Podcast Transcript

Early Decisions and Impact: An IL-23 Inhibitor in Bio-Naive Patients With PsA
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Speakers:
1. **Dr. Alvin Wells**
2. **Dr. Shikha Singla**

Run time length: 13:40 minutes

Topic		Speaker talking points
1	Opening (~38 seconds)	**Dr. Wells** Welcome to RheumNow. This podcast is sponsored by and developed by AbbVie U.S. Medical Affairs. My name is Alvin Wells. I'm a board-certified rheumatologist. I'm the Director of Rheumatology at the American Medical Group in Destin, Florida. I'm pleased to have one of my colleagues join me today, Dr. Singla. Welcome to the podcast. Do you mind introducing yourself? **Dr. Singla** I'm Shika Singla. I am an Associate Professor at the Medical College of Wisconsin and the Director of the Psoriatic Arthritis Program.
2	Clinical perspectives on the treatment journey with RZB in biologic-naive patients with PsA (~3 minutes)	**Dr. Wells** If you have a patient who has psoriatic arthritis, we know they can't get into the clinic to see us tomorrow, and research says if a patient with PsA has a diagnosis delay of over a year, that's going to result in worse disease progression and reduced remission rates.[1,2] There's also data that shows that even a diagnostic delay of 6 months has been associated with more radiologic damage and functional limitations.[3] Such studies suggest that an earlier diagnosis and earlier treatment is what we really should be focusing on. Let's talk about that, and what that really means for our patient with PsA, and some of the long-term benefits, Dr. Singla? **Dr. Singla** Dr. Wells, an abstract presented earlier this year at EULAR showed that patients with newly diagnosed moderate to severe psoriatic arthritis treated with biologics had better arthritis and skin outcomes, and these were measured by DAPSA and PASI scores at Week 24, compared to patients receiving a standard conventional DMARD therapy.[4] While some data potentially support the idea of treating psoriatic arthritis fast and hard with a biologic, how to best position biologics in PsA treatment algorithm is still being established. **Dr. Wells** What gets you motivated about treating a patient who's biologic-naive, and what kind of things do you take into mind?

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		Dr. Singla I believe in shared decision-making and individualized care for my patients. When evaluating a patient, I pay attention to the predominant disease manifestations and severity of the disease. I also consider comorbidities, such as depression, anxiety, diabetes, and inflammatory bowel disease.[5] The lifetime risk for developing IBD is more than 4 times greater for patients with psoriatic arthritis than in the general population.[6-8] This risk should be considered when selecting therapies, as some treatments for psoriatic arthritis may worsen or improve IBD.[6] According to GRAPPA guidelines, symptoms prompting IBD evaluation in patients with psoriatic arthritis include chronic diarrhea lasting for more than 3 months, nocturnal bowel symptoms, rectal bleeding, perianal fistulas, or abscesses, chronic abdominal pain, and weight loss.[6] In addition to guidelines, a real-world analysis based on claims data involving 130,000 patients with psoriatic arthritis highlighted additional risk factors that should be considered including a history of gastrointestinal procedures or tests, such as stool tests, previous diagnosis of gastroenteritis, nausea, vomiting, and family history of IBD.[9] Identifying these factors is important for appropriate referral and treatment choices.
3	Overview of KEEPsAKE Trial Program (~2 minutes)	**Dr. Wells** We also know that there's some research ongoing providing some long-term evidence of outcomes for our patients. Can you talk to the audience about that and introduce the KEEPsAKE Trial Program? **Dr. Singla** Of course, Dr. Wells. This program was developed to assess the efficacy and safety of risankizumab, let's call it risa, an IL-23–inhibiting antibody, in adult patients with active psoriatic arthritis.[10,11] There are actually two KEEPsAKE trials, both Phase III, double-blinded, randomized controlled trials, with the primary endpoint of ACR20 at Week 24.[10,11] KEEPsAKE 1 enrolled only bio-naive patients, and KEEPsAKE 2 enrolled both bio-naive patients and patients who have already been on a biologic and had inadequate response.[10,11] We are going to focus on KEEPsAKE 1, in which 483 participants were randomized to receive subcutaneous 150 mg risa at Weeks 0, 4, and 16, and 481 participants were randomized to receive placebo.[10] KEEPsAKE 1 met the primary endpoint, which was ACR20, and 57% of patients achieved this endpoint as compared to about one third of patients on placebo. Additionally, at Week 24, there were about one-third, 33.4%, treated with risa who achieved ACR50 compared to 11.3% in the placebo group. And 52.3% of participants treated with risa who had 3 or more percentage of body surface area due to psoriasis at baseline achieved 90% skin clearance, or PASI90, compared to about 10% in the placebo group.

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		Dr. Wells I think the nice thing that you highlighted in the KEEPsAKE trial, it not only works for the joints, but also for the skin. Let's take a look at those patients who were on risankizimab as their first biologic. How did they fare long-term, particularly with the joint outcomes?
4	KEEPsAKE 1 long-term efficacy (~2.5 minutes)	**Dr. Singla** In KEEPsAKE 1, an open-label extension period at 5 years showed that 73% of patients out of 483 in the risa arm remained in the study.[12] And out of these patients, 54% of patients receiving continuous risa achieved ACR20, 36.2% achieved ACR50, and 33.7% achieved minimal disease activity.[13] Looking at radiographic progression, while changes from baseline in psoriatic arthritis modified Total Sharp Score did not differ statistically at Week 24 between the risa and placebo groups, an exploratory analysis was performed and that showed that 92% of the patients treated with risa and 88% of patients in the placebo arm had no radiographic progression.[10] After 5 years, 88% or 298 of 337 patients receiving risa showed no radiographic progression.[13] Dr. Wells, it is so important to note that open-label extension trials, like the one we are describing, have a potential for enrichment of long-term data in the remaining patient population, since the patients who are unable to tolerate or do not respond to the drug often drop out. **Dr. Wells** So, taken together, the KEEPsAKE open-label extension suggests long-term benefits in those patients who are bio-naïve. I also want to discuss the post-hoc analysis of the KEEPsAKE trial data that looked at the maintenance of clinical responses after 5 years of risa treatment.[14] For bio-naive patients in KEEPsAKE 1 receiving risankizumab, 66.7% out of 267 patients who achieved ACR20 at Week 24 maintained the ACR20 response at approximately 5 years. 55% out of 151 patients who achieved the ACR50 at Week 24 maintained the ACR50 response at approximately 5 years. Improvements in skin were also seen, with 71.5% of respondents out of 144 patients at Week 24 maintaining the achievement of PASI90 at approximately 5 years. **Dr. Singla** Dr. Wells, these data provide such valuable information on long-term efficacy with risankizumab in both joints and skin. **Dr. Wells** At the end of the day, we gotta balance the efficacy with the safety. So, let's talk about some of the long-term safety data in patients treated with risankizumab.
5	KEEPsAKE 1 long-term safety (~1.75 minutes)	**Dr. Singla** At 5 years in the open-label extension of the KEEPsAKE 1 trial, no new safety signals were detected,[13] and the safety profile was similar to what was previously reported in patients with psoriasis.[15] In an integrated safety analysis with up to 6 years of exposure to risankizumab in psoriatic arthritis, the rate of events per 100 patient years was less than 0.1 for hypersensitivity, 1.6 for serious infection, less than 0.1 for opportunistic infections,

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		excluding tuberculosis and herpes zoster, there were no active TB cases, 0.3 for herpes zoster, and 6.6 for hepatic events.[16] The most common adverse events were similar to what you and I see in our clinics, which were upper respiratory tract infections, headaches, fatigue, injection site reactions, and tinea infection.[15] Additional information regarding the safety of risa in patients with psoriatic arthritis can be found on the RheumNow Therapeutic Updates page. Shared decision-making between a rheumatologist and patients with psoriatic arthritis is essential for identifying the most appropriate treatment approach. The long-term safety profile of treatment is a critical factor as part of the decision. **Dr. Wells** So, we talked about some of the long-term efficacy and safety in patients with PsA from the clinical trials. Some people say that doesn't really reflect my practice. I need some real-world data. Are there any kind of real-world studies out there with risankizumab?
6	Real-world persistence from US claims analysis (~30 seconds)	**Dr. Singla** Great question, Dr. Wells. A real-world study in patients with psoriatic arthritis was conducted to evaluate the persistence of first-line advanced therapies.[17] Persistence was defined as no treatment switch or discontinuation. The study found that 76.3% of patients with psoriatic arthritis persisted on risa at 12 months. It is important to note that this study was based on claims data, which can be incomplete, inaccurate, and have missing data sometimes.[18]
7	Final thoughts (~15 seconds)	**Dr. Wells** I don't know about my audience, but you got me fired up, Dr. Singla, because think about what you shared with us today. You talk about it in the clinic, we often focus on the initial effects of a therapy, but guess what? This is a chronic disease. I need to make sure that patients are going to be doing well long-term.
8	Closing (~45 seconds)	**Dr. Wells** I like what you said to start the whole podcast. You want to treat early and treat aggressive and use evidence-based medicine to help guide you and other providers to getting your patient with psoriatic arthritis under control. These are excellent points, Dr. Singla. Thank you so much for your time and talking with us today. **Dr. Singla** Thank you so much, Dr. Wells. **Dr. Wells** If you'd like to learn more about the KEEPsAKE trials and long-term safety of risankizumab in bio-naive patients with PsA, check out the RheumNow Therapeutics Updates page. If you're interested in learning more about the treatment response of risankizumab in bio-naive patients, please see the link to our previous RheumNow therapeutics update shown below this podcast. And finally, please listen to the risankizumab important safety considerations next. Thank you all for your time and thank you for listening.

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	Indication (~2 minutes)	Risankizumab, a humanized monoclonal antibody to IL-23, is indicated for the treatment of active psoriatic arthritis in adults and moderate to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy. Risankizumab is contraindicated in patients with a history of serious hypersensitivity reaction to risankizumab or any of the excipients. Serious hypersensitivity reactions, including anaphylaxis, may occur. If a serious hypersensitivity reaction occurs, discontinue risankizumab and initiate appropriate therapy immediately. Risankizumab may increase the risk of infections. Instruct patients to seek medical advice if signs or symptoms of clinically important infection occur. If such an infection develops, discontinue risankizumab until the infection resolves. Evaluate patients for tuberculosis infection prior to initiating treatment with risankizumab. Avoid use of live vaccines in patients treated with risankizumab. The most common adverse reactions (greater than or equal to 1%) are upper respiratory infections, headache, fatigue, injection site reactions, and tinea infections. Review accompanying risankizumab full Prescribing Information for additional information by visiting www.rxabbvie.com/pdf/skyrizi_pi.pdf or contact AbbVie Medical Information at 1-800-633-9110.

Abbreviations:

ACR20/ACR50, improvement of ≥20%/≥50% in American College of Rheumatology core criteria; DAPSA, Disease Activity in Psoriatic Arthritis score; DMARD, disease-modifying antirheumatic drug; EULAR, European Alliance of Associations for Rheumatology; GRAPPA, Group for Research and Assessment of Psoriasis and Psoriatic Arthritis; IBD, inflammatory bowel disease; IL, interleukin; PASI, Psoriasis Area and Severity Index; PASI90, improvement of ≥90% in PASI; PsA, psoriatic arthritis; TB, tuberculosis.

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