with 65% achieving clinical response and 24% achieving clinical remission.

Onscreen Text:
Short-term goals, Intermediate goals, Long-term goals

AMONG PATIENTS WITH MODERATE TO SEVERE UC

Nearly 2 in 3 Patients Taking Omvoh Achieved Clinical Response[a] at Week 12

Clinical response[a] (secondary endpoint):
65% for patients receiving Omvoh 300 mg IV Q4W (N=795)
43% for patients receiving placebo (N=267)
p<0.001

Clinical remission[b] (primary endpoint):
24% for patients receiving Omvoh 300 mg IV Q4W (N=795)
15% for patients receiving placebo (N=267)
p<0.001

The treatment differences between Omvoh and placebo groups were adjusted using Cochran-Mantel-Haenszel method that accounted for randomization stratification factors.

[a]Clinical response is defined as a decrease in the mMS of ≥2 points with ≥30% decrease from baseline, and either a decrease of ≥1 point in RB from baseline or RB=0 or 1.[1]

[b]Clinical remission based on mMS is defined as: SF=0 or 1, RB=0, and centrally read ES=0 or 1 (excluding friability).[1]
ES=endoscopic subscore; IV=intravenous; mMS=modified Mayo score; Q4W=every 4 weeks; RB=rectal bleeding; SC=subcutaneous; SF=stool frequency; UC=ulcerative colitis.

In LUCENT-2, improvements in clinical outcomes continued for those patients who achieved clinical response on Omvoh at Week 12.

At Week 52, 51% of patients on Omvoh achieved clinical remission, and 50% of patients on Omvoh were in corticosteroid-free remission.

Onscreen Text:
Short-term goals, **Intermediate goals**, Long-term goals

AMONG PATIENTS WHO ACHIEVED CLINICAL RESPONSE WITH OMVOH AT WEEK 12[1]

Omvoh Provided Sustained Clinical Remission Through Week 52[1]

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Clinical remission[a] (Primary endpoint)

51% for patients receiving Omvoh 200 mg SC Q4W (N=337)
27% for patients receiving placebo (N=169)
p<0.001

Corticosteroid-free remission (Secondary endpoint)
50% for patients receiving Omvoh 200 mg SC Q4W (N=337)
27% for patients receiving placebo (N=169)
p<0.001

Week 52 is defined as the 12-week induction study (LUCENT-1) plus the 40-week maintenance study (LUCENT-2) for 52 weeks of continuous treatment.[1]

The treatment differences between Omvoh and placebo groups were adjusted using Cochran-Mantel-Haenszel method that accounted for randomization identification factors.[1]

[a]Clinical remission based on mMS is defined as: SF=0 or 1, RB=0, and centrally read ES=0 or 1 (excluding friability).[1]
ES=endoscopic subscore; mMS=modified Mayo score; Q4W=every 4 weeks; RB=rectal bleeding; SC=subcutaneous; SF=stool frequency.

Dr. Cohen:
Omvoh also demonstrated endoscopic improvement and histologic-endoscopic mucosal improvement, or HEMI, at Week 52 with 58% and 43% of patients achieving endoscopic improvement and HEMI, respectively.

Onscreen Text:
Short-term goals, **Intermediate goals**, Long-term goals

AMONG PATIENTS WHO ACHIEVED CLINICAL RESPONSE WITH OMVOH AT WEEK 12[1]

Omvoh Demonstrated Endoscopic Improvement and HEMI at Week 52[1]

Endoscopic improvement[a]
58% for patients receiving Omvoh 200 mg SC Q4W (N=337)
30% for patients receiving placebo (N=169)
p<0.001

HEMI[b]
43% for patients receiving Omvoh 200 mg SC Q4W (N=337)
22% for patients receiving placebo (N=169)
p<0.001

Week 52 is defined as the 12-week induction study (LUCENT-1) plus the 40-week maintenance study (LUCENT-2) for 52 weeks of continuous treatment.[1]

The treatment differences between Omvoh and placebo groups were adjusted using Cochran-Mantel-Haenszel method that accounted for randomization identification factors.[1]

[a]Endoscopic improvement is defined as centrally read ES=0 or 1 (excluding friability).[1]

[b]HEMI is defined as achieving both endoscopic improvement (centrally read ES=0 or 1, excluding friability) and histologic improvement (no neutrophils in crypts or lamina propria, no crypt destruction, and no erosions, ulcerations, or granulation tissue based on the Geboes scoring system [Geboes score ≤2B.0]).[1,3]

ES=endoscopic subscore; HEMI=histologic-endoscopic mucosal improvement; Q4W=every 4 weeks, SC=subcutaneous.

