Transcript Details
This is a transcript of an educational program. Details about the program and additional media formats for the program are accessible by visiting: https://reachmd.com/programs/medical-industry-feature/anas-story-ulcerative-colitis-patient-journey/54423/

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

Ana's Story – A Real Patient Living With Ulcerative Colitis

Narrator:
Indications. 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.

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, 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
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Onscreen Text:
Hear from Ana, a young woman managing life with moderate to severe ulcerative colitis and dealing with its daily disruptive symptoms.

Her journey—from pre-diagnosis to the shared decision she and Dr. Lukasz Kwapisz made to manage her disease with Omvoh®—highlights the importance of collaborative care.

This video is intended for US healthcare providers.

Ana:
My name is Ana. I am originally from Caracas, Venezuela. I lived there for 12 years, and I moved to Miami, Florida. I recently graduated college from Northeastern University, and I am now living in Miami again, and I'm working in construction.

There's a big stigma and taboo around any gastrointestinal issues, and you don't really have anywhere to go to ask.

I want to bring awareness to ulcerative colitis, the condition that I have. I think it's a condition that's not talked about enough. There's not enough information out there.

I just want to do this so I can share my experience and hopefully help other people.

Onscreen Text:
Ana
Patient With Moderate to Severe Ulcerative Colitis Currently Being Treated With Omvoh[1]
Ana was compensated for her time.

Ana:
There's a big stigma and taboo around any gastrointestinal issues, and you don't really have anywhere to go to ask.

I want to bring awareness to ulcerative colitis, the condition that I have. I think it's a condition that's not talked about enough. There's not enough information out there.

I just want to do this so I can share my experience and hopefully help other people.

My first symptoms started showing up about three years ago. I was about to leave for my sophomore year of college when I started seeing blood in my stool.

I was very confused at the time; I didn't know why that was going on.

And the first time I kind of ignored it. But then after every day for a couple weeks, that turned into months. I was very concerned. I also started going to the bathroom a lot more frequently; I would say about 8 to 10 times a day.

I spent a couple of months feeling that way until I was able to come back to Miami to see a physician, and I had my first colonoscopy. And that's when I was diagnosed with UC.

When I was diagnosed in Miami, I had to go back to Boston for school.

It was very hard communicating my symptoms to the doctor through a phone.

And it was hard finding time between my classes and exams to go to the doctor to get the different treatments.

It became even harder since I had to travel every two months back to Miami, skip school, make arrangements with my professors so I just would be able to find treatment.

After I got diagnosed, I started trying different treatments, and they worked for a while. But for some reason or another, they stopped working.

I started experiencing “moon face” from one of the medications. At first, I knew it would be temporary, but then it started playing with my self-esteem.

I didn't feel my best. I didn't look like I wanted to look. And it was very frustrating.

But with a different one, I would feel very tired after my infusion, and I couldn't drive. I would always have to have someone with me when I would go, and I would lose the entire day.

This whole process of trying different medications took about two years.

It was very frustrating because once I started feeling better, I saw hope. But then I would start seeing symptoms again, and I would be a little devastated.

Onscreen Text:

Up to 65% of patients with UC/CD on conventional therapies[a] reported their treatment to be somewhat effective or not effective.[2,b]

Sample size: CD, N=189; UC, N=87.

Dr. Kwapisz:
So, I'm Doctor Lukasz Kwapisz. I'm an IBD specialist here in Miami. I work for Gastro Health and Baptist Hospital, and I'm an assistant professor for Florida International University.

Overall, I've been in practice for a little over 10 years looking after patients with inflammatory bowel disease, a personal passion of mine.

Onscreen Text:
Dr. Lukasz Kwapisz, MD
Assistant Professor, Florida International University
Gastroenterologist, Gastro Health and Baptist Hospitals

Dr. Kwapisz:
I had the pleasure of meeting Ana via telemedicine. She was splitting time between Boston and Miami, and as a result of that, we got to talk about her symptoms, and she was having many breakthrough symptoms that were affecting her in all aspects of her life.

As we follow the STRIDE-II guidelines, we have short-term, medium-term, and long-term goals. In the short term, we really wanted her symptoms to improve. We wanted her urgency and her abdominal pain to get better. In the medium term, we really wanted to see her biomarkers improve. And we did see that with fecal calprotectin and C-reactive protein showing improved levels. And ultimately our long-term target was showing endoscopic healing, and we performed a colonoscopy on her last month, and we saw endoscopic improvement, we saw histologic improvement, and we were very happy with her progress overall.

And the goal would be for her never to develop antibodies, never to develop breakthrough symptoms. And we're hopeful that with Omvoh, she is able to achieve that.

Onscreen Text:
Individual results may vary.

