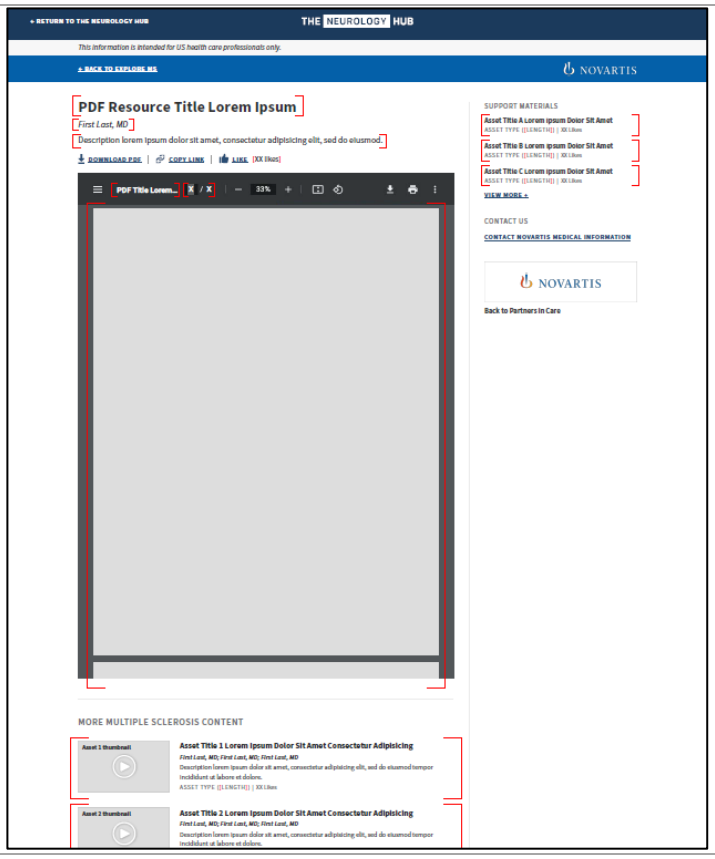
General Information

Title	**Expert Dialogue Newsletter, Edition 7: Clinical Perspectives on KESIMPTA and Questions Regarding its Route of Administration**
Description	Dr Robert Gilbert Jr shares his expert perspective on assessing patient adherence and addressing patient questions regarding self-injection with KESIMPTA
Speakers	Robert Gilbert Jr, MD
FUSE Code	269952
Screenshot of the Digital Education Lab (Template)	

Please note: Once approved, this piece will live on the KESIMPTA page of the Digital Education Lab, which contains the full ISI and a link to the PI.

KESIMPTA® (ofatumumab) EXPERT DIALOGUES

EDITION 7

AN INTERACTIVE NEWSLETTER SERIES, HIGHLIGHTING KEY MEDICAL EXPERT VIEWS ON ADHERENCE

Dr Robert Gilbert's

Clinical Perspectives

on KESIMPTA and questions regarding its route of administration

Robert Gilbert Jr, MD
Private Practice
Atlanta, GA

"I've been practicing for almost 40 years. I see a mixture of clinically isolated syndromes and SPMS, but RMS is the most common in my practice. **I find purpose in choosing a suitable and effective therapy for my patients. Their adherence gives me a better sense of security.**"

— Robert Gilbert Jr, MD

The perspectives provided within this newsletter by Dr Gilbert are his own and not reflective of his affiliation. The medical expert in this newsletter has been paid by Novartis Pharmaceuticals Corporation to provide their perspectives.

RMS, relapsing multiple sclerosis; SPMS, secondary progressive multiple sclerosis.

INDICATION

KESIMPTA 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.

Please see additional Important Safety Information throughout this newsletter. Click here for full Prescribing Information, including Medication Guide.

Links to https://www.novartis.com/us-en/sites/novartis_us/files/kesimpta.pdf

Kesimpta® (ofatumumab) 20 mg injection

IN THIS NEWSLETTER, DR GILBERT DISCUSSES

HCP, health care professional; RMS, relapsing multiple sclerosis.

IMPORTANT SAFETY INFORMATION (cont)

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.