Dr. Cohen:
Looking at subgroup data, bio-failed patients reached clinical and endoscopic goals with Omvoh at Week 52.

Specifically, 45% of bio-failed patients achieved clinical remission, and 50% achieved endoscopic improvement with Omvoh.

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In UC, Omvoh showed consistent efficacy regardless of biologic exposure.

Onscreen Text:
Short-term goals, **Intermediate goals**, Long-term goals

AMONG PATIENTS WHO ACHIEVED CLINICAL RESPONSE WITH OMVOH AT WEEK 12[1]

Bio-failed Patients Reached Clinical and Endoscopic Goals With Omvoh at Week 52[1]

Clinical remission[a]
Bio-naïve[c]
achieved clinical remission at Week 52

53% Omvoh 200 mg SC Q4W (N=208) vs 33% Placebo (N=109)

Bio-failed[c]
achieved clinical remission at Week 52

45% Omvoh 200 mg SC Q4W (N=121) vs 15% Placebo (N=59)

Endoscopic improvement[b]
Bio-naïve[c]
achieved endoscopic improvement at Week 52 62% Omvoh 200 mg SC Q4W (N=208) vs 35% Placebo (N=109)

Bio-failed[c]
achieved endoscopic improvement at Week 52 50% Omvoh 200 mg SC Q4W (N=121) vs 20% Placebo (N=59)

Prespecified subgroup analysis not controlled for multiplicity.

Week 52 is defined as the 12-week induction study (LUCENT-1) plus the 40-week maintenance study (LUCENT-2) for 52 weeks of continuous treatment.[1]

[a]Clinical remission based on mMS is defined as: SF=0 or 1, RB=0, and centrally read ES=0 or 1 (excluding friability).[1]

[b]Endoscopic improvement is defined as centrally read ES=0 or 1 (excluding friability).[1]

[c]Bio-failed is defined as prior biologic or JAKi failure includes loss of response, inadequate response, or intolerance to one or more biology therapy (TNF blocker or vedolizumab), or tofacitinib. Bio-naïve includes biologic-naïve and JAKi-naïve.[1]

ES=endoscopic subscore; JAKi=Janus kinase inhibitor; mMS=modified Mayo score; Q4W=every 4 weeks; RB=rectal bleeding subcore; SC=subcutaneous; SF=stool frequency subscore; TNF=tumor necrosis factor.

Dr. Cohen:
Omvoh also reduced bowel urgency severity, one of patients' most disruptive symptoms.

At Week 52, 39% of patients achieved bowel urgency improvement with Omvoh as measured by a weekly average score of 0 to 1 on the Urgency Numeric Rating Scale, or UNRS.

Onscreen Text:
Short-term goals, **Intermediate goals**, Long-term goals

AMONG PATIENTS WHO ACHIEVED CLINICAL RESPONSE WITH OMVOH AT WEEK 12[1]

Omvoh Reduced Bowel Urgency, One of UC Patients' Most Disruptive Symptoms[1,4,a,b]

39% for patients receiving Omvoh 200 mg SC Q4W (N=307)
23% for patients receiving placebo (N=160)
$p<0.001$

[a]Bowel urgency was assessed using an Urgency Numeric Rating Scale (UNRS) ranging from 0 (no urgency) to 10 (worst possible urgency).[1,5]

[b]Bowel urgency improvement was evaluated as the proportion of patients with a baseline UNRS weekly average score of ≥3 achieving

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a weekly average score of 0 to 1 at Week 40 in LUCENT-2.[1,3]

Q4W=every 4 weeks, SC=subcutaneous; UC=ulcerative colitis; UNRS=Urgency Numeric Rating Scale.

Dr. Cohen:
We've explored how Omvoh can support patients in the earlier stages of treatment through Week 52.

Let's look at the long-term results from LUCENT-3.

Among those patients who achieved clinical remission at Week 52 with Omvoh, 79% of them maintained it at 4 years.

