Transcript Details

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Real-World Patient Cases in RMS Care, Part 1: RMS and Treatment Considerations

Announcer:
Welcome to ReachMD.

This medical industry feature, titled “Real World Patient Cases in MS Care Part 1: Slowing RMS Progression” is sponsored by Novartis Pharmaceuticals Corporation and the presenters have been compensated for their time.

Dr. Pardo
You’re listening to ReachMD.

This medical industry feature, titled “KESIMPTA: Call for Cases podcast,” is sponsored by Novartis Pharmaceuticals Corporation. This program is intended for US health care professionals. The Important Safety Information for KESIMPTA will be available at all times underneath the player of this audio presentation. A link to the full Prescribing Information, including the Medication Guide, is available at the bottom of the presentation

The speakers have been compensated by Novartis Pharmaceuticals Corporation (NPC) to conduct this presentation.

Welcome, everyone, to our ReachMD podcast about KESIMPTA®, also called ofatumumab.

My name is Dr Gabriel Pardo, and I am a neurologist and the Director of the Oklahoma Medical Research Foundation Multiple Sclerosis Center of Excellence. I have been dedicated to the treatment and research of multiple sclerosis for over two decades.

This is part 1 of a series of 3 podcasts where we discuss real-world patients who were candidates for KESIMPTA. We'll share our clinical perspectives on each case, how we discussed treatment options with our patients, and what we considered when deciding on an appropriate therapy. Finally, we'll discuss why we felt KESIMPTA was a good option for these patients.

Let’s introduce our panel. John, let’s start with you.

Mr. Kramer
Hello, everyone! My name is John Kramer, and I am a physician assistant, practicing at St. Thomas Medical Partners here in Nashville, Tennessee. I have been in the field of MS now for the past 21 years.

Dr. Pardo
Thank you, John. Dr Bloch, can you introduce yourself?

Dr. Bloch
Hello! My name is Dr Melissa Bloch, and I am a MS neurologist at Renown Neurology in Reno, Nevada. I’ve been practicing here for 22 years.

Dr. Pardo
Thank you everyone, before we get started, I think it is important for our listeners to hear the indication for KESIMPTA. KESIMPTA is indicated for the treatment of relapsing forms of multiple sclerosis in adults. This includes clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease.

KESIMPTA is contraindicated in patients with active hepatitis B infection.

After the initial dosing period, KESIMPTA is a monthly, self-administered, subcutaneous injection and is available as a single-dose,

prefilled Sensoready® Pen.

Now, let me introduce you to our first patient, Jane, though that is not her real name.

Jane was referred to my practice in 2020. She is a 29-year-old African American female who has a fast-paced job as a circulating nurse in a surgical center, and her schedule is very demanding. However, she's able to keep physically active and is otherwise healthy with no comorbidities, including being a nonsmoker. Her health is clearly important to her, and she's a yoga instructor on the weekends. It was important for us to work together to identify a treatment option that will fit into her busy schedule, and a treatment option with proven efficacy and safety to help slow disability progression of her relapsing MS.

Dr. Bloch
How did Jane first present and how did she come to your practice?

Dr. Pardo
One day she noticed being unusually clumsy while picking up and handling surgical instruments during procedures. Then, later in the day, at home, she noticed numbness in her right hand. By the following morning, the sensory deficits extended to the distal forearm and she noticed horizontal double vision when looking to the right.

Mr. Kramer
Did she see a doctor right away?

Dr. Pardo
Jane was examined by a neurosurgeon at her workplace, who advised her to obtain a cervical spine MRI, which was ordered by her primary care physician. The MRI showed a gadolinium-enhancing intramedullary lesion at the level of C3. She was then referred to our MS center, where a left internuclear ophthalmoplegia, or INO, was identified. MRI of the brain showed multiple areas of T2 signal in the juxtacortical and periventricular white matter and in the pons, some of which had post-contrast enhancement.

Dr. Bloch
What was the initial treatment?

Dr. Pardo
Given the burden of disease, extent of inflammatory activity, and functional impact of her deficits, she received a 3-day course of high-dose IV steroids with partial improvement of her deficits. EDSS score went up 2.5 during the acute event, then to 1.0 two weeks after steroids, at which time she only had a subtle left INO without diplopia and no lingering sensory deficits. She met the McDonald diagnostic criteria and I diagnosed her with relapsing multiple sclerosis.

So Dr Bloch, what do you think about Jane's case?

