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/the-impact-of-zero-in-rheumatology/32264/

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

The Impact of Zero in Rheumatology

Dr. Shah:
Hi everyone, and welcome to BIMZELX & Cold Brew, a video series where we take a moment to slow down and have thoughtful conversation about emerging topics in rheumatology. I'm Dr. Monica Shah, a rheumatologist based in Florida.

Dr. Schwartzman:
I'm Dr. Monica Schwartzman, a rheumatologist practicing in New York City.

Dr. Wright:
And I'm Dr. Grace Wright, a rheumatologist also practicing in New York City. We're excited to be here together for this discussion.

Dr. Schwartzman:
You'll see questions appear on screen. We'll answer some as we go.

Dr. Shah:
Before we jump in, a quick word about BIMZELX. It's the first and only approved therapy that inhibits both IL-17A and IL-17F. It's indicated for adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, and active ankylosing spondylitis.

Today, we're exploring a different way of looking at disease control by aiming for zero disease activity in one or more domains. Then we'll dive into how BIMZELX can help achieve that. Dr. Schwartzman, how is this approach different to how we've defined disease control in the past?

Dr. Schwartzman:
What I see in my clinic is that most patients are dealing with symptoms across multiple domains. It's known that when patients meet outcome measures in clinical trials such as ACR50, ASAS40, and MDA they may still have active disease that disrupts everyday life. And patients don't just want partial improvement or daily reminders of their disease. What they really want is a complete absence of symptoms.

Dr. Wright:
The idea of zero disease activity in one or more domains is an important conversation, because our patients aren't coming in asking for an ACR score. They want their swollen joint gone or their sore heel gone.

Dr. Shah:
To get started, let's look at the bold primary endpoints that set the foundation for today's discussion. Dr. Wright, how are these endpoints different than what we've seen in previous clinical trials?

Dr. Wright:
We're used to seeing ACR20 or ASAS20 in clinical trials, but BIMZELX raised the bar by using ACR50 and ASAS40 at Week 16 as primary endpoints across PsA, nr-axSpA, and AS, respectively. BIMZELX met its primary endpoints across indications, showing significant improvement in PsA, nr-axSpA, and AS, all at Week 16 compared to placebo. These results were consistent in both bio-naïve and bio-experienced patients with PsA and across patients with nr-axSpA and AS.

Dr. Schwartzman:
These endpoints are important because they give us a standardized way to assess responses to treatment within clinical trials.

Dr. Wright:
Right, that's where the conversation is evolving. ACR50, ASAS40, and MDA represent important measures of meaningful improvement, but we ultimately strive to achieve zero disease activity in one or more domains.

Dr. Shah:
And that's where the idea of zero disease activity in one or more domains comes in. When I talk about zero in clinic, I'm referring to the absence of clinical signs, symptoms,
or progression of disease in a given domain, such as zero swollen joints, zero tender joints, zero inflamed entheses, zero plaques.

Dr. Schwartzman:
It's also worth looking at how these results came together across the trial designs. Let's start with the two Phase 3 clinical trials in patients with PsA, BE OPTIMAL and BE COMPLETE. Dr. Wright, can you give us a quick overview?

Dr. Wright:
Sure. These were two pivotal, Phase 3 trials designed to evaluate the efficacy and safety of BIMZELX for adults with active psoriatic arthritis. BE OPTIMAL included patients who were bio-naïve, while BE COMPLETE included patients who were bio-experienced. Both trials were randomized, double-blind, placebo-controlled trials with a primary endpoint of ACR50 at Week 16. Patients who completed Week 52 of BE OPTIMAL or Week 16 of BE COMPLETE were eligible to enroll in BE VITAL, the open-label extension study designed to evaluate the long-term safety and tolerability of BIMZELX up to 3 years.

BIMZELX was also studied in two other pivotal, Phase 3 trials, BE MOBILE 1 in adults with active nr-axSpA and BE MOBILE 2 in adults with active AS. Both trials were randomized, double-blind, placebo-controlled trials with a primary endpoint of ASAS40 at Week 16. Patients who completed Week 52 of either study were eligible to enroll in BE MOVING, the open-label extension study designed to evaluate the long-term safety and tolerability of BIMZELX up to 3 years.