Onscreen Text:
Short-term goals, Intermediate goals, **Long-term goals**

AMONG PATIENTS WHO ACHIEVED CLINICAL REMISSION[a] WITH OMVOH AT WEEK 52[6]

Omvoh Maintained Long-Term Clinical Remission[*] at 4 Years (Week 212)[6]

POST HOC ANALYSIS
79% of patients receiving Omvoh 200 mg SC Q4W (N=95) maintained clinical remission at 4 years, observed data

mNRI analysis showed 63% of patients maintained clinical remission (N=168) at 4 years (Week 212)[6]

LUCENT-3 is an open-label extension study. Open-label studies may have selection bias , as patients who cannot tolerate treatment or do not response may drop out of the study prior to the extension.[7]

Data are from a post hoc analysis of the mITT population in the long-term extension study.

mNRI analysis imputes the missing values, but patients that discontinue treatment are considered non-responders.

[*]Clinical remission was defined as: SF=0 or 1, RB=0; ES=0 or 1 (excluding friability).[1]

ES=endoscopic subscore; mITT=modified intent-to-treat; mMS=modified Mayo score; mNRI=modified non-responder imputation; NRI=non-responder imputation; RB=rectal bleeding; SC=subcutaneous; SF=stool frequency; Q4W=every 4 weeks.

Dr. Cohen:
Patients taking Omvoh also achieved long-term results at 4 years across the key secondary endpoints, including bowel urgency improvement, corticosteroid-free remission, endoscopic improvement, and HEMI.

Please note that open-label extension studies have limitations, including no placebo comparison and patients remaining in the extension study may have better outcomes than patients who left the study.

Onscreen Text:
Short-term goals, Intermediate goals, **Long-term goals**

AMONG PATIENTS WHO ACHIEVED CLINICAL REMISSION[a] WITH OMVOH AT WEEK 52[8]

Patient Taking Omvoh Achieved Long-Term Results Across Key Secondary Outcomes at 4 Years (Week 212)[8]

POST HOC ANALYSIS
Bowel urgency improvement[b]:
69% for patients receiving Omvoh 200 mg SC Q4W (N=89)

Corticosteroid-free clinical remission[c]:
79% for patients receiving Omvoh 200 mg SC Q4W (N=127)

Endoscopic improvement[d]:
83% for patients receiving Omvoh 200 mg SC Q4W (N=104)

HEMI[e]:
69% for patients receiving Omvoh 200 mg SC Q4W (N=99)

mNRI analyses showed 55% of patients achieved bowel urgency improvement (N=154), 63% of patients achieved corticosteroid-free clinical remission (N=168), 67% achieved endoscopic improvement (N=168), and 55% achieved HEMI (N=168) at 4 years (Week 212)[8]

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LUCENT-3 is an open-label extension study. Open-label studies may have selection bias, as patients who cannot tolerate treatment or do not response may drop out of the study prior to the extension

Data are from a post hoc analysis of the mITT population in the long-term extension study

mNRI analysis imputes the missing values, but patients that discontinue treatment are considered non-responders

The relationship between HEMI and disease progression and long-term outcomes is not known

*Clinical remission was defined as SF=0 or 1; RB=0; ES=0 or 1 (excluding friability).[1]

[a]Bowel urgency improvement: UNRS=0 to 1.[1]

[b]Corticosteroid-free clinical remission is defined as clinical remission at Week 212 with no corticosteroid use for ≥12 weeks prior to Week 212.[1]

[c]Endoscopic improvement is defined as ES=0 or 1 (excluding friability).[1]

[d]HEMI is defined as achieving both endoscopic improvement (centrally read ES= 0 or 1, excluding friability) and histologic improvement (no neutrophils in crypts or lamina propria, no crypt destruction, and no erosions, ulcerations, or granulation tissue based on the Geboes scoring system [Geboes score ≤2B.0]).

ES=endoscopic subscore; HEMI=histologic-endoscopic mucosal improvement; mITT=modified intent-to-treat; mMS=modified Mayo score; mNRI=modified non-responder imputation; Q4W=every 4 weeks; RB=rectal bleeding; SC=subcutaneous; SF= stool frequency; URNS=Urgency Numeric Rating Scale.

Dr Cohen:
Looking at the safety profile of Omvoh, the most common adverse reactions included upper respiratory tract infections, arthralgia, injection site reactions, rash, headache, and herpes viral infections.

