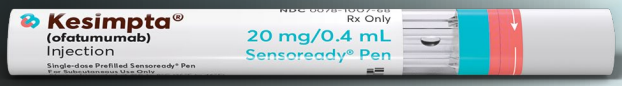
Kesimpta® (ofatumumab) 20 mg injection

START WITH KESIMPTA, THE POWER OF THE PEN[1*]



Choose KESIMPTA for your treatment-naïve RMS patients

CAYLEE
VOLLEYBALL COACH, OUTDOOR ENTHUSIAST
STARTED KESIMPTA FIRST LINE IN 2022

Real patient taking KESIMPTA who was compensated for time. Individual results may vary.
ARR, annualized relapse rate; CDP, confirmed disability progression; Gd+, gadolinium-enhancing; MRI, magnetic resonance imaging; RMS, relapsing multiple sclerosis.
*As evidenced by ARR, MRI (Gd+ T1 and T2 lesions), and 3- and 6-month CDP. Primary end point, ARR reduction of 51% (0.11 vs 0.22), 58% (0.10 vs 0.25).[1]

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

Contraindications: KESIMPTA is contraindicated in patients with active hepatitis B virus (HBV) infection, or history of hypersensitivity to ofatumumab, or life-threatening injection-related reaction to KESIMPTA. Hypersensitivity reactions have included anaphylaxis and angioedema.

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.

Please see additional Important Safety Information on the following pages.
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Choose KESIMPTA first for your treatment-naïve RMS patients like Caylee

Caylee

Volleyball Coach,
Outdoor Enthusiast

Patient history

- Diagnosed in 2021 after experiencing optic neuritis
- First relapse in December 2021
- Initial MRI scan revealed 10 Gd+ T1 lesions in the brain and spinal cord and 3 NE T2 lesions
- EDSS score: 2.0*
- Needed a treatment with powerful efficacy† that would allow her to continue coaching and traveling

Caylee's experience with KESIMPTA

- Started KESIMPTA® first line in January 2022 at age 23
- As of her last checkup in July 2024, Caylee has shown no NE lesions
- Likes that treatment doesn't interfere with her game schedule

40% of patients in KESIMPTA trials were treatment naïve[2]

EDSS, Expanded Disability Status Scale; NE, new or enlarging.
*As defined by Kurtzke's Functional Systems and EDSS in Multiple Sclerosis, 2011.[3]
†As evidenced by ARR, MRI (Gd+ T1 and T2 lesions), and 3- and 6-month CDP. Primary end point, ARR reduction of 51% (0.11 vs 0.22), 58% (0.10 vs 0.25).[1]

IMPORTANT SAFETY INFORMATION (cont)

Infections (cont)**:** 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.

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Your first choice matters.

Start with the powerful efficacy of KESIMPTA[1]

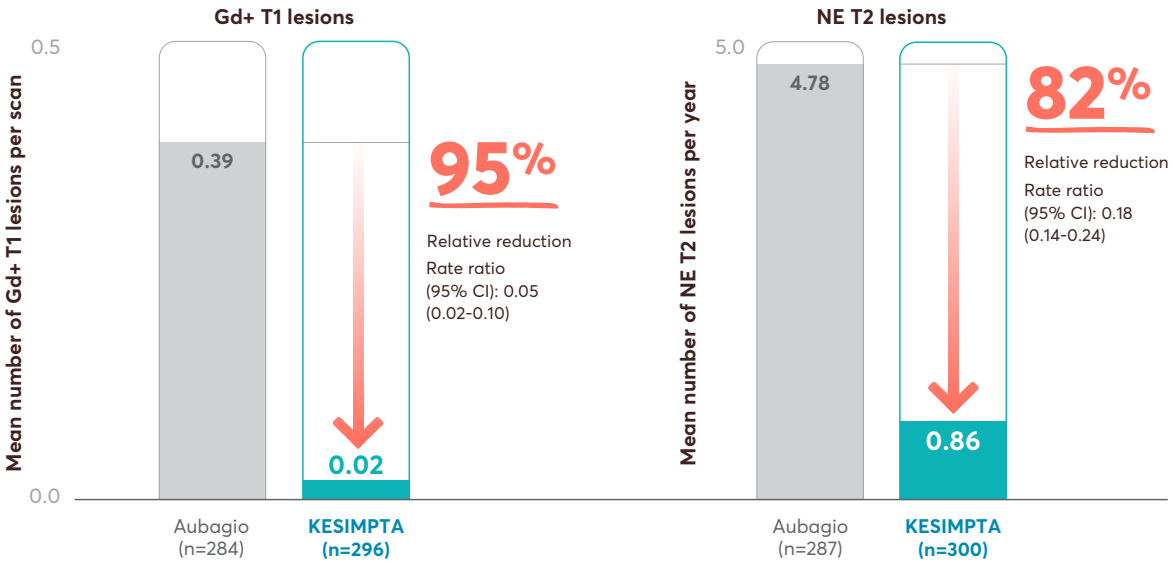
Superior ARR reduction of up to 58% vs Aubagio® (teriflunomide)[1]