Dr. Bloch
Well, relapsing multiple sclerosis symptoms differ from patient to patient and can manifest in a variety of ways. Some of the physical signs that can be tracked over time include weakness or problems with ambulation and coordination, numbness or loss of sensation, and muscle spasticity. However, changes in some functional domains may be more subtle, such as trouble with memory or concentration, vision problems, bowel or bladder and sexual dysfunction, and difficulty with speech or swallowing. Jane is a surgical nurse and is experiencing visual abnormalities, which is worrisome. She also has spinal cord lesions on her MRI and is clearly having symptoms. Our goal is to keep her walking and moving as much as possible.

Dr. Pardo
Let me open it up to the group. What are your initial impressions of this patient case? Do you think a high efficacy disease-modifying therapy (DMT) may be appropriate? John, let's start with you.

Mr. Kramer
What struck me about this case was that Jane has certain prognostic factors that could potentially put her at risk for a poor prognostic outcome with her disease. She is African American, with significant lesion load at baseline and enhancing lesions. Jane had a multifocal onset of disease activity with sensory and brainstem symptom involvement. She has improved from her relapse, but it is too early to tell if her deficits are permanent.

Because Jane is relatively young, I would suggest a high efficacy therapy to give her the chance to slow disability progression.

Dr. Bloch
I agree with John. High efficacy treatment is appropriate because of her prognostic factors. Jane also had multiple lesions on her brain and spinal cord, and a common goal of treatment is to reduce lesion development. High lesion burden may indicate that a high efficacy

therapy is warranted.

Mr. Kramer
How did you approach the conversation with Jane about diagnosis and treatment?

Dr. Pardo
Well, after I shared my diagnosis with her, she wanted to know everything about relapsing MS. So I explained the disease course and possible symptoms. Then she wanted additional resources to read on her own. When I got into the topic of treatment, I emphasized the importance of starting therapy as soon as possible to slow the disease course. She was eager to start treatment, but I also made sure to explain that there is no cure and that we can only help delay the disability progression.

Dr. Bloch
I agree, it's good to emphasize that. What were Jane's treatment goals?

Dr. Pardo
Yes, it is. I asked Jane what she was looking for in a treatment. She was very anxious that a relapse could occur at any time. She also wanted to reduce disability progression, since being a nurse at a surgical center requires a high degree of mobility and dexterity. John, how do you approach the conversation about diagnosis and treatment with your patients?

Mr. Kramer
I explain that RMS is a disease that attacks the neurons in the brain and spinal cord and that it's important to start treatment right away to slow disease progression. I discuss with patients that our goal with treatment is to reduce relapses, reduce the risk of new MRI lesions, and reduce risk of further accumulation of physical disability.

Dr. Pardo
I agree with you both. I recommended KESIMPTA to Jane because of the pivotal clinical data and route of administration.

When I consider a DMT, one consideration is whether or not the patient fits within the baseline demographics of the clinical studies for that DMT. Looking at the eligibility criteria, I saw that Jane's characteristics aligned with those of the patient population studied in the Phase 3 ASCLEPIOS trials for KESIMPTA. For example, patients in the Phase 3 trials had an EDSS score between 0 and 5.5, were 18 to 55 years old, and had active disease in the previous 2 years. To recap, Jane is 29 years old, diagnosed with relapsing MS with an EDSS score of 1.0 after she recovered from the relapse, and she had several gadolinium-enhancing lesions at the time of presentation.

Dr. Bloch
Jane was worried about relapses, and I agree with her goal of finding a treatment that is effective at reducing relapses. In my experience, relapses affect patients in a variety of ways.

Dr Pardo, we're all familiar with teriflunomide as a treatment for relapsing multiple sclerosis. How did you explain the KESIMPTA relapse data to Jane?

Dr. Pardo
The reason I showed Jane the KESIMPTA data was because in the trial, there was a significant reduction in the annualized relapse rate in comparison to teriflunomide. Based on the primary endpoint, this would translate to approximately 1 relapse every 10 patient-years.

John, what are your thoughts about these data and what they mean for this patient?

Mr. Kramer
Given how much a relapse impacts my patients', many of my patients prioritize reducing relapses. When presenting relapse data, it's important that the relapse data align with my patient's goals and clinical picture. KESIMPTA is a high efficacy therapy that has head-to-head data against another FDA-approved DMT, teriflunomide, which is shown to reduce the annualized relapse rate and risk of disability progression in RMS patients.

Mr. Kramer
Dr Pardo, you mentioned that Jane had multiple T2 lesions in her brain and spinal cord, including gadolinium-enhancing lesions. This sounds like she has a high lesion burden. Was this also a consideration for choosing KESIMPTA?

Dr. Pardo
Yes. I explained that it's important to reduce the number of new lesions that develop. I then reviewed the KESIMPTA MRI end points with her. I said that KESIMPTA was shown to be very effective at reducing the number of lesions, and I pointed out the enhancing lesions on her MRI scan. KESIMPTA also reduced the number of new and enlarging T2 lesions compared to teriflunomide, which was also important.

Dr. Bloch
Another treatment goal for Jane was to slow disability progression, since she works in surgery and is on her feet all day. I think the KESIMPTA disability progression data are very relevant here. KESIMPTA significantly reduced the risk of 3-month and 6-month confirmed disability progression compared to teriflunomide in a pooled Phase 3 population.

Were you able to explain disability progression results to Jane?

Dr. Pardo
Yes, once I reviewed the MRI and exam results, Jane and I had an open discussion about the natural evolution of the disease if she were to be untreated and the accumulation of permanent disability. I explained that the mechanism for potential accumulation of disability involves components of inflammatory activity with relapses and lesions in the MRI.

Mr. Kramer
When discussing treatment goals, we think about relapse reduction, MRI activity, and slowing disability progression.

There was a post hoc analysis that was done with ASCLEPIOS I and II based on relapse activity, disease worsening, gadolinium-enhancing T1 lesions, and new/enlarging T2 lesions called NEDA-3, however no conclusions of clinical outcomes can be drawn. Because of our limited time today, listeners can find more information about NEDA-3 at kesimptahcp.com.

Dr. Pardo
Safety can make therapeutic choices challenging, because there's uncertainty about disease progression and a need to weigh relapsing MS risk versus treatment risk.

Choosing a treatment approach that considers disease activity, safety, and individual patient factors is critical to management relapsing MS and is something that I try to take into account when I meet with patients.

Jane had significant disease activity on her MRI scan. I believe KESIMPTA is appropriate based on its safety profile.

Mr. Kramer
I agree about the safety profile of KESIMPTA. In the Phase 3 studies, KESIMPTA had a safety profile similar to teriflunomide. The percentage of patients with adverse events leading to discontinuation was also similar between the KESIMPTA and teriflunomide arms —between 5% and 6% in both trials. I'd also like to note that KESIMPTA is an injectable therapy, and local injection-site reactions were all mild to moderate in severity.

The most common adverse reactions >10% are upper respiratory tract infection, headache, injection-related reactions, and local injection-site reactions.

Dr. Bloch
How did Jane feel about injections?

Dr. Pardo
Jane had never been on any DMT before, so she didn't have prior experiences with injections for managing her relapsing MS.

Mr. Kramer
What about access to an infusion center?

Dr. Pardo
Well, Jane lives in a city with several infusion centers, but it’s hard for her to take time from work to go there, especially for more than a day. She also has limited sick days, so it may be difficult to commit to infusion dates.

Dr. Bloch
My practice has an attached infusion center, but sometimes there’s an infusion cost on top of the medication cost, which makes it more expensive for patients. I also have patients who live 2 to 4 hours away from my infusion center, so home therapies are especially important for our rural communities. Many patients also preferred at-home therapies during the pandemic to avoid public or crowded spaces.

Mr. Kramer
Dosing frequency also seems to be a concern for your patient. A monthly at-home won’t have that daily reminder that she has to take a treatment for her RMS. To that end, the Alongside™ KESIMPTA® program can provide ongoing support to supplement the treatment plan. There’s an option for patients to receive monthly injection reminders via phone, text, or email, which may be useful for some of my patients.

Dr. Pardo
So to conclude, after discussing various data and decision factors with Jane, we ultimately chose KESIMPTA. Our main reasons were the efficacy and the flexibility it gives her. Her priorities were to make sure that her treatment fit into her routine. Being able to administer KESIMPTA means she can spend her time where she wants.

Dr. Bloch
Thanks for telling us about Jane, Dr Pardo. Is there anything else you'd like to add?

Dr. Pardo
Yes, one final observation is that Novartis makes it easy to get a patient started on KESIMPTA. The Bridge program provides immediate access to treatment and financial assistance for patients who have commercial insurance, but whose paperwork is still processing. This was especially helpful for Jane. My practice staff also can process the paperwork for KESIMPTA and contact Novartis with any issues.

Thank you for listening. In the next episode, John Kramer will discuss the concerns and considerations that compelled one of his patients to switch from a high efficacy infusion to KESIMPTA.

INDICATION AND IMPORTANT SAFETY INFORMATION

KESIMPTA (ofatumumab) is indicated for the treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.

IMPORTANT SAFETY INFORMATION

Contraindication: KESIMPTA is contraindicated in patients with active hepatitis B virus infection.