Onscreen Text:
OMVOH SAFETY DATA IN ADULT PATIENTS ACROSS UC TRIALS

Most Common Adverse Reactions[a] in LUCENT-1 and -2[1,3]

During LUCENT-1, the 12 week induction study compared 958 patients on Omvoh 300 mg IV Q4W[b] to 321 patients on placebo. During LUCENT-2, the 40 week maintenance study compared 389 patients on Omvoh 200 mg SC Q4W[c] to 192 patients on placebo.

Upper respiratory tract infections[d] were reported by 72 patients (8%) on Omvoh and 20 patients (6%) on placebo during induction and 53 patients (14%) on Omvoh and 23 patients (12%) on placebo during maintenance.

Arthralgia were reported by 20 patients (2%) on Omvoh and 4 patients (1%) on placebo during induction and 26 patients (7%) on Omvoh and 8 patients (4%) on placebo during maintenance.

Injection site reactions[e] were reported by 34 patients (9%) on Omvoh and 8 patients (4%) on placebo during maintenance.

Rash[f] was reported by 16 patients (4%) on Omvoh and 2 patients (1%) on placebo during maintenance.

Headache was reported by 16 patients (4%) on Omvoh and 2 patients (1%) on placebo during maintenance.

Herpes viral infection[g] was reported by 9 patients (2%) on Omvoh and 1 patient (1%) on placebo during maintenance.

In LUCENT-1, infusion-related hypersensitivity reactions were reported by 4 (0.4%) patients treated with Omvoh and 1 (0.3%) patient treated with placebo.[1]

[a]Occuring in ≥2% of patients and higher frequency than placebo.

[b]Omvoh 300 mg as an IV infusion at Weeks 0, 4, and 8.[1]

[c]Omvoh 200 mg as an SC injection at Week 12 and every 4 weeks thereafter for up to an additional 40 weeks.[1]

[d]Upper respiratory tract infections includes related terms (eg, COVID-19, nasopharyngitis, pharyngitis, rhinitis, sinusitis, and upper respiratory tract infections).[1]

[e]Injection site reactions include related terms (eg, erythema, hypersensitivity, pain, reaction, and urticaria at the injection site).[1]

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[f]Rash is composed of several similar terms.[1]

[e]Herpes viral infection includes related terms (eg, herpes zoster, herpes simplex, and oral herpes).[1]

COVID-19=coronavirus disease 2019; IV=intravenous; Q4W=every 4 weeks; SC=subcutaneous.

Dr. Cohen:
Additionally, no new safety signals were identified during 4 years of treatment with Omvoh as you can see from the table on select adverse events reported in the LUCENT trials.

Onscreen Text:

Select Adverse Events in LUCENT-1 and LUCENT-2[3]

During LUCENT-1, the 12 week induction study compared 958 patients on Omvoh 300 mg IV to 321 patients on placebo. During LUCENT-2, the 40 week maintenance study compared 389 patients on Omvoh 200 mg SC to 192 patients on placebo.

Infections were reported by 145 patients (15.1%) on Omvoh and 45 patients (14.0%) on placebo during induction and 93 patients (23.9%) on Omvoh and 44 patients (22.9%) on placebo during maintenance.

Serious infections[a] occurred in 7 patients (0.7%) of patients on Omvoh and 2 patients (0.6%) on placebo during induction and, during maintenance, 3 patients (0.8%) on Omvoh and 3 patients (1.6%) on placebo.

Opportunistic infections[b] occurred in 5 patients (0.5%) on Omvoh and 1 patient (0.3%) on placebo during induction and 5 patients (1.3%) on Omvoh and no patients on placebo during the maintenance study.

Adjudicated cerebrocardiovascular events occurred in 1 patient (0.1%) on Omvoh and 2 patients (0.6%) on placebo during induction and no patients on Omvoh and 1 patient (0.5%) on placebo during maintenance. Major adverse cardiac events (MACE)[c] occurred in no patients on Omvoh or placebo during induction and no patients on Omvoh and 1 patient (0.5%) on placebo during maintenance.

Malignancies[d] occurred in 2 patients (0.2%) on Omvoh and no patients (0%) on placebo during induction; 1 patient (0.3%) on Omvoh and 1 patient (0.5%) on placebo during maintenance. Non-melanoma skin cancer (NMSC) occurred in no patients on Omvoh or placebo during induction and no patients on Omvoh and 1 patient (0.5%) on placebo during maintenance. Malignancies excluding NMSC occurred in 2 patients (0.2%) on Omvoh and no patients on placebo during induction and 1 patient (0.3%) on Omvoh and no patients on placebo during maintenance.