Phase 3 pivotal study results: respectively for each trial, results for the primary end point: ARR reduction, 51% (0.11 vs 0.22), 58% (0.10 vs 0.25); for the key secondary end points: reduction of number of Gd+ T1 lesions per scan, 98% (0.01 vs 0.46), 94% (0.03 vs 0.52); reduction of annualized rate of NE T2 lesions, 82% (0.72 vs 4.00), 85% (0.64 vs 4.16); 3-month CDP risk reduction, 34% (10.9% vs 15.0%).

Phase 3 study design: ASCLEPIOS I and II were 2 identical, randomized, active-controlled, double-blind Phase 3 studies in patients with RMS, approximately 40% of whom were DMT treatment naïve. Patients were randomized to double-dummy SC KESIMPTA (20 mg every 4 weeks) or oral Aubagio (14 mg daily) for up to 30 months. Primary end point was ARR. Key end points were number of Gd+ T1 lesions and annualized rate of NE T2 lesions, and reduction in risk of 3-month CDP. Treatment duration was variable based on end-of-study criteria. Maximum duration: 120 weeks; median duration: 85 weeks.[1]

In a post hoc analysis of pooled ASCLEPIOS data,

95% reduction in mean Gd+ T1 lesion activity in treatment-naïve patients[4]



Negative binomial regression model.

This post hoc study assessed the benefit–risk profile of KESIMPTA vs Aubagio, comprising clinical and MRI data in a subpopulation of recently diagnosed treatment-naïve participants from the combined ASCLEPIOS I and II trial populations.[4]

Post hoc study design: Efficacy and safety data were drawn from the pooled ASCLEPIOS subpopulation of protocol-defined treatment-naïve patients who were within 0.1–2.9 years from diagnosis (median 0.35 and 0.36 years for KESIMPTA and Aubagio patients, respectively). Of the 1882 participants randomly assigned to treatment in ASCLEPIOS I and II, 615 (32.7%) were both recently diagnosed and treatment naïve at baseline (KESIMPTA, 314; Aubagio, 301).[4]
No conclusions can be drawn.

CI, confidence interval; DMT, disease-modifying therapy; SC, subcutaneous.

IMPORTANT SAFETY INFORMATION (cont)

Hepatitis B Virus (cont)**:** *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.

Kesimpta® (ofatumumab) 20 mg injection

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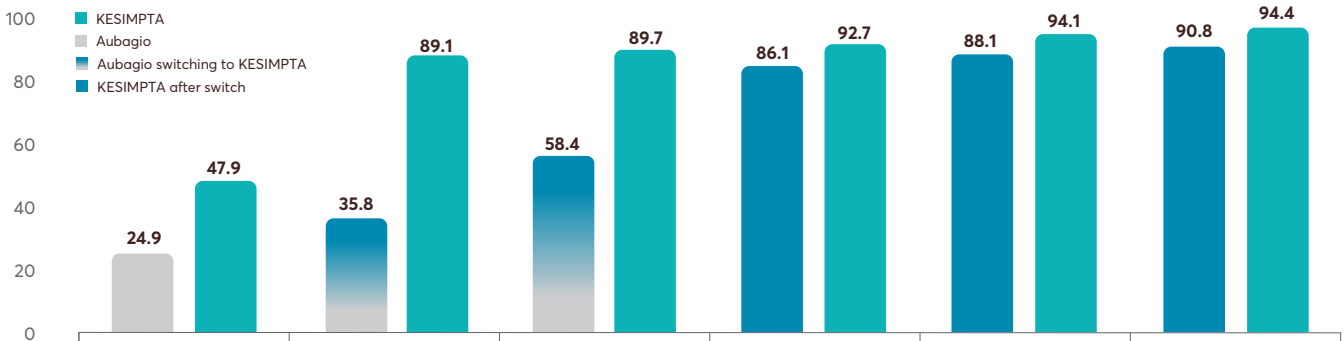
No evidence of disease activity (NEDA-3) for 94% of treatment-naïve patients at year 6[5]