Dr. Shah:
I know that was a lot to digest. Let's take a pause to answer some of the questions that popped up. Dr. NiaRheum asked "If ACR20/50/70 are already challenging milestones, why should we shift focus toward aiming for zero disease activity? What benefits does that bring for patients?" Dr. Schwartzman, what are your thoughts?

Dr. Schwartzman:
That's a great question! Zero doesn't replace ACR or ASAS responses. It builds on them. If a patient still has lingering swollen joints or enthesitis, reaching zero disease activity in even one of those domains can have a real impact. And in psoriasis, for example, rheumatologists have already been striving for zero disease activity and we've helped patients achieve PASI100 or 100% skin clearance.

Dr. Wright:
As rheumatologists, we're always trying to manage expectations about individualizing treatment goals. For some patients, aiming higher may bring us closer to what they're hoping for from therapy.

Dr. Shah:
In clinical practice, we often see patients with disease activity in one or more domains. And that burden shows up in all kinds of ways.

Dr. Wright:
Before we dive in, I want to mention that from here on out, we're going to be looking at data from the open-label extension studies using observed case analyses, where patients with missing data at a specific time were not included. The limitations of the open-label extension were that there was a lack of a comparator past Week 16, as well as the use of select study populations that were more likely to show drug effect. All patients were dosed at 160 mg every 4 weeks. We're going to be seeing this data throughout the video, so this is important to keep in mind.

So let's discuss how BIMZELX puts zero within reach in one or more domains. We are covering 4 patient populations: PsA bio-naïve, PsA bio-experienced, nr-axSpA, and AS. In PsA, the domains shown are swollen joint count, tender joint count, enthesitis, dactylitis, skin psoriasis, and nail psoriasis. In nr-axSpA and AS, the domains shown are swollen joint count, tender joint count, and enthesitis. Radiographic progression data is shown in PsA bio-naïve and AS patient populations.

Today, we will dive deeper into a few of these important domains, but please see BIMZELXhcp.com to view all the data.

Dr. Shah:
In my practice, I see patients with PsA struggling with swollen joints. For patients with AS or nr-axSpA, I see them struggling with

enthesitis. Let's touch on enthesitis in patients with PsA first. Dr. Schwartzman, what are your thoughts on the enthesitis data in bio-experienced patients with PsA?

Dr. Schwartzman:
We see in patients who had enthesitis at baseline, they had a baseline LEI, or Leed's Enthesitis Index score, of around 3. That could be someone who has 3 tender entheses, for example at their Achilles, knee, and elbow. At Week 16, 50% of patients on BIMZELX achieved zero sites of enthesitis, and by Week 100, 69% of bio-experienced patients with PsA achieved zero enthesitis.

Dr. Wright:
The data is encouraging. When enthesitis improves, patients in my practiceoften say they can move without that constant enthesitis-related pain.

Dr. Shah:
Exactly. With BIMZELX, we have seen meaningful reductions in enthesitis and in some patients, resolution.

Let's keep going with bio-experienced patients with PsA, this time looking at plaque psoriasis. Dr. Schwartzman, what do we see in the data?

Dr. Schwartzman:
Looking at the BE COMPLETE trial of bio-experienced patients with PsA with plaque psoriasis greater than or equal to 3% body surface area at baseline, 60% of patients on BIMZELX taking 160 mg every 4 weeks achieved zero plaque psoriasis—as measured by PASI 100—at Week 16 and by Week 100, 76% reached zero plaque psoriasis. This type of improvement means some patients may be able to wear black again without their skin leaving flakes behind.

Dr. Wright:
Dr. BThomas_Rheum commented and makes a good point. Clear skin is often a priority for my patients with PsA that have active skin psoriasis. Imagine what it would be like for these patients if they didn't have visible plaques on their skin.

Dr. Shah:
Totally agree. And we know skin is just one aspect of PsA. Let's turn our focus to joints, specifically in patients who are bio-naïve. Dr. Schwartzman, can you walk us through that data from the BE OPTIMAL study?