Immediate hypersensitivity reactions[e] occurred in 10 patients (1.0%) on Omvoh and 1 patient (0.3%) on placebo during induction; 7 patients (1.8%) on Omvoh and 2 patients (1.0%) on placebo during maintenance.

Hepatic events occurred in 15 patients (1.6%) on Omvoh and 1 patient (0.3%) on placebo during induction; 12 patients (3.1%) on Omvoh and 4 patients (2.1%) on placebo during maintenance.

Select Adverse Events in UC (Long-Term)[9]

The LUCENT-3 Long-Term Open-Label Extension (160 weeks) had 339 Omvoh patients with up to 4 years of exposure, totaling 896.9 patient years.

In the long-term extension study, 10 (2.9%) [EAIR 1.1] of patients on Omvoh had serious infections[a], 7 (2.1%) [EAIR=0.8] had opportunistic infections[b], 5 (1.5%) [EAIR=0.6] had adjudicated cerebrocardiovascular events, 1 (0.3%) [EAIR=0.1] had MACE[c], 5 (1.5%) [EAIR=0.6] had malignancies[d], no patients had NMSC, 5 (1.5%) [EAIR=0.6] patients had malignancies excluding NMSC, 8 (2.4%) [EAIR=0.9] had immediate hypersensitivity reactions[e], and 16 (4.6%) [EAIR=1.8] had hepatic events.

Certain adverse events, such as MACE and malignancy, require longer observation periods and larger patient exposure to ascertain risk. Lilly continues to conduct long-term safety studies to evaluate the safety of Omvoh.

[a]In LUCENT-1, serious infections were reported by less than 1% in both groups. Serious infections in the Omvoh group included intestinal sepsis, listeria sepsis, and pneumonia. In LUCENT-2, through Week 40, a case of COVID-19 pneumonia was reported as a serious infection in the Omvoh group.

[b]In LUCENT-1, 1 case of herpes zoster infection was reported in the placebo group, and 1 case of esophageal candidiasis, 2 of cytomegalovirus colitis, 1 of herpes zoster infection, and 1 of intestinal tuberculosis were reported in the Omvoh group; cytomegalovirus colitis was severe in 1 patient. In LUCENT-2, 1 case of oral candidiasis and 4 cases of herpes zoster infection were reported in the

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Omvoh group. Herpes zoster infection was severe in 1 patient. Other opportunistic infections during both LUCENT-1 and LUCENT-2 were mild to moderate.

[c]In LUCENT-1, there were no instances of MACE. In LUCENT-2, 1 instance of MACE (ischemic stroke) occurred in the placebo group.

[d]During LUCENT-1, colon adenocarcinoma occurred in 2 patients in the Omvoh group. During LUCENT-2, non-melanoma skin cancer (basal cell carcinoma) occurred in 1 patient in the placebo group and gastric cancer in 1 patient in the Omvoh group.

[e]During LUCENT-1, no serious hypersensitivity or anaphylactic reactions occurred. During LUCENT-2, 1 case of anaphylaxis occurred in the placebo group.

[f]EAIRs are per 100 PY. The EAIR per 100 PY can be interpreted as an estimated number of first occurrences of the adverse reaction of interest if 100 patients were treated for 1 year.

COVID-19=coronavirus 2019; EAIR=exposure-adjusted incidence rate; IV=intravenous; MACE=major adverse cardiovascular events; NMSC=non-melanoma skin cancer; PY=patient-years; Q4W=every 4 weeks; SC=subcutaneous; UC=ulcerative colitis.

Dr. Cohen:
It's been a pleasure sharing Omvoh's 4-year long-term data in UC. It's exciting to know that wherever your patients are in their treatment journey, Omvoh may be able to help—not just for short-term relief but for a chance at sustained, long-term remission.