NEDA-3 status up to 6 years of KESIMPTA® treatment[5,6]



	Year 1 ASCLEPIOS		Year 2 ASCLEPIOS		Year 3 ALITHIOS		Year 4 ALITHIOS		Year 5 ALITHIOS		Year 6 ALITHIOS	
n	289	290	265	265	245	252	230	233	219	222	207	216
OR (95% CI):	3.44 (2.33-5.08), *P*<0.001		16.02 (9.88-25.98), *P*<0.001		6.75 (4.11-11.09), *P*<0.001		2.02 (1.07-3.80), *P*=0.029		2.45 (1.19-5.04), *P*=0.015		1.93 (0.89-4.21), *P*=0.098	
No confirmed relapses	80.3%	89.0%	89.4%	95.8%	95.1%	96.0%	96.5%	96.1%	96.3%	99.1%	96.6%	97.7%
No Gd+ T1 lesions	78.5%	97.9%	75.5%	99.6%	94.3%	100.0%	99.6%	100.0%	98.6%	99.5%	99.5%	100.0%
No NE T2 lesions	33.6%	56.6%	42.3%	95.1%	67.8%	96.4%	93.9%	97.4%	96.3%	97.7%	96.1%	98.6%
No 6-month CDP	91.0%	95.5%	94.7%	96.6%	95.5%	97.2%	95.2%	98.3%	95.4%	97.3%	97.1%	98.1%

ALITHIOS study design: ALITHIOS (N=1703) is an open-label, umbrella extension, Phase 3b, single-arm study evaluating long-term (up to 6 years) safety, tolerability, and effectiveness of KESIMPTA (20 mg SC) in subjects with RMS. The study enrolled 1367 RMS patients from the ASCLEPIOS I and II trials who continued KESIMPTA treatment. A long-term (up to 6 years) analysis (n=465) was conducted to evaluate efficacy in the recently diagnosed treatment-naïve subgroup treated with KESIMPTA. A long-term (up to 6 years) safety analysis was conducted to evaluate IgM/IgG levels and their association with serious infection. 366/465 (78.7%) of treatment-naïve patients were still receiving KESIMPTA at data cutoff (September 25, 2023).[5,9,10]

NEDA-3 post hoc analysis design: All patients from the pivotal trial, full analysis set population (all randomized patients with assigned treatments) and who received KESIMPTA® in the ALITHIOS extension study (data cutoff: September 25, 2023) 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. 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 1-year time intervals across 6 years. Within the prespecified time period, patients who achieved NEDA-3 experienced no 6-month CDP; no confirmed relapse; no Gd+ T1 lesions; no NE T2 lesions; and no discontinuation from the study drug due to either lack of efficacy or death.[5,7]

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.[7,8]

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.[7] **No conclusions of clinical outcomes can be drawn.**

IgG, immunoglobulin G; IgM, immunoglobulin M; OR, odds ratio.

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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NEDA-3 is defined as the absence of MS relapses, MRI lesions, and 6-month CDP

At year 6, treatment-naïve patients on KESIMPTA showed[6]:

No confirmed relapses	No MRI lesions	No 6-month CDP
97.7%	No Gd+ T1 lesions: 100% No NE T2 lesions: 98.6%	98.1%

MS, multiple sclerosis.