Dr. Schwartzman:
In this study, bio-naïve patients had a mean swollen joint count of 9 at baseline. Can you imagine having 9 swollen joints across areas like your hands, wrists, and shoulders? By Week 16, 50% of patients taking BIMZELX achieved zero swollen joints, and by Week 104, 75% reached zero swollen joints.

Dr. Shah:
It's meaningful to see that level of disease activity drop to zero disease activity in swollen joints and have it sustained out to 2 years. Dr. EllenBRheum wants to know how we see these results in our practice. I have seen similar results in my practice. For some patients taking BIMZELX, that can mean being able to put on their wedding rings again.

I want to stay on bio-naïve patients with PsA, but let's switch gears to radiographic results. Dr. Schwartzman, can you take us through the data?

Dr. Schwartzman:
Certainly. I think this is one of the most important endpoints for many rheumatologists. 89% of patients taking BIMZELX who were bio-naïve with PsA had zero radiographic progression at Week 52, which is defined as a change from baseline in the van der Heijde modified Total Sharp Score of less than or equal to 0.5. That kind of structural preservation is exactly what we hope to see for our patients.

Dr. Wright:
And when we are aiming for meaningful response, we also need to be aware of the potential risks and have those discussions with our patients. Let's take a look at the safety profile.

In the BE OPTIMAL and BE COMPLETE Phase 3 trials, the most common adverse reactions occurring in greater than or equal to 2% of the BIMZELX group were upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infection. Those patients who completed these trials were able to enroll in the BE VITAL open-label extension trial, where BIMZELX demonstrated a consistent safety profile in both bio-naïve and bio-experienced patients with PsA for up to 3 years. Oral candidiasis cases were generally mild to moderate and most did not lead to treatment discontinuation, with zero cases of systemic candidiasis reported through 2 years.

Dr. Shah:
Here are the exposure-adjusted incidence rates of treatment-emergent adverse events of interest per 100 patient-years through 3 years. BIMZELX is approved with no contraindications and no boxed warning. Warnings and precautions include suicidal ideation and behavior, infections, tuberculosis, liver biochemical abnormalities, and inflammatory bowel disease.

Let's keep our focus on radiographic progression, but move to results in those with AS. Dr. Wright, what jumps out to you from the AS radiographic progression data.

Dr. Wright:
In the BE MOVING OLE, 85% of patients with AS who were taking BIMZELX had zero radiographic progression at Week 104. That means these patients experienced a change from baseline of mSASSS that was less than or equal to 0.5. This is the kind of outcome I hope for in my AS patients.

Dr. Shah:
I couldn't agree more. While this might not be something the patient comes in talking about, radiographic progression is something we're interested in monitoring.

Let's talk about one more. We touched on enthesitis in PsA, but we should discuss the impact of enthesitis in nr-axSpA. Dr. Schwartzman, care to walk us through?

Dr. Schwartzman:
In the BE MOBILE 1 clinical trial, improvement in enthesitis was based on the MASES score. The nr-axSpA patients who had baseline MASES greater than zero presented with around 5 sites of active enthesitis. By Week 16, 52% of patients taking BIMZELX achieved zero enthesitis as measured by achieving MASES equals zero, and by Week 104, 64% achieved zero sites of enthesitis.

Dr. Shah:
In the BE MOBILE 1 and BE MOBILE 2 Phase 3 trials, which evaluated nr-axSpA and AS patients, the most common adverse reactions occurring in 2% or more of nr-axSpA patients included upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections. The most common adverse reactions occurring in 2% or more of AS patients included upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection. Those patients who completed these trials were able to enroll in the BE MOVING open-label extension trial, where BIMZELX demonstrated a consistent safety profile in patients with either nr-axSpA or AS for up to 3 years.

Candidiasis cases were generally mild to moderate and most did not lead to treatment discontinuation, with zero cases of systemic candidiasis reported through 2 years.

Dr. Wright:
Here are the exposure-adjusted incidence rates of treatment-emergent adverse events of interest per 100 patient-years through 3 years. BIMZELX is approved with no contraindications and no boxed warning. Warnings and precautions include suicidal ideation and behavior, infections, tuberculosis, liver biochemical abnormalities, and inflammatory bowel disease.

