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Switching to a Different Treatment: A Look Into a Subcutaneous Treatment Option for RMS

Announcer:

Welcome to ReachMD. This medical industry feature, titled, "How KESIMPTA (ofatumumab) Offers an SC Treatment Option for Patients Looking to Switch Therapies" is sponsored by Novartis Pharmaceuticals Corporation and the presenters have been compensated for their time.

Dr Avila:

We often hear patients expressing interest in changing their treatment for relapsing multiple sclerosis, or RMS. Today we are here to discuss a real-world patient who was on RMS infusion therapy and was interested in learning more about other disease-modifying therapies, or DMTs. This is a case that highlights shared decision-making between Dr Cabot and her patient, Jack, to find an appropriate therapy to help Jack reach his treatment goals.

My name is Dr Mirla Avila. I'm an MS specialist and the director of the MS clinic in Lubbock, Texas. I'm joined today by my colleague, Dr Ann Cabot.

Dr Cabot:

Thank you, Dr Avila. I'm Dr Ann Cabot and I work in a suburban environment in Concord, New Hampshire at Concord Hospital, an NMSS Center of Excellence.

Now, Dr Avila, I want to talk about a patient of mine—let's call him Jack—who was on an infusion therapy for a couple of years. But he had recently brought up his interest in learning more about other treatment options that might better align with his lifestyle.

Dr Avila:

Thank you for the context, Dr Cabot. Would you tell us more about Jack's story?

Dr Cabot:

Yes, Jack is a 35-year-old male with RMS. He initially presented with left hand weakness and vertigo. His MRI showed multiple lesions characteristic for demyelinating disease, and he was started on an injectable DMT, but then switched to an oral DMT.

I started seeing Jack at this point and we switched him to an infusion therapy. At this time, Jack expressed an interest in switching therapies.

Dr Avila:

When you were discussing other treatment options with Jack, which characteristics or aspects were important to him?

Dr Cabot:

Jack expressed to me that he felt it was difficult for him to schedule infusions and travel to and from the infusion center for his treatments. Because of this, he wanted to find a treatment that allowed him the flexibility of administering at home.

Dr Avila:

I have similar experiences with my patients because many of my patients live in rural areas and need to drive hours to the nearest

infusion site. This may not be feasible for some, so at-home administration is a topic of discussion for my patients.

Which therapy did you recommend Jack to switch to when he mentioned his concerns?

Dr Cabot:

Jack and I reviewed a variety of different options. After aligning on his treatment goals and personal preferences, we decided to get him started on KESIMPTA.

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

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

Please listen until the end for the full Important Safety Information.

Dr Avila:

What made you consider KESIMPTA for Jack and other RMS patients like him?

Dr Cabot:

Jack, in particular, communicated that the route of administration and the ability to self-administer were 2 of the most important factors to him. As Jack's physician, listening to his lifestyle preferences was very important for me in this shared decision-making process.

Dr Avila:

As a health care professional, I value efficacy first and foremost. So, I would want to choose a treatment approach where I felt confident in a therapy's efficacy.

Announcer:

When we look at the efficacy data, at the end of the Phase 3 ASCLEPIOS I trial, we see that the annualized relapse rates, or ARRs, for KESIMPTA and teriflunomide were 0.11 and 0.22, respectively. In the ASCLEPIOS II trial, the ARRs for KESIMPTA and teriflunomide were 0.10 and 0.25, respectively. KESIMPTA significantly reduced relapses by 51% in ASCLEPIOS I and 58% in ASCLEPIOS II compared to the active comparator, teriflunomide.

In a post hoc analysis of pooled data from ASCLEPIOS I and II, early and continued relapse reduction was observed over the study period. KESIMPTA demonstrated reductions in ARR within the first 3 months, and time intervals over 2 years. The ARR, at a 95% confidence interval, was estimated separately for each time interval by fitting a negative binomial regression model adjusted for treatment as a factor.

There were 946 patients on KESIMPTA and 936 patients on teriflunomide experiencing a reduction in the ARR of 0.236 vs 0.373, respectively, from month 0 to 3. From month 0 to 27, the reduction in the ARR was 0.123 vs 0.258 for KESIMPTA and teriflunomide, respectively. Please note that no conclusions can be drawn.

And now, let's get back to our conversation with Dr Avila and Dr Cabot.

Dr Avila:

Why were these data important to you and Jack? How did you explain the efficacy of KESIMPTA to him?

Dr Cabot:

One thing I told Jack and like to tell all my patients when explaining efficacy data is the fact that KESIMPTA was studied in a head-to-head trial versus teriflunomide. This is reassuring to both practitioners and patients like Jack, especially when the data showed statistical superiority in terms of efficacy.