NEDA-3 post hoc analysis design: All patients from the pivotal trial, full analysis set population (all randomized patients with assigned treatments) and who received KESIMPTA® in the ALITHIOS extension study (data cutoff: September 25, 2023) 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. 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 1-year time intervals across 6 years. Within the prespecified time period, patients who achieved NEDA-3 experienced no 6-month CDP; no confirmed relapse; no Gd+ T1 lesions; no NE T2 lesions; and no discontinuation from the study drug due to either lack of efficacy or death.[5,7]

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.[7] **No conclusions of clinical outcomes can be drawn.**

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.

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 and Hypersensitivity Reactions: KESIMPTA can result in systemic injection-related reactions and hypersensitivity reactions, which may be serious or life-threatening. Injection-related reactions with systemic symptoms occurred most commonly within 24 hours of the first injection, but were also observed with later injections.

Kesimpta® (ofatumumab) 20 mg injection

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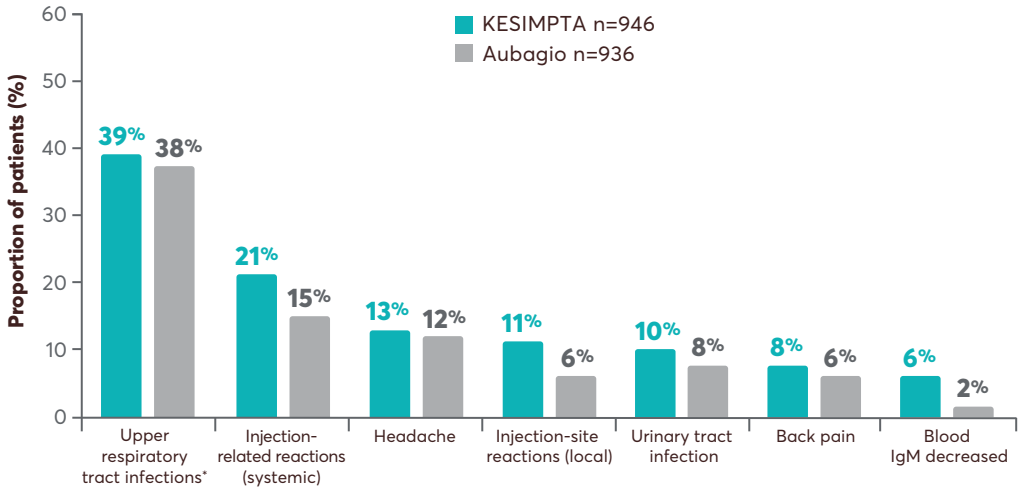
An established safety profile comparable to Aubagio, an oral therapy

Safety across pooled ASCLEPIOS I and II studies[1]



(≥5% with KESIMPTA and a greater incidence than Aubagio)

Rate of infections

The overall rate of infections and serious infections in patients treated with KESIMPTA® was similar to Aubagio (51.6% vs 52.7%, and 2.5% vs 1.8%, respectively).[1]

Treatment discontinuations

Pooled data from both clinical trials show that treatment discontinuation rates due to adverse events were similar between KESIMPTA (5.7%) and Aubagio (5.2%).[11]

The most common cause of discontinuation in patients treated with KESIMPTA was low IgM (3.3%), defined in trial protocols as IgM at 10% below the LLN.[1]

Treatment-induced ADAs were detected in 2 of 914 (0.2%) KESIMPTA-treated patients; no patients with treatment-enhancing or neutralizing ADAs were identified.[1]

No new safety signals were identified in the extension trial up to 6 years[10]

ADA, anti-drug antibody; LLN, lower limit of normal.
*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.[1]

IMPORTANT SAFETY INFORMATION (cont)

Injection-Related Reactions and Hypersensitivity Reactions (cont)**:** There were no life-threatening injection reactions in RMS clinical studies.

In the post-marketing setting, additional systemic injection-related reactions and hypersensitivity reactions have been reported, including anaphylaxis, angioedema, pruritus, rash, urticaria, erythema, bronchospasm, throat irritation, oropharyngeal pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, dizziness, nausea, and tachycardia.