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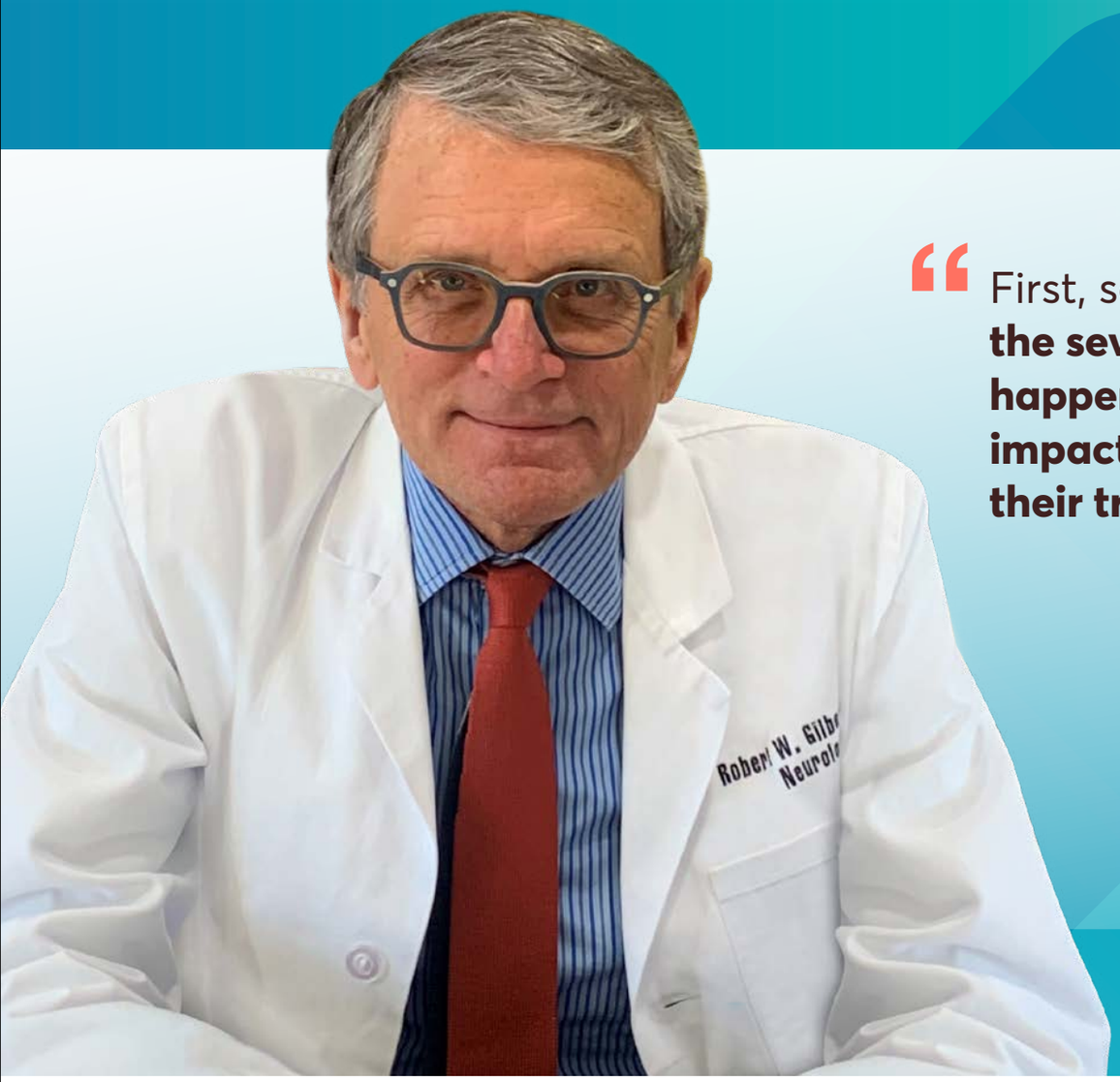
HOW DO YOU EMPHASIZE THE IMPORTANCE OF ADHERENCE FOR YOUR PATIENTS?



"First, set expectations. **Patients should be aware of the severity of the disease, disease progression often happens over years rather than months, MS can have an impact on their lives, and they need to be consistent with their treatment.**[1-3]

Based on our experiences, the patient will progress without treatment. If I need to get into specifics, I can talk about how the patient could have brain shrinkage, loss of cognitive ability, or loss in the ability to perform common tasks if their MS is uncontrolled.[1]"

MS, multiple sclerosis.

IMPORTANT SAFETY INFORMATION (cont)

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.

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WHAT ARE SOME OF THE QUESTIONS YOUR PATIENTS HAVE AND YOUR RESPONSES WHEN DISCUSSING KESIMPTA®?

"Does it hurt?"

Links to page 5 within this document

"Will I have any problems or side effects with KESIMPTA?"

Links to page 6 within this document

"How will treatment impact my schedule?"

No visible needle

"Some patients, especially those who may have used older MS treatments, often think injection treatment means pushing a large syringe into their muscle. That's where I find the demo Sensoready® Pen can change their perspective as it is subcutaneous. I explain the concept, show the pen, and educate the patient on how to use it. Patients have control over their administration, but they must be comfortable first.[4]

If the patient has other questions during treatment, our practice has a patient portal where they can ask us questions. I also inform the patient that Novartis has the Alongside™ KESIMPTA support program, which I like to mention early. It can provide the patient with reassurance knowing they have support."

MS, multiple sclerosis.

IMPORTANT SAFETY INFORMATION (cont)

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.

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WHAT ARE SOME OF THE QUESTIONS YOUR PATIENTS HAVE AND YOUR RESPONSES WHEN DISCUSSING KESIMPTA®?

Links to page 4 within this document

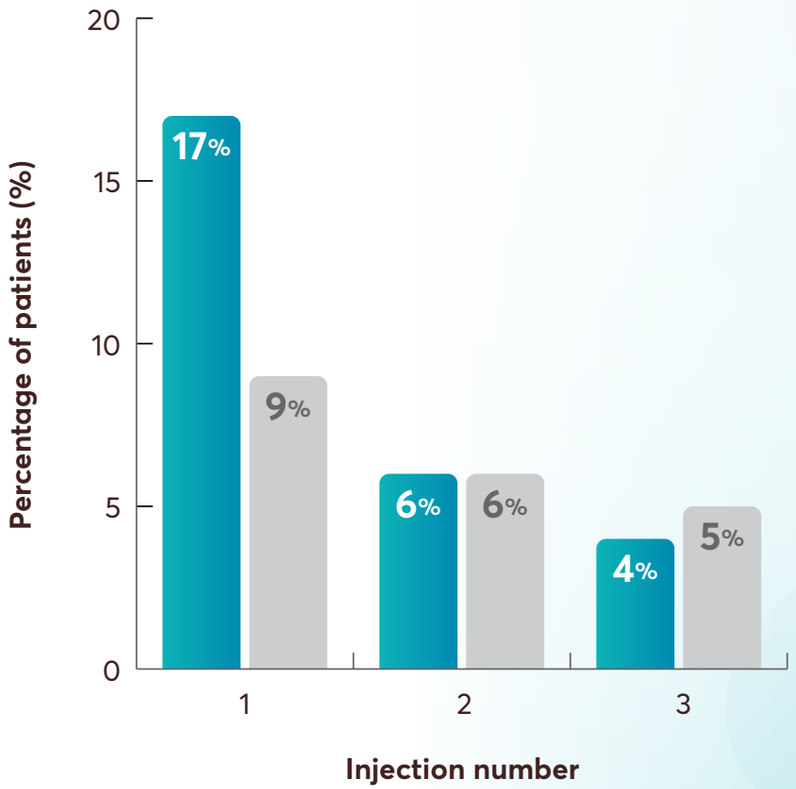
"Does it hurt?"

"Will I have any problems or side effects with KESIMPTA?"