Dr Avila:

Definitely. The head-to-head efficacy is one of the big reasons why some of my patients and I have chosen KESIMPTA.

How is Jack doing now since starting KESIMPTA?

Dr Cabot:

So far, Jack has expressed that he is doing well on KESIMPTA, which makes me happy. In his most recent appointments, his MRI, labs,

and symptoms were stable, and he showed no changes in his spine lesions. As a health care professional, hearing that the patient feels good about their decision, but also seeing that they're doing well clinically is a really great feeling. Please note that individual results may vary.

Dr Avila:

I agree, it is very rewarding to see patients doing well on a different therapy.

With disease-modifying therapies for RMS, many health care professionals and patients prioritize safety. Patients usually feel knowledgeable and comfortable with their current therapies. So, when they do switch for route of administration preferences, one of the main questions they have is around the safety profile of the new agent they are considering to switch to.

Warnings and precautions for KESIMPTA include infections, injection-related reactions, reduction in immunoglobulins, and fetal risk.

The most common adverse reactions with incidence greater than 10% in patients taking KESIMPTA were upper respiratory tract infection, headache, injection-related reactions, and local injection-site reactions.

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.

Continues on the topic of safety, one concern we hear from patients is the idea of an injection.

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 appropriate trained health care professional. If injection-related reactions occur, symptomatic treatment is recommended.

How would you present the injection data to a patient and what would you highlight?

Dr Cabot:

In my experiences, nurses play a huge role in patient education around KESIMPTA. We have pamphlets that our nurses give to every patient that highlight key safety points, including injection-related reactions, to make patients feel more informed with starting treatment.

Dr Avila:

At my practice site, unfortunately, I don't have a nurse who focuses on patient education. So I usually educate patients not only on safety, but administration as well.

Tell us more about the administration of KESIMPTA and how you described it to Jack when he was switching over to KESIMPTA.

Dr Cabot:

So, for Jack's case, he had made it clear to me that he was looking to switch his therapy to align with his desired lifestyle.

Jack mentioned that he wanted a therapy that he could self-administer so that he would not have to schedule appointments and travel to an infusion center.

Taking that into consideration, I let Jack know that KESIMPTA is available as a subcutaneous auto-injector, called the Sensoready® Pen, that can be administered at home.

It's a preloaded device with audible and visual cues to help with administration.

Dr Avila:

For needle averse patients, the design of the Sensoready Pen allows the user not to see the needle.

For example, I had a patient who when initially diagnosed said he didn't want an injectable. I said, listen, I understand how you feel, let me demonstrate how administering KESIMPTA would be. Once he was able to see the pen for himself, he wanted to give KESIMPTA a try. He has been on KESIMPTA now for 6 months and has been doing well with self-administration.

For some patients, it really helps to see the pen before making a decision, especially for needle-averse patients.

Now that we discussed KESIMPTA, how was your experience with starting Jack on KESIMPTA?

Dr Cabot:

That's a great question Dr Avila. KESIMPTA has this great program called the Alongside Bridge Program, which covers patients for up to 12 months while coverage is pursued.

It's much easier for me to start a medication like KESIMPTA for patients like Jack because the bridge program has been very easy to navigate. I can prescribe the medication and feel confident that, if I write it, at least I'll get some feedback very quickly on how things are going.

Dr Avila:

I have also had the same experience with the bridge program. It has been very helpful with coverage and getting KESIMPTA to my patients quickly.

Thank you for sharing your experience with your patient, Jack. His patient case really resonates with what I commonly see at my practice site. Before we wrap this up, what would you say KESIMPTA has to offer patients looking to switch therapies?

Dr Cabot:

With KESIMPTA, we get the flexibility of self-administration.

What about you? What would you say KESIMPTA has to offer your patients?

Dr Avila:

I use KESIMPTA in many of my patients. And the main thing that stands out to me with KESIMPTA is its route of administration and the flexibility that the subcutaneous route may provide.

Ultimately, it is very important to consider that the decision for changing a patient's treatment approach is a shared decision.

Announcer:

IMPORTANT SAFETY INFORMATION

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

WARNINGS AND PRECAUTIONS

Infections: Serious, including life-threatening or fatal, bacterial, fungal, and new or reactivated viral infections have been observed during and following completion of treatment with anti-CD20 B-cell depleting therapies. 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 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.

Please see full Prescribing Information, including Medication Guide at the bottom of this presentation.

Announcer:

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

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