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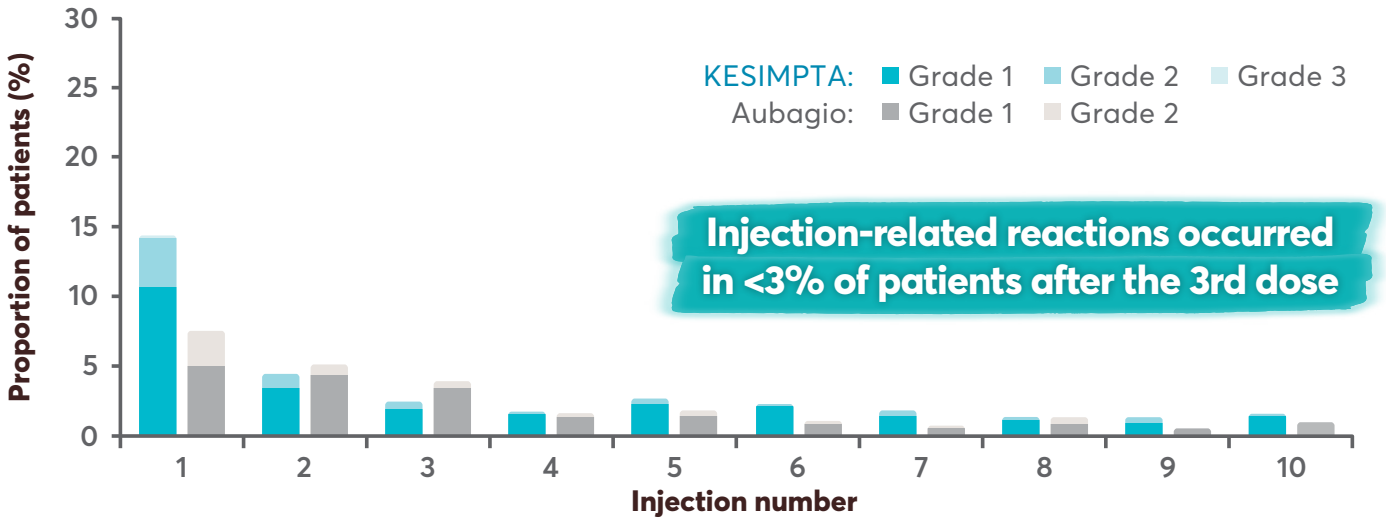
Demonstrated tolerability profile

CLICK HERE TO START YOUR PATIENTS TODAY

Injection-related reactions (systemic) by injection in the ASCLEPIOS trials[1,11,12]



- The incidence of injection-related reactions (systemic) was highest with the first injection (14.4%), decreasing with subsequent injections (4.4% with second, <3% with third injection)[1]
- Two (0.2%) patients treated with KESIMPTA reported serious injection-related reactions[1]
- The most frequently reported symptoms (≥2%) included fever, headache, myalgia, chills, and fatigue[1]
- Patients who took Aubagio in the trials received placebo injections. Over the trial period, systemic and local injection reactions were reported in 21% and 11% of patients treated with KESIMPTA compared to 15% and 6% of patients treated with Aubagio who received matching placebo injections, respectively[1]

IMPORTANT SAFETY INFORMATION (cont)

Injection-Related Reactions and Hypersensitivity Reactions (cont)**:** Most cases were not serious and occurred with the first injection. Symptoms of systemic injection-related reactions may be clinically indistinguishable from acute hypersensitivity reactions.

The first injection of KESIMPTA should be performed under the guidance of an appropriately trained health care professional. If systemic injection-related reactions occur, initiate appropriate therapy.

Patients who experience symptoms of systemic injection-related reactions or hypersensitivity reactions with KESIMPTA should be instructed to seek immediate medical attention. If local injection-related reactions occur, symptomatic treatment is recommended.