Please see additional Important Safety Information and safety data throughout. Please see accompanying Prescribing Information and Medication Guide for Omvoh. Please see Instructions for Use included with the devices.

Among patients with moderate to severe UC who achieved clinical response with Omvoh at Week 12, 51% of patients achieved clinical remission at Week 52.

Please continue watching for trial design and additional data.

Dr. Kwapisz:
Well, Omvoh is a really great therapy in ulcerative colitis. We have data to support its use in bio-naive patients, as well as the bio-failure patients. We love the dosing of every four weeks, keeping the drug at a nice, steady state. And ultimately when we're looking at patients' symptoms that are quite disruptive from an urgency perspective, we have great data that backs up its use. And in real life, we're seeing very good results that are showing improvements in patients' lives, especially from an urgency perspective.

Onscreen Text:
Omvoh has also been shown to reduce bowel urgency in UC, one of patients' most disruptive symptoms.[1,3] Among patients who achieved clinical response with Omvoh at Week 12, 39% of patients achieved bowel urgency improvement (UNRS=0 to 1) at Week 52.[1,4,5]

Dr. Kwapisz:
Take a look at Omvoh's clinical trial design and Omvoh's clinical trial data through Week 52.

Onscreen Text:
Please continue watching for trial design and additional data.

Dr. Kwapisz:
Hey Ana, how are you?

Ana:
Good, and you?

Dr. Kwapisz:
Here we are, one year later since we met. Do you remember at that time, I know you had seen a few of my colleagues, and they were discussing your condition—ulcerative colitis.

You were having symptoms. When we were thinking of a therapy, do you remember what was going through your head? What priorities you were hoping would come to the front and we could discuss?

Ana:
Well, definitely one of my priorities was convenience. So, I was coming back from Boston to Miami every couple of weeks to do my treatment, and it was very inconvenient having to skip class or ask for accommodations.

So that was one of my highest priorities, something that would be more convenient in the way that I received my medication.

Also, I wanted something that would be able to control my symptoms quickly and that wouldn't make me feel better and then worse.

I remember the first conversation we had; we talked about my situation and we discussed different treatment options. And then you opened the floor for me to do my own research and to really pick whatever related and resonated most with myself.

Dr. Kwapisz:
And I remember one thing that really struck me is when we had that first conversation, you were telling me that at that Week 6 mark, not only was there some blood and diarrhea and gas, but really urgency. And I don't know if you remember really that moment or what that felt like in your day- to-day life, whether at school, whether at work, whether at a restaurant, with friends.

But what did that feel like when you were feeling those symptoms?

Ana:
The urgency was frustrating. It was inconvenient, and it was just annoying. I had to figure out where the closest bathroom was at all times, wherever I was, whether it was a place that I knew or it was new to me, and just having to plan ahead for an urgency that I knew would come, I wanted that to stop.

Dr. Kwapisz:
Yeah.

Ana:
So that was one of my main priorities when I came to you.

Dr. Kwapisz:
Yeah. I consider many things, and I think it's important to know that we can't, you know, have one broad paintbrush for every patient. It needs to be personalized. It needs to be specific and tailored to someone's needs. And that shared decision-making really comes in handy.

When I presented those three options, is there something that made you kind of gravitate more towards Omvoh in that context as well?

Ana:

When you presented the pill option, I just didn't want to have that responsibility every single day. And then with Omvoh, it was more appealing just because I had been coming from an infusion. So, the first three doses for Omvoh are infusions.

And since I would be back here for summer, it was convenient. It was attractive. And after when I would go back to Boston, I could start the self-injections at home.

And that was really a turning point for me.

And when I started the treatment, I started feeling better immediately. I wasn't tired right after the medication, and I could go on about my day with Omvoh.

Onscreen Text:
For adults with moderate to severe UC[1]
Induction dosing begins with IV infusions[a] of Omvoh 300 mg at Weeks 0, 4, and 8.
For maintenance, dosing transitions to subcutaneous injections[b] of Omvoh 200 mg via 1 injection at Week 12 and every 4 weeks thereafter.

[a]For at least 30 minutes.[1]
[b]Omvoh is intended for use under the guidance and supervision of a healthcare professional. Patients and/or caregivers may inject after training in proper technique.[1]

Dr. Kwapisz:
For you, that safety aspect, what did you—how did you feel about the safety of Omvoh when we were talking about it?

Ana:
Well, of course, when I look at any medication, I look at how it's going to affect me today but also in the future. And I definitely looked for an option that would allow me to do that without having to look for different treatments or jeopardize me in that sense.

Dr. Kwapisz:
Take a look at Omvoh's Safety Information and Prescribing Information.

Onscreen Text:
Omvoh's full Important Safety Information can be found at the end of the video.