WARNINGS AND PRECAUTIONS

Infections

An increased risk of infections has been observed with other anti-CD20 B-cell depleting therapies. KESIMPTA has the potential for an increased risk of infections including serious bacterial, fungal, and new or reactivated viral infections; some have been fatal in patients treated with other anti-CD20 antibodies. The overall rate of infections and serious infections in KESIMPTA-treated patients was similar to teriflunomide-treated patients (51.6% vs 52.7%, and 2.5% vs 1.8%, respectively). The most common infections reported by KESIMPTA-treated patients in relapsing MS (RMS) trials included upper respiratory tract infection (39%) and urinary tract infection (10%). Delay KESIMPTA administration in patients with an active infection until resolved.

Consider the potential increased immunosuppressive effects when initiating KESIMPTA after an immunosuppressive therapy or initiating an immunosuppressive therapy after KESIMPTA.

Hepatitis B Virus

Reactivation: No reports of hepatitis B virus (HBV) reactivation in patients with MS treated with KESIMPTA. However, HBV reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death, has occurred in patients treated with ofatumumab at higher intravenous doses for chronic lymphocytic leukemia (CLL) than the recommended dose in MS and in patients treated with other anti-CD20 antibodies.

Infection: KESIMPTA is contraindicated in patients with active hepatitis B disease. Fatal infections caused by HBV in patients who have not been previously infected have occurred in patients treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. Perform HBV screening in all patients before initiation of KESIMPTA. Patients who are negative for HBsAg and positive for HB core antibody [HBcAb+] or are carriers of HBV [HBsAg+], should consult liver disease experts before starting and during KESIMPTA treatment.

Progressive Multifocal Leukoencephalopathy

No cases of progressive multifocal leukoencephalopathy (PML) have been reported for KESIMPTA in RMS clinical studies; however, PML resulting in death has occurred in patients being treated with ofatumumab at higher intravenous doses for CLL than the recommended dose in MS. In addition, JC virus infection resulting in PML has also been observed in patients treated with other anti-CD20 antibodies and other MS therapies. If PML is suspected, withhold KESIMPTA and perform an appropriate diagnostic evaluation. If PML is confirmed, KESIMPTA should be discontinued.

Vaccinations

Administer all immunizations according to immunization guidelines: for live or live-attenuated vaccines at least 4 weeks and, whenever

possible at least 2 weeks prior to starting KESIMPTA for inactivated vaccines. The safety of immunization with live or live-attenuated vaccines following KESIMPTA therapy has not been studied. Vaccination with live or live-attenuated vaccines is not recommended during treatment and after discontinuation until B-cell repletion.

Vaccination of Infants Born to Mothers Treated with KESIMPTA During Pregnancy

For infants whose mother was treated with KESIMPTA during pregnancy, assess B-cell counts prior to administration of live or live-attenuated vaccines. If the B-cell count has not recovered in the infant, do not administer the vaccine as having depleted B-cells may pose an increased risk in these infants.

Injection-Related Reactions

Injection-related reactions with systemic symptoms occurred most commonly within 24 hours of the first injection, but were also observed with later injections. There were no life-threatening injection reactions in RMS clinical studies.

The first injection of KESIMPTA should be performed under the guidance of an appropriately trained health care professional. If injection-related reactions occur, symptomatic treatment is recommended.

Reduction in Immunoglobulins

As expected with any B-cell depleting therapy, decreased immunoglobulin levels were observed. Monitor the levels of quantitative serum immunoglobulins during treatment, especially in patients with opportunistic or recurrent infections and after discontinuation of therapy until B-cell repletion. Consider discontinuing KESIMPTA therapy if a patient with low immunoglobulins develops a serious opportunistic infection or recurrent infections, or if prolonged hypogammaglobulinemia requires treatment with intravenous immunoglobulins.

Fetal Risk

Based on animal data, KESIMPTA can cause fetal harm due to B-cell lymphopenia and reduce antibody response in offspring exposed to KESIMPTA in utero. Transient peripheral B-cell depletion and lymphocytopenia have been reported in infants born to mothers exposed to other anti-CD20 B-cell depleting antibodies during pregnancy. Advise females of reproductive potential to use effective contraception while receiving KESIMPTA and for at least 6 months after the last dose.

Most common adverse reactions

(>10%) are upper respiratory tract infection, headache, injection-related reactions, and local injection-site reactions.

Announcer:

This program was sponsored by Novartis Pharmaceuticals Corporation. If you missed any part of this discussion, visit reach-m-d-dot-com-industryfeature. This is ReachMD. Be Part of the Knowledge.

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