Kesimpta® (ofatumumab) 20 mg injection

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Easy-to-use pen[13,14]*

1 MINUTE A MONTH

when the patient is ready to administer—at home or on the go[1,15†‡]

KESIMPTA® is delivered in a pre-filled autoinjector pen[1†]

- Only 0.4 mL per injection
- **No premedication** is required prior to treatment[§]
- **No monitoring** is required after administration[§]
- The Sensoready® Pen can be kept at room temperature (up to 86°F) for up to a week[†]
- The Sensoready Pen needle diameter is 29 gauge, smaller than a pediatric needle (range 22-25 gauge)[16,17]

~8 out of 10 treatment-naïve patients still on treatment after 6 years in the open-label extension study[5]

*Based on a cross-sectional survey of adult RMS patients (N=105) in the US who self-administered KESIMPTA with the Sensoready Pen within the previous 12 months. A total of 8 attributes of KESIMPTA Pen use were assessed, including "easy and simple to use," "easy to prepare," and "convenient/flexible to travel with." 89.5% of patients scored a 4 or 5 on both characteristics of overall ease of use and ease of monthly dosing schedule (convenience). Questionnaire has not been validated. Initiation of KESIMPTA in patients may be influenced by insurance and availability (among other issues). Hence, data should be cautiously interpreted.[13,14]

†KESIMPTA Sensoready Pens must be refrigerated at 2°C to 8°C (36°F to 46°F). Keep product in the original carton to protect from light until the time of use. Do not freeze. To avoid foaming, do not shake. If necessary, KESIMPTA may be stored at room temperature below 30°C (86°F) for up to 7 days and returned to the refrigerator, to be used within the next 7 days.[1]

‡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 begins after the initial dosing period, which consists of 20 mg SC doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA.[1,15]

§Only limited benefit of premedication with corticosteroids, antihistamines, or acetaminophen was observed 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.[1]

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.

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Alongside™ KESIMPTA aims to deliver seamless onboarding

9 out of 10 patients with commercial insurance are covered,* with **>80%** having first-line coverage[18,19]

81% of patients with commercial insurance have first-line coverage.[18,19]

$ No out-of-pocket costs reported in 97% of claims for commercially insured patients using the $0 copay card[20†]

Don't wait weeks—start today with samples‡

The Alongside KESIMPTA Bridge Program covers your commercially insured patients for up to 12 months while coverage is pursued. Just check the box on the Start Form.

*Based on Managed Markets Insight & Technology, LLC database as of May 2024.[18]

†Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance who are initially denied coverage may receive free KESIMPTA for up to 12 months while seeking coverage. Patients with commercial insurance who have coverage for KESIMPTA may receive up to $18,000 in annual copay benefits. Novartis reserves the right to rescind, revoke, or amend this program without notice. Additional limitations may apply. See complete Terms & Conditions at start.kesimpta.com.

‡Sample program is only available to patients who are determined to be appropriate candidates for treatment with KESIMPTA and is intended to give patients a chance to see if KESIMPTA may be right for them.

References: 1. Kesimpta. Prescribing information. Novartis Pharmaceuticals Corp. **2.** Hauser SL, Bar-Or A, Cohen JA, et al. ASCLEPIOS I and ASCLEPIOS II trial groups. Ofatumumab versus teriflunomide in multiple sclerosis. *N Engl J Med*. 2020;383(6):546-557. **3.** Kappos L. Neurostatus scoring: definitions for a standardised, quantified neurological examination and assessment of Kurtzke's Functional Systems and Expanded Disability Status Scale in Multiple Sclerosis. 2011. Accessed May 1, 2024. https://www.neurostatus.net/media/specimen/Definitions_0410-2_s.pdf **4.** Gärtner J, Hauser SL, Bar-Or A, et al. Efficacy and safety of ofatumumab in recently diagnosed, treatment-naïve patients with multiple sclerosis: results from ASCLEPIOS I and II. *Mult Scler*. 2022;28(10):1562-1575. **5.** Pardo G, Hauser SL, Bar-Or A, et al. Longer-term (up to 6 years) efficacy of ofatumumab in people with recently diagnosed and treatment-naive relapsing multiple sclerosis. S31.003. Presented at: 76th American Academy of Neurology Annual Meeting; April 13-18, 2024; Denver, CO. **6.** Data on file. Summary of NEDA-3 components per year. Novartis Pharmaceuticals Corp; East Hanover, NJ. June 2024. **7.** Data on file. OMB157G (ofatumumab). Statistical overview. Novartis Pharmaceuticals Corp; East Hanover, NJ. December 2019. **8.** Giovannoni G, Turner B, Gnanapavan S, Offiah C, Schmierer K, Marta M. Is it time to target no evident disease activity (NEDA) in multiple sclerosis? *Mult Scler Relat Disord*. 2015;4(4):329-333. **9.** Hauser SL, Cross AH, Winthrop K, et al. Safety experience with continued exposure to ofatumumab in patients with relapsing forms of multiple sclerosis for up to 3.5 years. *Mult Scler*. 2022;28(10):1576-1590. **10.** Wiendl H, Hauser SL, Nicholas J, et al. Longer-term safety and efficacy of ofatumumab in people with relapsing multiple sclerosis for up to 6 years. P9.010. Presented at: 76th American Academy of Neurology Annual Meeting; April 13-18, 2024; Denver, CO. **11.** Data on file. OMB157G (ofatumumab). Summary of clinical safety. Novartis Pharmaceuticals Corp; East Hanover, NJ. January 2020. **12.** Hauser SL, Bar-Or A, Cohen JA, et al. ASCLEPIOS I and ASCLEPIOS II trial groups. Ofatumumab versus teriflunomide in multiple sclerosis. Supplemental appendix. *N Engl J Med*. 2020;383(6):546-557. **13.** Ross AP, Nicholas J, Tai MH, et al. Real-world satisfaction and experience with injection and autoinjector device for ofatumumab indicated for multiple sclerosis. LB09. Presented at: Consortium of Multiple Sclerosis Centers Annual Meeting; May 31-June 3, 2023; Aurora, CO. **14.** Novartis KESIMPTA Sensoready® pen survey HEORUSV201392. June 2022. **15.** Data on file. Injection time. Novartis Pharmaceuticals Corp; East Hanover, NJ. June 2020. **16.** Data on file. Supplemental US Scientific Question and Answer (Q&A) Document. Novartis Pharmaceuticals Corp; East Hanover, NJ. June 2021. **17.** Centers for Disease Control. You call the shots: vaccine administration needle gauge and length. Updated August 2020. Accessed July 2024. https://www.cdc.gov/vaccines/hcp/admin/downloads/vaccine-administration-needle-length.pdf **18.** Data on file. Coverage Change-ESI. Novartis Pharmaceuticals Corp; East Hanover, NJ. May 2024. **19.** Data on file. First-line commercial coverage. Novartis Pharmaceuticals Corp; East Hanover, NJ. October 2024. **20.** Data on file. 97 percent OOP. Novartis Pharmaceuticals Corp; East Hanover, NJ. July 2024.

IMPORTANT SAFETY INFORMATION (cont)

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.

Alongside™ Kesimpta® (ofatumumab) 20 mg injection

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START WITH KESIMPTA, THE POWER OF THE PEN[1*]

Powerful efficacy*

Up to 98% reduction in mean Gd+ T1 MRI lesion activity vs Aubagio[1]

Easy-to-use pen[13,14†]

1 minute a month when the patient is ready to administer—at home or on the go[1,15‡§]

Proven safety profile[10]

With no new safety signals identified at 6 years

Don't wait weeks—start today with samples[‖]

*As evidenced by ARR, MRI (Gd+ T1 and T2 lesions), and 3- and 6-month CDP. Primary end point, ARR reduction of 51% (0.11 vs 0.22), 58% (0.10 vs 0.25).[1]

†Based on a survey of adult RMS patients (N=105) in the US who self-administered KESIMPTA® within the previous year. 89.5% of patients scored a 4 or 5 on ease of use. Questionnaire has not been validated.[13,14]

‡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 begins after the initial dosing period, which consists of 20 mg SC doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA.[1,15]

§KESIMPTA Sensoready Pens must be refrigerated at 2°C to 8°C (36°F to 46°F). Keep product in the original carton to protect from light until the time of use. Do not freeze. To avoid foaming, do not shake. If necessary, KESIMPTA may be stored at room temperature below 30°C (86°F) for up to 7 days and returned to the refrigerator, to be used within the next 7 days.[1]

‖Sample program is only available to patients who are determined to be appropriate candidates for treatment with KESIMPTA and is intended to give patients a chance to see if KESIMPTA may be right for them.

IMPORTANT SAFETY INFORMATION (cont)

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

Please see additional Important Safety Information on the previous pages.
Click here for full Prescribing Information, including Medication Guide.

Kesimpta® (ofatumumab) 20 mg injection

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