Ana:
My day-to-day since I started using Omvoh changed. I was able to regain control of my symptoms and feel much better than I have in the past three years.
Also, it has become very convenient to receive treatment because I don't have to travel back and forth anymore like I used to before, and I don't have to lose an entire day with Omvoh. Instead, I have the self-injections and administer at home. I receive them a couple of days before my treatment is due, and I'm able to administer it myself, which is something that I would never thought I would be able to do because I have a fear of needles, and with Omvoh, the injection is made so that you don't see the needle.

Onscreen Text:
In two studies, 94% of adults agreed the Pen device was easy to use and were confident in their ability to use it.[6-8,a]

[a]Results from two studies using a similar approved Pen with the same use steps for a single injection. For Crohn's disease, Omvoh has additional steps as a full dose requires two injections. Omvoh is intended for use under the guidance and supervision of a healthcare provider. Before the first injection, a healthcare provider should demonstrate how to prepare and inject Omvoh. Read the detailed Instructions for Use on how to use Omvoh the correct way.

Ana:
I've been on Omvoh for a year, and now I feel more in control of my symptoms. I had a very free childhood, and when I started feeling symptoms for UC three years ago, I felt like the disease was controlling me. But ever since starting Omvoh a year ago, I now feel like I

can control the disease.

My life at home and at work now, I am able to live them with fewer disruptions.

I can go to work without having to take days off for my treatment. And when I'm out with friends, I don't have to worry about where the closest bathroom is, or I don't have to revolve my day around finding convenient times to go to the bathroom.

Onscreen Text:
Individual results may vary.

Ana:
What I would tell physicians is first: listen to each individual person's story. It is very taboo to talk about things like this. So, providing the space for patients to be comfortable.

Working with Dr. Kwapisz, and finding Omvoh as my treatment option, I've been able to reach my goals. I was able to graduate university, and now I'm starting my first job and reach my goals as they come.

Dr. Kwapisz:
Omvoh was approved for UC based on its induction and maintenance trials. Clinical remission at Week 12 was the primary endpoint in the induction trial, LUCENT-1, and Omvoh patients who achieved clinical response continued on to the maintenance trial, LUCENT-2, where the primary endpoint was clinical remission at Week 52.

Onscreen Text:
The Efficacy and Safety of Omvoh Were Studied in Adult Patients With Moderately to Severely Active UC in the LUCENT Clinical Trials[1,9]

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.[9]

[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. Kwapisz:
In LUCENT-1, after 12 weeks, 65% of patients taking Omvoh achieved clinical response versus 43% taking placebo, and 24% of Omvoh patients achieved clinical remission compared to 15% placebo patients.

At Week 52, 51% of [all] patients on Omvoh achieved clinical remission versus 27% on placebo.

Onscreen Text:
Decreases in rectal bleeding and stool frequency subscores were observed as early as Week 3 in subjects treated with Omvoh compared to subjects on placebo[10,11]

For adults with moderate to severe UC[1]

Nearly 2 in 3 patients taking Omvoh achieved clinical response[a] at Week 12

Clinical response[a] and Clinical Remission at Week 12

Clinical response (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

Clinical Remission at Week 52[1]

51% 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 (LUCENT-1) plus the 40-week maintenance study (LUCENT-2) for 52 weeks of continuous treatment.[1]

[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.

Dr. Kwapisz:
In addition, in LUCENT-2, among Omvoh patients who achieved clinical response at Week 12, patients taking Omvoh also achieved significant improvements in bowel urgency, corticosteroid-free remission, endoscopic improvement, and the combination of histologic and Endoscopic mucosal improvement at Week 52.

Onscreen Text:
Among moderate to severe UC patients who achieved clinical response with Omvoh at Week 12[1]

Patients taking Omvoh achieved results across key secondary outcomes at Week 52[1,4,5]

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

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

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

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

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

[a]Bowel urgency improvement was evaluated as the proportion of patients with a baseline UNRS weekly average score of ≥3 achieving a weekly average score of 0 to 1 at Week 52 in LUCENT-2.[1,5]

[b]Corticosteroid-free clinical remission is defined as clinical remission at Week 40 with no corticosteroid use for ≥12 weeks prior to Week 40.[1]

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

[c]LUCENT-2 was not designed to evaluate the relationship of HEMI at Week 40 to disease progression and long-term outcomes. HEMI is defined as achieving both endoscopic improvement (centrally read endoscopy subscore of 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]).[1,4]

ES=endoscopic subscore; HEMI=histologic-endoscopic mucosal improvement; Q4W=every 4 weeks; SC=subcutaneous; UNRS=Urgency Numeric Rating Scale.

Onscreen Text 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.

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:

References:

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Onscreen Text: