Transcript Details
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Real-World Patient Cases in RMS Care, Part 2: Considering Other Treatment Options

Announcer:

Welcome to ReachMD. This medical industry feature, titled “Real-World Patient Cases in MS Care, Part 2: Switching Therapies” is sponsored by Novartis Pharmaceuticals Corporation, and the presenters have been compensated for their time.

Mr. Kramer

Welcome back! Who is the right patient for KESIMPTA? Today, we'll discuss one of my real-world patients. I’m John Kramer physician assistant, and I practice as St. Thomas Medical Partners here in Nashville, Tennessee. I’ve worked in the field of MS now for the past 21 years, and I’m joined for the second installment in a 3-part audio podcast series by 2 of my fellow MS experts, Dr Gabriel Pardo and Dr Melissa Bloch.

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

Hello, everyone! My name is Dr Gabriel Pardo. 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 of multiple sclerosis for over two decades.

Mr. Kramer

Before we get into it, first we should tell our listeners about 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 HBV infection.

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

My patient, who lives 50 miles away from the nearest infusion center and is currently on high efficacy therapy with no disease activity, wanted to switch to a therapy that he can do on his own. After discussing with my patient, we wanted to continue a high efficacy therapy. We'll call my patient "Mike," though that's not his real name. Mike was a 40-year-old white male diagnosed with RMS 3 years ago. He had no comorbidities and no history of smoking. Adding to that, he had a long commute to his job, but his work hours were otherwise typical. He also had a young family and coached his kids' sports teams.

Dr. Bloch

So what were his first symptoms?

Mr. Kramer

Well, he first noticed numbness, tingling, and weakness in his legs. The symptoms got worse when he did high-intensity workouts at the gym. After about 2 months, though, the symptoms seemed to have resolved, and he stopped thinking about them. Unfortunately, 4

months after that, he noticed that he couldn't run as well when playing with his kids.

Dr. Pardo

Is that when he saw his primary care physician about these symptoms?

Mr. Kramer

Yes, because Mike knew something just wasn't right. His PCP suspected that his symptoms were neurological and referred him to my clinic. His neurological exam was abnormal, and there was evidence of upper motor neuron weakness in his legs, greater on the right side than the left. His sensory exam was abnormal as well, with decreased vibratory sensation loss in his feet compared to his upper extremities. I became concerned that his symptoms were possibly related to MS, and looking back, I realize that based on his exam he was already at a 2.5 score on the EDSS.

Dr. Bloch

What did his MRI results show?

Mr. Kramer

His brain and cervical cord MRI showed evidence for an enhancing lesion in the periventricular white matter, and a single T2 lesion seen at C5 in the cervical cord. The supporting laboratory MS rule-outs were unremarkable. Considering that he had 2 incidents localizable to the central nervous system in the setting of enhancing and non-enhancing lesions, I felt confident telling him that this was multiple sclerosis.

Dr. Pardo

Mike also presented with myelitis, which was confirmed with the MRI showing that the patient did have a lesion in his spinal cord plus active lesions in the brain, so the diagnosis of relapsing MS was clear.

Because there was early involvement of the spinal cord and brainstem, there was a higher level of concern regarding prognosis.

The sensory loss described in the lower extremity was secondary to the spinal cord lesion and was also a poor prognostic factor regarding his ability to preserve his gait and mobility long term. Sensory ataxia may develop, which affects the ability to walk and accumulates over time.

Dr. Bloch

I agree; the MRI results seemed to match the patient’s symptoms. Since he was already showing some effects on disability progression, I'd want to choose a treatment that could help reduce disability progression and reduce new lesions.

What did you decide to prescribe, and how's he doing now?

Mr. Kramer

It’s been 3 years since his diagnosis, and I’m happy to report that clinically and radiographically Mike has done well, with reduced relapses and no new lesion activity on MRI since treatment initiation.

However, while he's doing well from a clinical perspective, he asked if it was possible to switch to a different medicine.

Dr. Pardo

If his current therapy was managing his disease well, why did he want to switch?

Mr. Kramer

At one of our regular checkups, Mike told me that going to and from the infusion center took a big chunk of time away from childcare and his personal life. Overall, infusions took too much time away from his kids and job.

Mike isn't the first patient of mine to have these reasons to switch from infusions to injectables. But in my experience, it can take a few years for patients to feel comfortable enough to voice these concerns with their HCP.

Dr. Pardo

I want to step back and say there are a few reasons, in my clinical experience, where I would consider switching my patients to a different medication. First, if the patient is having issues on their current DMT, that would be a reason to consider a treatment change. The second is if the patient has increased disease activity despite being on therapy. In that case, I would switch a patient to a different

mechanism of action. The third consideration for switching can be logistics.

Mike was doing well from a clinical perspective on his current medication. So I would be inclined to keep him on a high efficacy therapy. However, he spent a lot of time driving to an infusion center and voiced that he wanted to spend more time with his family, so I would consider switching.

John, I want to build on your earlier point about getting patients to feel comfortable sharing their treatment experiences and offer my approach. I try to set the tone at the very beginning of the patient–doctor relationship that we are both committing to a long-term relationship. Like any other relationship, we have to rely on honesty and full disclosure for it to work.

I think it is the responsibility of the health care professional to bring up issues that individuals might not think about discussing, they might be embarrassed about, or they think are not relevant, but they are. So there is a degree of diligence that we have to have during the interview. I go point by point, discussing the potential manifestations and side effects so that not only do we encourage patients to be spontaneous, but we also go back and specifically review these aspects.

Dr. Bloch

I agree, Gabriel. I've also had patients want to switch because of flexibility reasons. Some patients live far from an infusion center and can't take the time to get there. Others like being able to take a medication from home.

Mr. Kramer

So now let's talk about why KESIMPTA was appropriate for Mike, based on the clinical data. Generally speaking, KESIMPTA has a favorable safety profile, comparable to Aubagio. The safety profile of KESIMPTA was similar to teriflunomide in the Phase 3 studies. The proportion of patients with adverse events was 83.6% for KESIMPTA and 84.2% for teriflunomide. For both therapies, adverse events leading to treatment discontinuation were also similar, between 5% and 6%.

Dr. Bloch

I agree that safety is important for a lot of patients. KESIMPTA having a similar safety profile to teriflunomide is encouraging.

Dr. Pardo

A lot of my patients are concerned about injections. How did you discuss this with Mike?

Mr. Kramer

I agree, injections are a concern for many of my patients too, and tolerability is top-of-mind for many patients whenever they start a new drug.

I asked Mike if he had a general aversion to needles and he said no. So I told him that KESIMPTA was a self-injectable therapy that he could take at home. He liked the idea, but immediately asked about injection related reactions.

I told Mike he might experience upper respiratory tract infections, systemic injection-related reactions, headache, and local injection-site reactions. 99.8% of injection-related reactions are mild to moderate in severity.

Another piece of data I like to emphasize to patients like Mike is that the injection related reactions in clinical studies were highest with the first injection and decreased with the subsequent injections.

No premedication is required for KESIMPTA.

Dr. Pardo

I tell my patients who are hesitant to inject themselves 3 things: one, the frequency of administration of KESIMPTA is once a month, after initial dosing. Two, the injection is a prefilled, autoinjector device. And three, as John mentioned, the injections were well tolerated in clinical studies.

Dr. Bloch

I've found it can also help to explain to my patients that the first injection has a highest rate of systemic injection related reactions, and those rates of reactions usually decrease with later injections. Plus, 99.8% of injection-related reactions were mild to moderate in severity.

Mr. Kramer

If they ask me why the Sensoready® Pen is different, I tell them that injections are only monthly.

There is also a survey that Novartis performed to investigate patient and nurse preferences for using the autoinjector Sensoready® Pen compared to other DMT autoinjectors.

Interviews and surveys were performed on 80 RMS patients and 50 nurses who were experienced in training patients on 2 to 6 different DMT autoinjector pens.

In the survey, participants were to compare attributes of the KESIMPTA Sensoready® autoinjector pen with those of other DMT autoinjectors, some of which are not available in the US. The Sensoready® Pen was not injected during the survey nor were all devices compared against each other by participants. A total of 17 attributes were assessed, including “easy to grip the pen,” “visual feedback after completion of the injection,” and “audible feedback after completion of the injection.”

The study measured various autoinjector pen attributes covering ease of use, pen features, and usage parameters.

Approximately 9 out of 10 nurses and 8 out of 10 patients preferred Sensoready® Pen attributes, with the 2 highest preferences being “easy to perform self-injection with the pen” and the “process required to start injection.”

Dr. Pardo

So how about your patient Mike? How did he do with the Sensoready® Pen? What does he think about the injection time and monthly dosing?

Mr. Kramer

Mike was noticeably surprised by how intuitive the Sensoready® Pen was to use.

When patients are ready to inject, it takes less than 1 minute a month to administer. I remind my patients to review the complete instructions for use for more detailed instructions on preparation and administration of KESIMPTA.

Dr. Bloch

How did he like the Alongside™ KESIMPTA support program?

Mr. Kramer

He found these very helpful, especially the Alongside™ KESIMPTA support services that reinforce the treatment plan and offer video-chat injection training. He also liked the monthly text messages reminding him to take his medication. Plus, there's a Bridge program for commercially insured patients so they can have immediate access to treatment without having to wait for a benefits verification.

80% of commercial patients receive their first bridge dose in 5 days or less.

Dr. Bloch

With the Alongside support program, patients receive peace of mind when they receive their medication.

Dr. Pardo

I understand that patient preferences regarding route of administration are important, but it's also critical to manage Mike's disease.

Mr. Kramer

When we look at the data, in two Phase 3 pivotal trials, KESIMPTA significantly reduced the annualized relapse rate relative to the active comparator teriflunomide. This was the primary end point of both studies and I think it was a strong result.

Dr. Bloch

You mentioned Mike's MRI findings, so the data for KESIMPTA for gadolinium-enhancing and T2 lesions must have been relevant when making a treatment decision.

I explain to my patients how important it is to limit the new development of lesions. Lesions mean additional damage and are a sign that MS is active. The data for KESIMPTA on reduction of T1 and T2 lesions gives me the confidence in using this medication.

Mr. Kramer

KESIMPTA showed significant reductions in both gadolinium enhancing T1 lesions and T2 lesions compared to teriflunomide in both

Phase 3 trials.

Dr. Pardo

I agree. In my view, the disease activity that Mike presented with, in particular the sensory loss in the lower extremity secondary to a spinal cord lesion, is a risk factor for progression and warrants a high efficacy therapy like KESIMPTA. I remember Mike was also very worried about farther physical deterioration. It would probably reassure him to know that KESIMPTA also significantly reduced the risk of 3-month confirmed disability progression by 34.4% and 6-month confirmed disability progression by 32% compared to teriflunomide in the pooled Phase 3 trials.

Mr. Kramer

Thanks for talking with me, Dr Bloch and Dr Pardo! So to sum up, my patient Mike agreed that KESIMPTA was the right choice for several reasons.

First, being on self-administered KESIMPTA means Mike can spend time where he wants, at home, at work, or anywhere.

Second, the rate of injection-related reactions and the fact that the majority of those reactions were mild to moderate in severity. Importantly for me, the incidence of these reactions decreased over subsequent injections.

And finally, being on an efficacious therapy was critical for slowing disability progression.

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.

Important Safety Information for KESIMPTA will be available underneath the podcast and a link to the full Prescribing Information, including the Medication Guide, is available at the bottom of the presentation.