Onscreen Text:
FOR ADULTS WITH MODERATE TO SEVERE UC[1]

Reach for Your UC Goals With Omvoh[1]

Omvoh is an IL-23p19 antagonist that offers[1]:

BOWEL URGENCY REDUCTION DATA

- Week 52
- 4 years[a]

CONSISTENT EFFICACY REGARDLESS OF BIOLOGIC EXPOSURE

- Clinical remission Week 52
- Endoscopic improvement Week 52

LONG-TERM DATA

- Clinical remission maintenance data 4 years[a]
- Endoscopic improvement and HEMI data 4 years[a]
- No new safety signals 4 years[a]

[a]212 weeks.
HEMI=histologic-endoscopic mucosal improvement; IL=interleukin; UC=ulcerative colitis.

Dr. Cohen:
Visit Lilly Play to watch additional videos on Omvoh or visit omvoh.lilly.com/hcp for more information.

Please continue watching for additional Important Safety Information.

Onscreen and Narrator:
WARNINGS AND PRECAUTIONS
Onscreen Only:
ADDITIONAL IMPORTANT SAFETY INFORMATION for Omvoh (mirikizumab-mrkz).

Hypersensitivity Reactions
Serious hypersensitivity reactions, including anaphylaxis during intravenous infusion, have been reported with Omvoh administration. Infusion-related hypersensitivity reactions, including mucocutaneous erythema and pruritus, were reported during induction. If a severe hypersensitivity reaction occurs, discontinue Omvoh immediately and initiate appropriate treatment.

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Infections
Omvoh may increase the risk of infection. Do not initiate treatment with Omvoh in patients with a clinically important active infection until the infection resolves or is adequately treated. In patients with a chronic infection or a history of recurrent infection, consider the risks and benefits prior to prescribing Omvoh. Instruct patients to seek medical advice if signs or symptoms of clinically important acute or chronic infection occur. If a serious infection develops or an infection is not responding to standard therapy, monitor the patient closely and do not administer Omvoh until the infection resolves.

Tuberculosis
Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Omvoh. Do not administer Omvoh to patients with active TB infection. Initiate treatment of latent TB prior to administering Omvoh. Consider anti-TB therapy prior to initiation of Omvoh in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Monitor patients for signs and symptoms of active TB during and after Omvoh treatment. In clinical trials, subjects were excluded if they had evidence of active TB, a history of active TB, or were diagnosed with latent TB at screening.

Hepatotoxicity
Drug-induced liver injury in conjunction with pruritus was reported in a clinical trial subject following a longer than recommended induction regimen. Omvoh was discontinued. Liver test abnormalities eventually returned to baseline. Evaluate liver enzymes and bilirubin at baseline and for at least 24 weeks of treatment. Monitor thereafter according to routine patient management. Consider other treatment options in patients with evidence of liver cirrhosis. Prompt investigation of the cause of liver enzyme elevation is recommended to identify potential cases of drug-induced liver injury. Interrupt treatment if drug-induced liver injury is suspected, until this diagnosis is excluded. Instruct patients to seek immediate medical attention if they experience symptoms suggestive of hepatic dysfunction.

Immunizations
Avoid use of live vaccines in patients treated with Omvoh. Medications that interact with the immune system may increase the risk of infection following administration of live vaccines. Prior to initiating therapy, complete all age-appropriate vaccinations according to current immunization guidelines. No data are available on the response to live or non-live vaccines in patients treated with Omvoh.

ADVERSE REACTIONS
Most common adverse reactions associated with Omvoh (≥2% of subjects and at a higher frequency than placebo) in ulcerative colitis treatment are upper respiratory tract infections and arthralgia during the induction study (UC-1), and upper respiratory tract infections, injection site reactions, arthralgia, rash, headache, and herpes viral infection during the maintenance study (UC-2).

Most common adverse reactions associated with Omvoh in the Crohn's disease study (CD-1) (≥5% of subjects and at a higher frequency than placebo) are upper respiratory tract infections, injection site reactions, headache, arthralgia, and elevated liver tests.

Omvoh injection is available as a 300 mg/15 mL solution in a single-dose vial for intravenous infusion, and as a 100 mg/mL solution or a 200 mg/2 mL solution in a single dose prefilled pen or prefilled syringe for subcutaneous injection. Refer to the Prescribing Information for dosing information.

Onscreen Only:

MR HCP ISI CD APP

This is not the complete Important Safety Information for Omvoh. Please see the beginning of this video for additional. Important Safety Information and accompanying Prescribing Information and Medication Guide. Please see Instructions for Use included with the devices.

Onscreen Text:
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10. Data on file. DOF-MR-US-0104. Lilly USA, LLC.

Onscreen Text:

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