Links to page 6 within this document

"How will treatment impact my schedule?"

INCIDENCE OF INJECTION-RELATED REACTIONS BY INJECTION[5]



99.8% of injection-related reactions were mild to moderate[4]

The most frequently reported symptoms **≥2%** were fever, headache, myalgia, chills, and fatigue[4]

> "To me, **it's important to set expectations about treatment with KESIMPTA**.
>
> Some mild injection-related reactions may occur, though in clinical trials we see that their frequency tends to diminish with each subsequent dose.[4*]"

*In clinical trials, 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.

IMPORTANT SAFETY INFORMATION (cont)

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.

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Kesimpta® (ofatumumab) 20 mg injection

WHAT ARE SOME OF THE QUESTIONS YOUR PATIENTS HAVE AND YOUR RESPONSES WHEN DISCUSSING KESIMPTA®?

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"Does it hurt?" | **"Will I have any problems or side effects with KESIMPTA?"** | **"How will treatment impact my schedule?"**

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Continue reading to hear the story of a real patient

"After I first provide guidance on how to use the KESIMPTA Sensoready® Pen, most patients are comfortable, and the **first dose is usually administered at home**.[4] My patients appreciate the flexibility of not needing to come back into the office for each subsequent dose. Since the administration usually takes less than 1 minute,[6] my patients comment that they can fit KESIMPTA into their normal lifestyle."

— Robert Gilbert Jr, MD

Christine

1 minute[4,6*] **vs 2 to 4 hour infusion**[7]

KESIMPTA
KESIMPTA is administered in 1 minute a month subcutaneously[4,6]

ocrelizumab[7†]
Ocrelizumab is dosed twice yearly via infusion

This chart is only intended to show administration times. **No conclusions of comparative efficacy and safety should be drawn.** Please refer to the product's specific prescribing information for complete dosing and administration instructions.

The case presented here is based on a real patient in our expert's practice. A few details have been changed, including the patient's name.

*As per stability technical specification data, when the patient is ready to inject, it typically takes less than 1 minute a month to administer. Once-monthly dosing occurs after the initial dosing period, which consists of 20 mg subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instruction on preparation and administration of KESIMPTA.[4]

†See ocrelizumab Prescribing Information for complete dosing and administration instructions.

IMPORTANT SAFETY INFORMATION (cont)

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.

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WHAT ARE SOME QUESTIONS THAT YOUR PATIENTS ASK WHEN DISCUSSING KESIMPTA®, AND HOW DO YOU RESPOND?

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Christine

"I have a patient with MS—Christine, who is a 42-year-old female with 2 kids. She works full-time as a nurse practitioner. She didn't want her dose of medication to involve commuting and sitting for infusions, which she felt would take time away from her normal schedule. While patients still need to be monitored, as in the case of immunoglobulin levels, not needing to come in for their doses is appealing. For patients like Christine, KESIMPTA® may be the treatment option of choice.

Also, I find that patients who travel a lot with their job or worry about taking daily oral medications may do well on a once-monthly method of treatment.[4]"

— Robert Gilbert Jr, MD

The case presented here is based on a real patient in our expert's practice. A few details have been changed, including the patient's name.

*As per stability technical specification data, when the patient is ready to inject, it typically takes less than 1 minute a month to administer. Once-monthly dosing occurs after the initial dosing period, which consists of 20 mg subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instruction on preparation and administration of KESIMPTA.[4]

†See Ocrevus Prescribing Information for complete dosing and administration instructions. Ocrevus is a registered trademark of Genentech USA, Inc.

IMPORTANT SAFETY INFORMATION (cont)

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.

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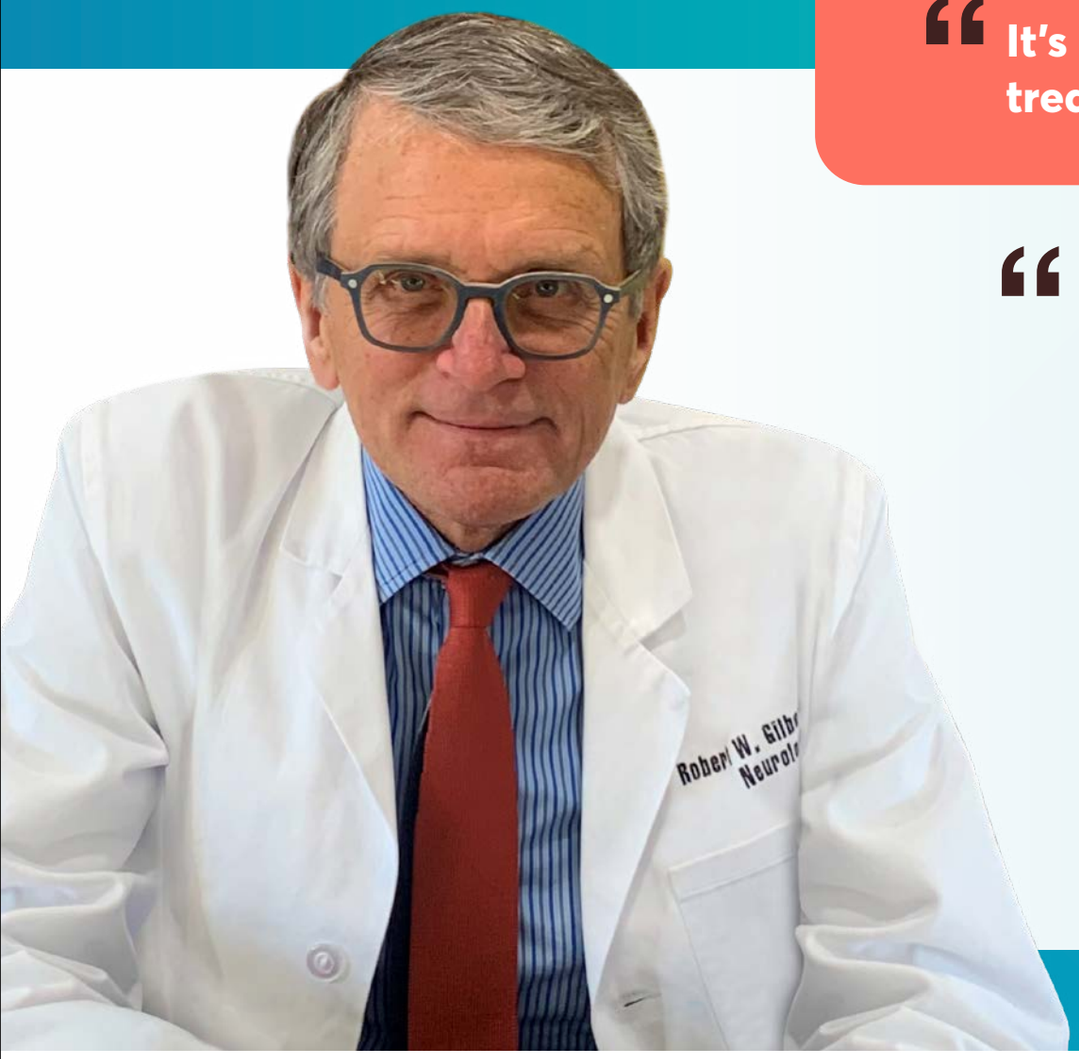
HOW DO YOU ASSESS ADHERENCE FOR YOUR PATIENTS WITH RMS?



“It’s important for HCPs to confirm how the patient is taking their treatment and if they are on an appropriate schedule.”

“Patients might have a good day or a bad day, and that can depend on so many variables. I find it more reliable to use the patient history and ask **questions about their quality-of-life**.

I recommend that HCPs listen for **concerning phrases** and investigate further if they arise.

If you see a discrepancy, **open-ended questions** can help identify red flags.”

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HCP, health care professional; RMS, relapsing multiple sclerosis.

IMPORTANT SAFETY INFORMATION (cont)

Vaccinations (cont): *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.

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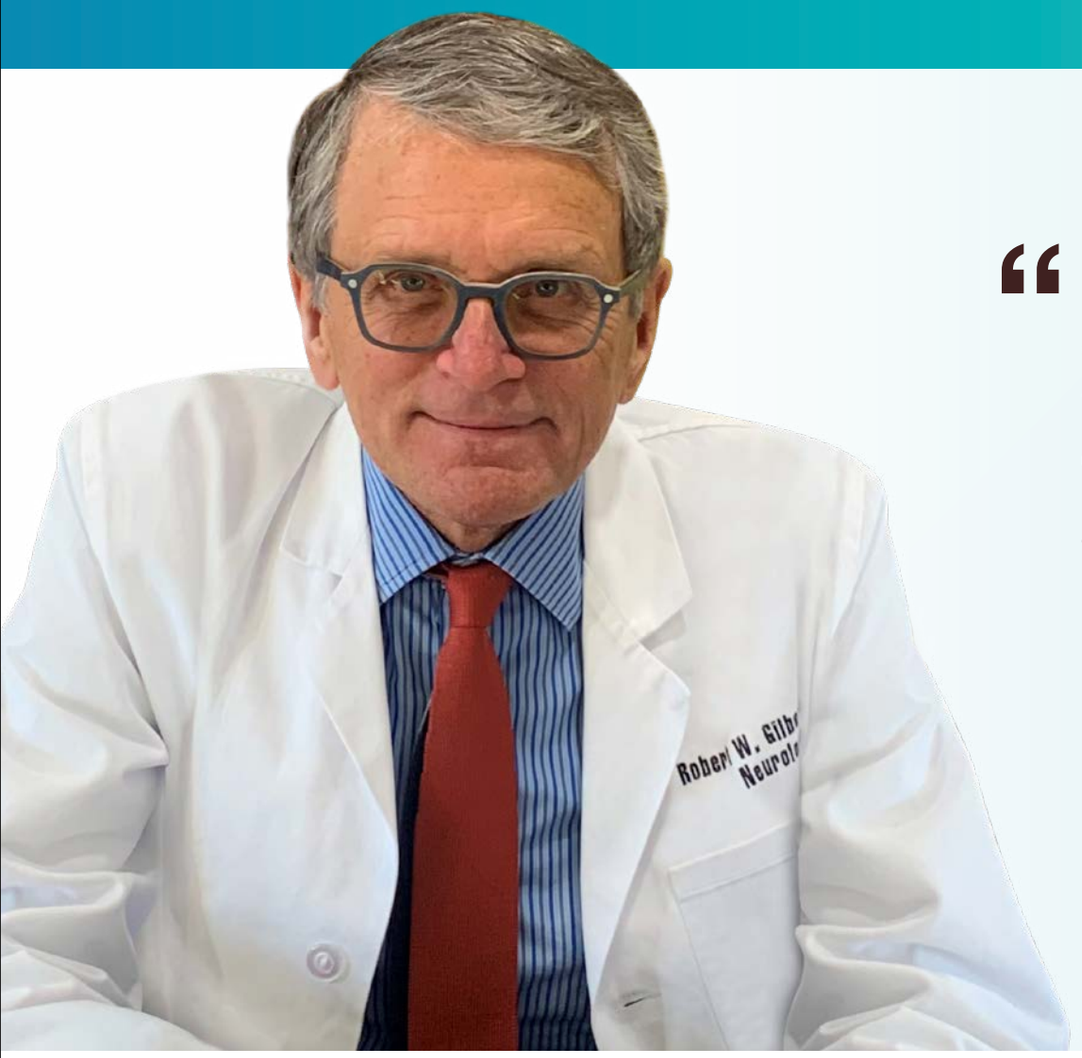

> “Patients might have a good day or a bad day, and that can depend on so many variables. I find it more reliable to use the patient history and ask **questions about their quality-of-life**.”

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- How does your ability to perform a certain activity compare with 6 months ago?
- How are you handling the everyday demands of life in comparison to earlier dates?
- How has your confidence changed regarding your ability to walk or go to work?

HCP, health care professional; RMS, relapsing multiple sclerosis.

IMPORTANT SAFETY INFORMATION (cont)

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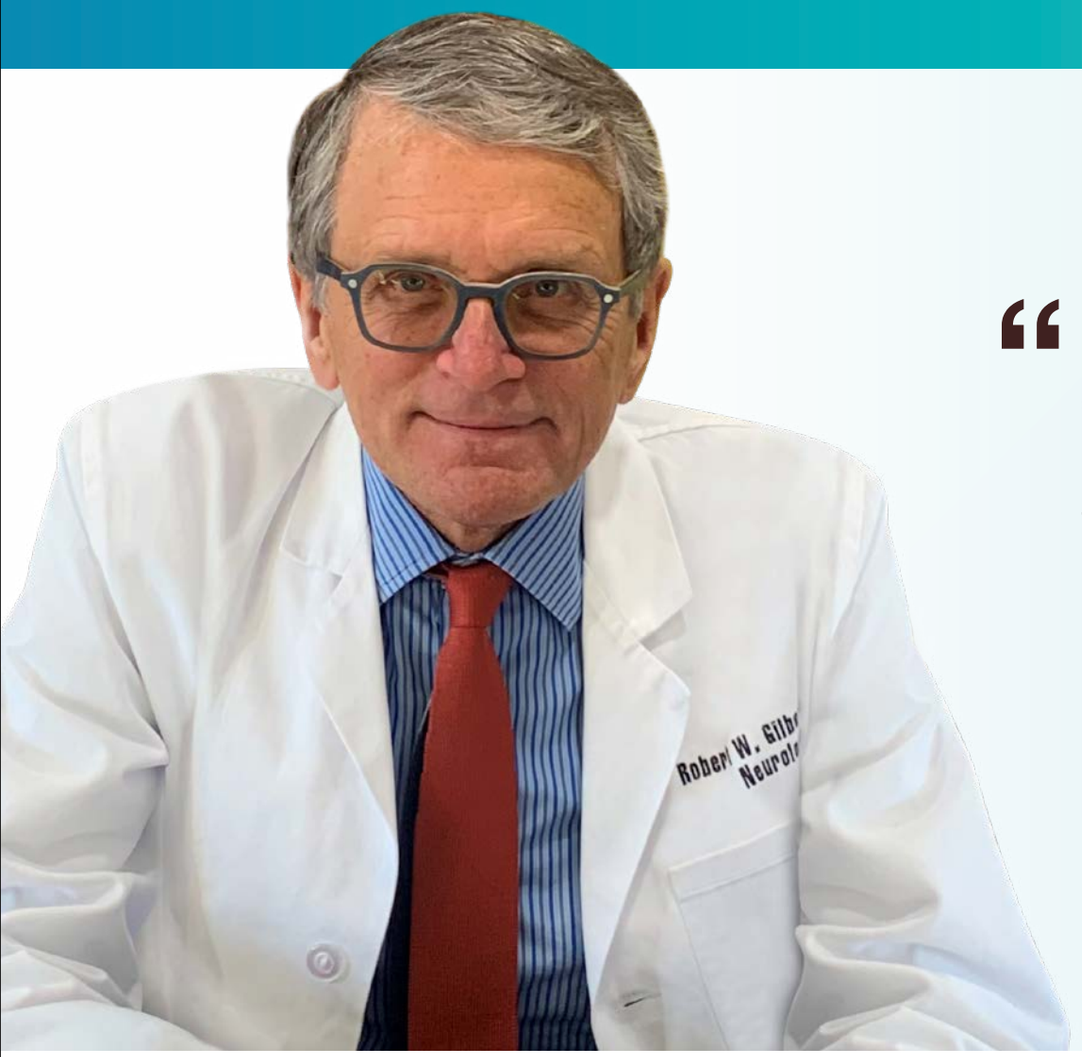
HOW DO YOU ASSESS ADHERENCE FOR YOUR PATIENTS WITH RMS?



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> “I recommend that HCPs listen for **concerning phrases** and investigate further if they arise.”

- I’m not feeling well
- I think I’m having a relapse
- Maybe I’m getting worse?

HCP, health care professional; RMS, relapsing multiple sclerosis.

IMPORTANT SAFETY INFORMATION (cont)

Vaccinations (cont): *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.

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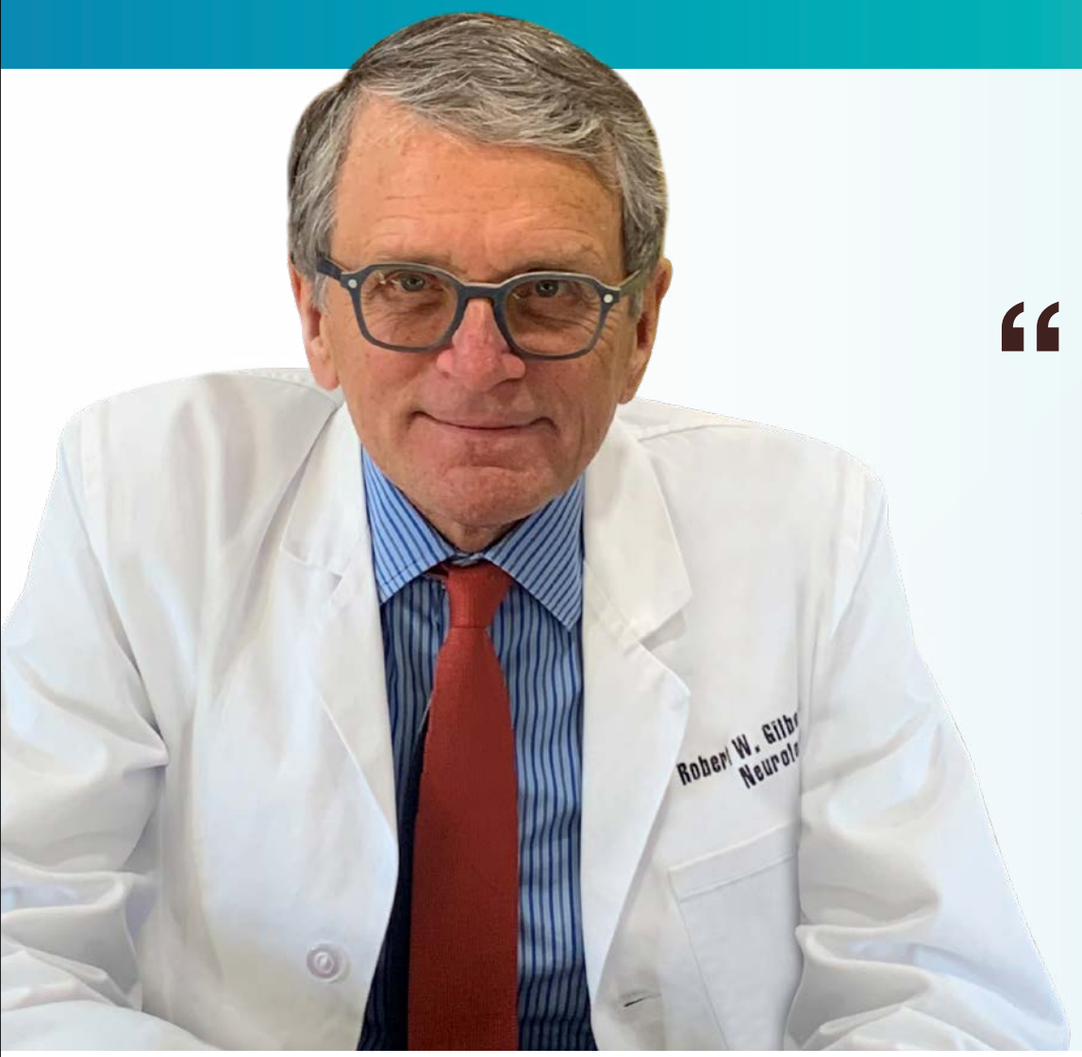

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> “If you see a discrepancy, **open-ended questions** can help identify red flags.”

- How many doses have you missed?
- What issues have you had with receiving the medication?
- What else could you tell us about how you take your medication?

HCP, health care professional; RMS, relapsing multiple sclerosis.

IMPORTANT SAFETY INFORMATION (cont)

Vaccinations (cont): *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.

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WHAT WOULD YOU LIKE TO TELL OTHER HCPs WHO MIGHT BE HESITANT TO PRESCRIBE KESIMPTA®?

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Safety | **Efficacy** | **NEDA**

In Phase 3 clinical studies, the proportion of patients with adverse reactions was similar and treatment discontinuations due to adverse reactions were similar in the KESIMPTA and teriflunomide groups.[4,8]

	ASCLEPIOS I		ASCLEPIOS II	
	Teriflunomide n=462	**KESIMPTA** n=465	**Teriflunomide** n=474	**KESIMPTA** n=481
Any adverse reaction	82.3%	82.2%	86.1%	85%
Adverse reaction leading to treatment discontinuation	5.2%	5.8%	5.3%	5.6%

Adverse reactions in patients with RMS with an incidence of at least 5% with KESIMPTA and a greater incidence than teriflunomide*

	Teriflunomide 14 mg n=936 %	**KESIMPTA** 20 mg n=946 %
Upper respiratory tract infections†	38	39
Injection-related reactions (systemic)‡	15	21
Headache	12	13
Injection-site reactions (local)‖	6	11
Urinary tract infection	8	10
Back pain	6	8
Blood immunoglobulin M decreased	2	6

> **I want to keep my patients on a safe and effective therapy.** To me, the safety data are most reassuring. In addition, KESIMPTA has an efficacy benefit with MRI as seen in the clinical data comparing it to an existing MS therapy, teriflunomide.[4,8]
>
> I also use the term NEDA quite a bit with my patients. In my mind, reassuring our patients with this information and regularly providing long-term data will help ensure patient compliance.

HCP, health care professional; MRI, magnetic resonance imaging; MS, multiple sclerosis; NEDA, no evidence of disease activity; RMS, relapsing multiple sclerosis.

*Pooled data from ASCLEPIOS I and II.

†Includes the following: nasopharyngitis, upper respiratory tract infection, influenza, sinusitis, pharyngitis, rhinitis, viral upper respiratory infection, tonsillitis, acute sinusitis, pharyngotonsillitis, laryngitis, pharyngitis streptococcal, viral rhinitis, sinusitis bacterial, tonsillitis bacterial, viral pharyngitis, viral tonsillitis, chronic sinusitis, nasal herpes, tracheitis.

‡Symptoms observed included fever, headache, myalgia, chills, and fatigue.

‖The most frequently reported symptoms (2% or greater) included erythema, pain, itching, and swelling.

IMPORTANT SAFETY INFORMATION (cont)

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.

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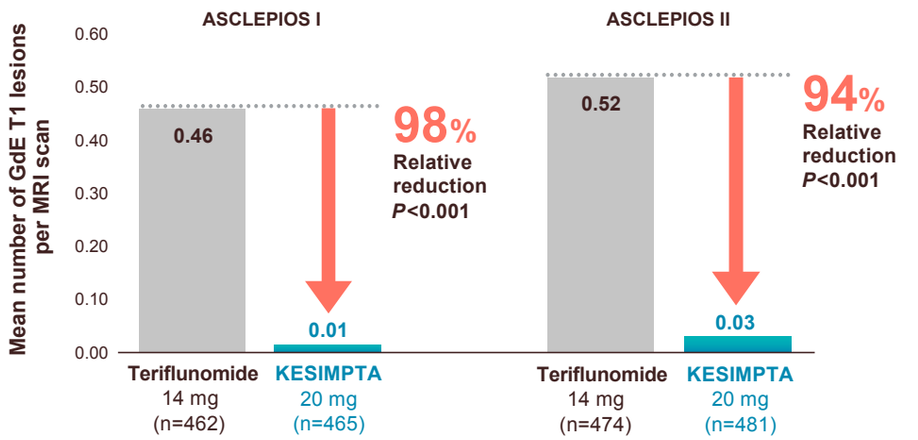
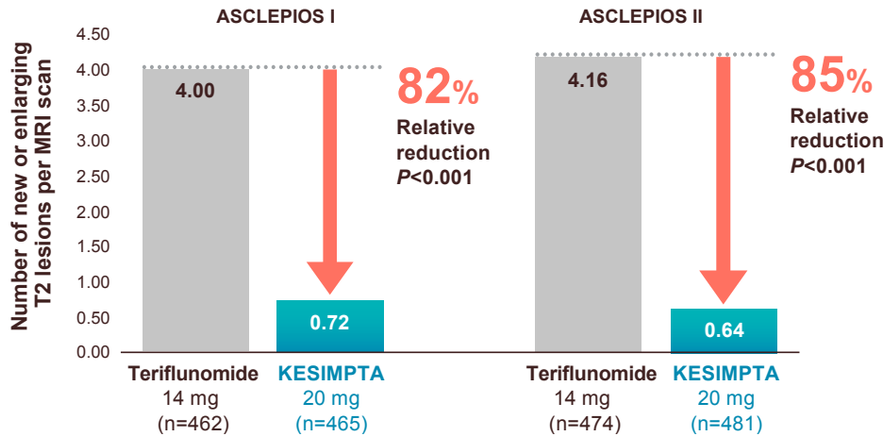
Safety | **Efficacy** | **NEDA**

KESIMPTA showed significant reductions across the primary, clinical, and MRI end points[4,8]

MEAN NUMBER OF GdE T1 LESIONS PER MRI SCAN



NUMBER OF NEW OR ENLARGING T2 LESIONS PER MRI SCAN



ADJUSTED ARR

ASCLEPIOS I

51.0% Relative reduction ARR (*P*<0.001)

0.11 KESIMPTA vs 0.22 teriflunomide

ASCLEPIOS II

58.0% Relative reduction ARR (*P*<0.001)

0.10 KESIMPTA vs 0.25 teriflunomide

PROSPECTIVE POOLED ANALYSIS

CDP*

32% Relative reduction 3-month CDP (*P*=0.003)

10.9% KESIMPTA vs 15.0% teriflunomide

34% Relative reduction 6-month CDP (*P*=0.01)

8.1% KESIMPTA vs 12.0% teriflunomide

ARR, annualized relapse rate; CDP, confirmed disability progression; EDSS, Expanded Disability Status Scale; GdE, gadolinium enhancing; HCP, health care professional; MRI, magnetic resonance imaging; NEDA, no evidence of disease activity.

*Disability progression was defined as an increase in EDSS score of at least 1.5, 1, or 0.5 points in patients with a baseline EDSS score of 0, 1 to 5, or 5.5 or greater, respectively.

IMPORTANT SAFETY INFORMATION (cont)

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.

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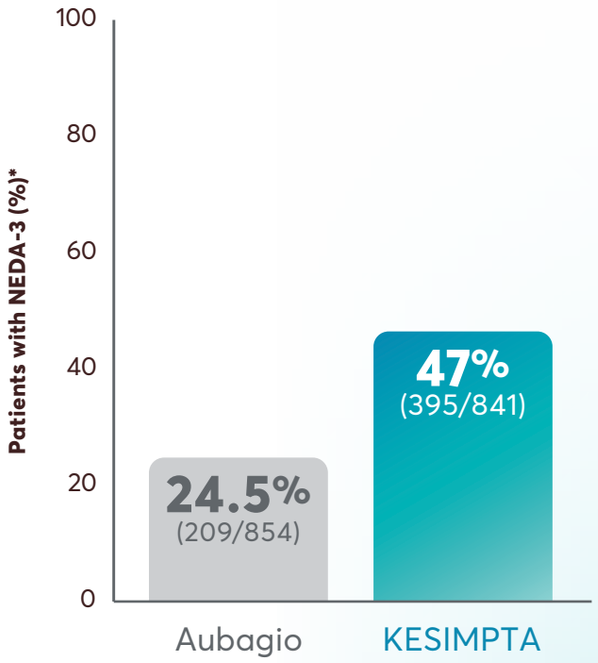
Links to page 13 within this document

Safety | **Efficacy** | **NEDA**

No evidence of disease activity (NEDA-3)[9]

POST HOC ANALYSIS OF ASCLEPIOS I AND II

0-12 months



Percentage of patients treated with KESIMPTA achieving individual component measures of NEDA-3*

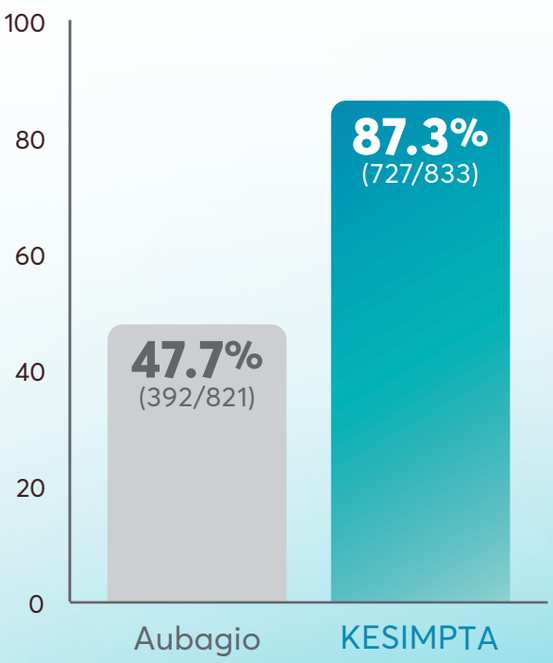
No confirmed relapses
87%

No GdE T1 lesions
98.1%

No new/enlarging T2 lesions
55.5%
(without re-baselining)

No 6-month CDW
93.8%

12-24 months



Percentage of patients treated with KESIMPTA achieving individual component measures of NEDA-3*

No confirmed relapses
93.3%

No GdE T1 lesions
98.7%

No new/enlarging T2 lesions
94.9%
(without re-baselining)

No 6-month CDW
97.7%

Re-baselining for year 2 (months 12-24) was conducted at month 12 to adjust for impact of disease activity prior to treatment initiation (T2 lesions) and continuing through the first year of treatment. This re-baselining allows for the accurate measure of the disease activity as measured in year 2.[10,11]

Limitations: This analysis considers patients without evidence of disease activity (which may also include patients with partially missing information) as NEDA-3. A sensitivity analysis was conducted for the population of patients who completed the full 24 months of treatment.[10]

No conclusions of clinical outcomes can be drawn.

Up to 9 out of 10 patients taking KESIMPTA® achieved NEDA-3 in year 2

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Continue reading about the NEDA-3 post hoc analysis design >

CDW, confirmed disability worsening; DMT, disease-modifying therapy; GdE, gadolinium enhancing; HCP, health care professional; NE, no evidence; NEDA, no evidence of disease activity.

*Defined as no 6-month confirmed disability worsening, no confirmed RMS relapse, no new/enlarging T2 lesions, and no GdE lesions.

IMPORTANT SAFETY INFORMATION (cont)

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.

Please see additional Important Safety Information throughout this newsletter. Click here for full Prescribing Information, including Medication Guide.

Links to https://www.novartis.com/us-en/sites/novartis_us/files/kesimpta.pdf

Kesimpta® (ofatumumab) 20 mg injection

WHAT WOULD YOU LIKE TO TELL OTHER HCPs WHO MIGHT BE HESITANT TO PRESCRIBE KESIMPTA®?

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Safety | Efficacy | NEDA

NEDA-3 post hoc analysis design

Population

All patients from the pivotal trial full analysis set population (all randomized patients with assigned treatments) were included in the intent-to-treat principle, but patients who discontinued from the study drug prematurely for reasons other than "lack of efficacy" or "death" and had NEDA-3 before early discontinuations were excluded.[10]

Methods

The outcomes presented here are the proportion of study patients within a treatment group who met the NEDA-3 criteria vs those who did not. The proportion of patients meeting NEDA-3 criteria was analyzed cross-sectionally in time intervals including year 1 (month 0-12) or in year 2 (month 12-24).[10]

NEDA-3 Criteria[10]

Within the prespecified time period (ie, 0-12 months and 12-24 months), patients who achieved NEDA-3 experienced no

- 6-month CDW
- Confirmed relapse
- ≥1 GdE T1 lesions
- ≥1 NE T2 lesions
- Discontinuation from the study drug due to either lack of efficacy or death

% Achieving NEDA-3[9]

Calculated as n/M, where n is the number of patients who achieved NEDA-3 and M is the total number of patients in the treatment group.

Re-baselining After Year 1[10,11]

1. For the year 2 (12-24 month) analysis, all components of NEDA-3 were re-baselined, meaning outcomes were recalculated relative to the month 12 baseline vs month 0
2. Analyses of NEDA-3 using a re-baselining approach may more closely reflect the effects of DMTs
3. Re-baselining is utilized to reflect a truer representation of a DMT's steady state of efficacy unconfounded by any initial disease activity carried over from baseline and recent prebaseline disease state

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Continue reading about the post hoc analysis of ASCLEPIOS I and II >

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IMPORTANT SAFETY INFORMATION (cont)

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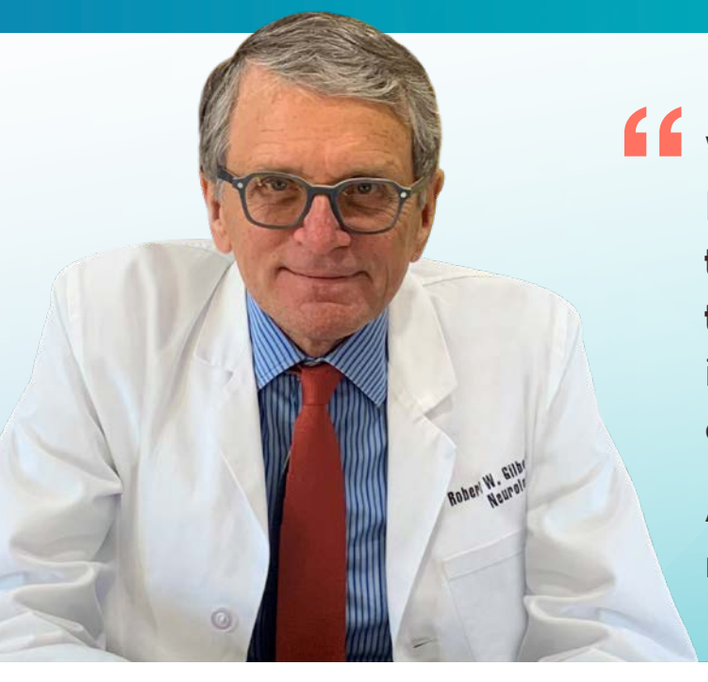
Kesimpta® (ofatumumab) 20 mg injection

WHAT HAS BEEN YOUR OVERALL EXPERIENCE WITH PATIENT ADHERENCE TO KESIMPTA®?



"When I assess how my patients are handling treatment with KESIMPTA, I do not typically hear problems with set up, tolerability, or adherence. **Once they administer KESIMPTA a few times, I feel confident that they will remain on therapy, as supported by the interim analysis and clinical trials**, which showed that in the KESIMPTA arm, the discontinuation rates due to adverse reactions were 6.5% and 5.7%, respectively.[12]

Also, I find that patients who travel a lot with their job or worry about taking daily oral medications might do well on a once-monthly method of treatment.[4]"

—Robert Gilbert Jr, MD

IMPORTANT SAFETY INFORMATION (cont)

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.

Links to https://www.novartis.com/us-en/sites/novartis_us/files/kesimpta.pdf

Please see additional Important Safety Information throughout this newsletter. Click here for full Prescribing Information, including Medication Guide.

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