Dr. Shah:
The data show that BIMZELX demonstrated efficacy over time in bio-naïve and bio-experienced patients with PsA and in nr-axSpA and AS patients, respectively. We covered how some patients achieved zero in one or more domains, such as swollen joints, enthesitis, psoriasis, and radiographic progression.

We've talked about the data and what zero disease activity means to us, but what does it mean for patients? What impact does this have?

Dr. Schwartzman:
I had a patient with AS that showed erosive disease on MRI, who did not respond to a TNF inhibitor. She had enthesitis of the Achilles and elbows that played a big role in preventing her from pursuing professional dancing. BIMZELX helped her get to zero enthesitis. Now she can put on her dance shoes without her Achilles hurting.

Dr. Wright:
One of my patients with PsA had longstanding joint involvement in his hands, knees, wrists. Over time taking BIMZELX, we started seeing fewer swollen joints. And then at one follow-up, he had no swollen joints. He said, "I didn't realize how much discomfort I'd gotten used to." That comment really stuck with me. Let's take another question.

“How do you talk to patients about zero without setting unrealistic expectations?” When I bring up the idea of zero disease activity in one or more domains, I always frame it as a treatment goal, not a guarantee. I will say something like, “We’re working to lower the inflammation as much as we can. For some people, that can mean certain symptoms, like swollen joints or enthesitis, may resolve.”

Dr. Schwartzman:
Exactly. We are always cautious about not over-promising. It is about showing patients what is possible, while still managing expectations. It gives them something to hope for, especially when they have been living with symptoms for a long time.

Dr. Shah:
Let’s bring this back to practice. How do you each think about integrating zero in one or more domains when setting treatment goals? Dr. Schwartzman, do you want to start us off?

Dr. Schwartzman:
Sure! Zero in one or more domains is becoming part of how I frame intent. If a patient has high disease burden in a specific domain, I think more critically about choosing a therapy that gives us a shot at resolution. Of course, every patient is different, and while the goal may be zero in one or more domains, it’s important to take an individualized approach considering disease severity, history, and what matters most to each patient. I make sure to weigh the potential risks and benefits when assessing treatment approach as well.

Dr. Wright:
I usually introduce it once we’ve made progress but still may have active disease. If they still have a few swollen joints or persistent enthesitis, it’s a way to say, “We’re close! Let’s keep going.”

Dr. Shah:
To shift the mindset, we also need to shift the language, right?

Dr. Wright:
Yes. Traditional metrics like ACR and ASAS responses matter, but patients respond to clearer targets, like swollen joints or plaques.

Dr. Schwartzman:
Having conversations with our patients about what their treatment goals are helps us understand which domains they are seeking to improve.

Dr. Shah:
Thank you for joining us for this episode of BIMZELX & Cold Brew. We hope these conversations help you think differently about treatment approaches and support the way you care for your patients! Please stay tuned for the Important Safety Information for BIMZELX, and see the full Prescribing Information. And keep your eyes out for the next video in the series!

Announcer:
INDICATIONS
BIMZELX (bimekizumab-bkzx) is indicated for the treatment of adults with active psoriatic arthritis, active non-radiographic axial spondyloarthritis with objective signs of inflammation, active ankylosing spondylitis, moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy, and moderate-to-severe hidradenitis suppurativa.

IMPORTANT SAFETY INFORMATION

Suicidal Ideation and Behavior
BIMZELX may increase the risk of suicidal ideation and behavior (SI/B). A causal association between treatment with BIMZELX and increased risk of SI/B has not been definitively established. Prescribers should weigh the potential risks and benefits before using BIMZELX in patients with a history of severe depression or SI/B. Advise monitoring for the emergence or worsening of depression, suicidal ideation, or other mood changes. If such changes occur, instruct to promptly seek medical attention, refer to a mental health professional as appropriate, and re-evaluate the risks and benefits of continuing treatment.

Infections
BIMZELX may increase the risk of infections, including serious infections. Do not initiate treatment with BIMZELX in patients with any 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 BIMZELX. Instruct patients to seek medical advice if signs or symptoms suggestive of clinically important infection occur. If a patient develops such an infection or is not responding to standard therapy, monitor the patient closely and do not administer BIMZELX until the infection resolves.

Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with BIMZELX. Avoid the use of BIMZELX in patients with active TB infection. Initiate treatment of latent TB prior to administering BIMZELX. Consider anti-TB therapy prior to initiation of BIMZELX in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Closely monitor patients for signs and symptoms of active TB during and after treatment.

Liver Biochemical Abnormalities
Elevated serum transaminases were reported in clinical trials with BIMZELX. Test liver enzymes, alkaline phosphatase, and bilirubin at baseline, periodically during treatment with BIMZELX, and according to routine patient management. If treatment-related increases in liver enzymes occur and drug-induced liver injury is suspected, interrupt BIMZELX until a diagnosis of liver injury is excluded. Permanently discontinue use of BIMZELX in patients with causally associated combined elevations of transaminases and bilirubin. Avoid use of BIMZELX in patients with acute liver disease or cirrhosis.

Inflammatory Bowel Disease
Cases of inflammatory bowel disease (IBD) have been reported in patients treated with IL-17 inhibitors, including BIMZELX. Avoid use of BIMZELX in patients with active IBD. During BIMZELX treatment, monitor patients for signs and symptoms of IBD and discontinue treatment if new onset or worsening of signs and symptoms occurs.

Immunizations
Prior to initiating therapy with BIMZELX, complete all age-appropriate vaccinations according to current immunization guidelines. Avoid the use of live vaccines in patients treated with BIMZELX.

MOST COMMON ADVERSE REACTIONS

Most common (≥1%) adverse reactions in plaque psoriasis and hidradenitis suppurativa include upper respiratory tract infections, oral candidiasis, headache, injection site reactions, tinea infections, gastroenteritis, herpes simplex infections, acne, folliculitis, other candida infections, and fatigue.

Most common (≥2%) adverse reactions in psoriatic arthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, and urinary tract infections.

Most common (≥2%) adverse reactions in non-radiographic axial spondyloarthritis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, cough, fatigue, musculoskeletal pain, myalgia, tonsillitis, transaminase increase, and urinary tract infections.

Most common (≥2%) adverse reactions in ankylosing spondylitis include upper respiratory tract infections, oral candidiasis, headache, diarrhea, injection site pain, rash, and vulvovaginal mycotic infection.

Please see the full Prescribing Information at BIMZELXhcp.com.

References:

1. BIMZELX [prescribing information]. Smyrna, GA: UCB, Inc.
2. Data on file. UCB, Inc., Smyrna, GA.
3. Ritchlin CT, et al. *Ann Rheum Dis.* 2023;82(11):1404–1414.
4. Mease PJ, et al. *Rheumatol Ther.* 2024;11(5):1363–1382.
5. Coates LC, et al. *Nat Rev Rheumatol.* 2022;18(8):465–479.
6. Ward MM, et al. *Arthritis Rheumatol.* 2019;71(10):1599–1613.
7. Gossec L, et al. *J Rheumatol.* 2018;45(1):6–13.
8. Mease PJ, et al. *Semin Arthritis Rheum.* 2018;47(6):786–796.
9. Almodóvar R, et al. *Reumatol Clin (Engl Ed).* 2021;17(6):343–350.
10. McInnes IB, et al. *Lancet.* 2023;401(10370):25–37.
11. Merola JF, et al. *Lancet.* 2023;401(10370):38–48.
12. van der Heijde D, et al. *Ann Rheum Dis.* 2023;82(4):515–526.

13. van der Heijde D, et al. *Ann Rheum Dis.* 2023;82(4)(suppl):S1–S27.
14. Gossec L, et al. Poster presented at: EULAR 2025; June 11–14, 2025; Barcelona, Spain. POS1294.
15. McInnes IB, et al. Poster presented at: EULAR 2025; June 11–14, 2025; Barcelona, Spain. POS0105.
16. Baraliakos X, et al. *Rheumatology (Oxford).* 2025;64(6):3534–3546.
17. Baraliakos X, et al. *Ann Rheum Dis.* 2024;83(2):199–213.