Kesimpta® (ofatumumab) 20 mg injection

MS, multiple sclerosis.
Jamie-Lynn is a real patient taking KESIMPTA. Individual results may vary.

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.

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

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

It's not too soon to start your early RMS patients on a B-cell therapy[1,3,4]

Meet Jamie-Lynn—switched from infusion to KESIMPTA in 2023

Award-winning actor, mom of 2, MS advocate

> I was on an infusion for my RMS, but my doctor and I decided it was time for a switch. I needed a treatment with powerful efficacy* that also fit into my busy life.[†‡]

Patient history

- Diagnosed with RMS while filming her hit TV show
  - Proactively discussed a treatment change with her doctor
  - Travels frequently with long hours on set

Jamie-Lynn's experience with KESIMPTA

- Treatment has been working for her
- Loves being able to self-administer KESIMPTA® at home or on set
- Appreciates the hands-on patient support of Alongside™ KESIMPTA

Jamie-Lynn is a real patient taking KESIMPTA. 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.[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 subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA.[1,2]

‡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]

IMPORTANT SAFETY INFORMATION (cont)

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.

Please see additional Important Safety Information on the following pages.
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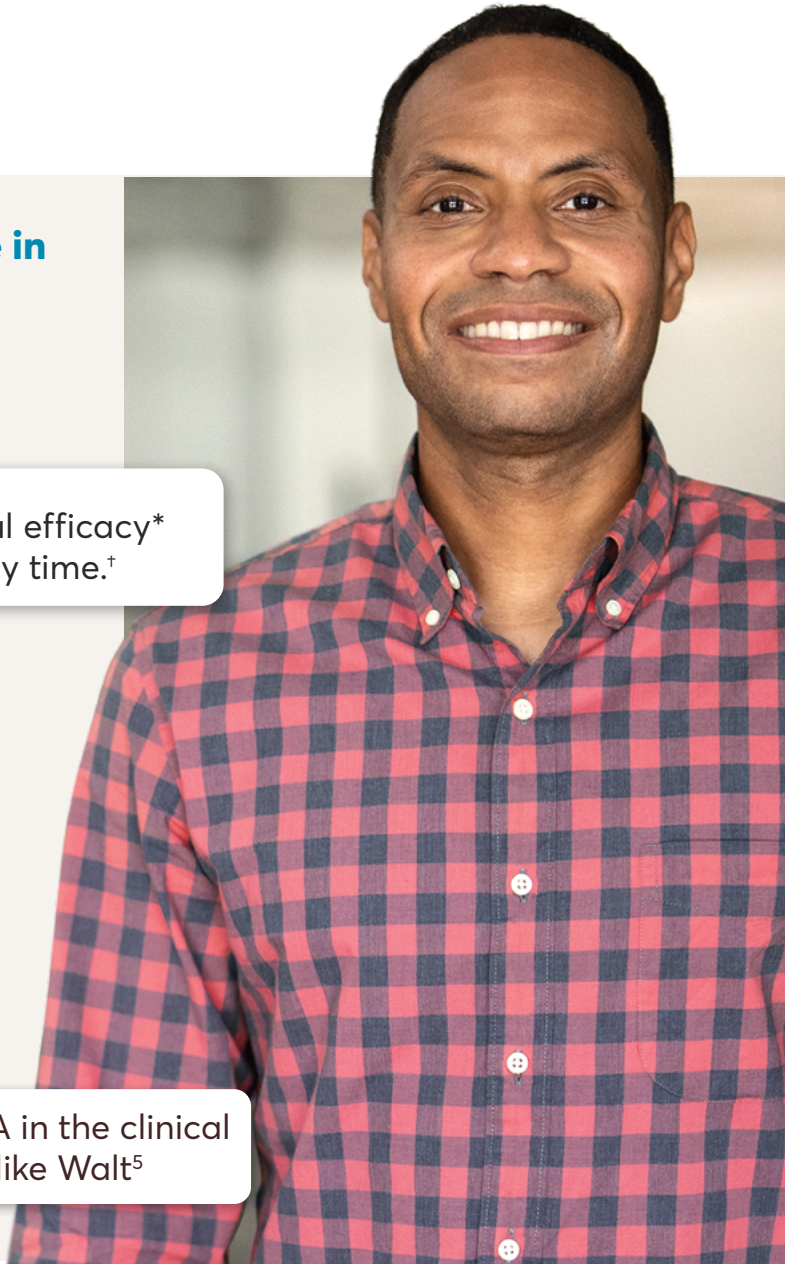
Meet Walt—initiated KESIMPTA first-line in April 2021

Dad, husband, aerospace engineer



> I wanted to start on a treatment with powerful efficacy* that I could take at home or on the go—on my time.†

Patient history

- Diagnosed with RMS in early 2021 following a relapse
- Prefers the idea of home administration with an autoinjector
- Avid biker

Walt's experience with KESIMPTA

- Finds his check-ins with his Alongside Coordinator helpful

40% of patients taking KESIMPTA in the clinical trials were treatment naïve, like Walt[5]

Walt is a real patient taking KESIMPTA. Individual results may vary.

*As evidenced by ARR, MRI (Gd+ T1 and T2 lesions), and 3- and 6-month CDP.[1]

†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]

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

KESIMPTA delivered powerful efficacy vs Aubagio® (teriflunomide)[1,6,7]

DISCOVER MORE ABOUT THE EFFICACY OF KESIMPTA

Superior ARR reductions of up to 58% vs Aubagio

Primary end point: relative reduction in annualized relapses vs Aubagio of 51% (0.11 vs 0.22) in ASCLEPIOS I and 58% (0.10 vs 0.25) in ASCLEPIOS II

Near complete suppression of Gd+ T1 and T2 lesion activity[1,5]

Up to **98%** reduction in mean Gd+ T1 lesions per scan vs Aubagio*

Up to **85%** reduction in mean NE T2 lesions per year vs Aubagio*

MRI end points: reduction in mean Gd+ T1 lesions per scan vs Aubagio of 98% (0.01 vs 0.46) in ASCLEPIOS I and 94% (0.03 vs 0.52) in ASCLEPIOS II; reduction of mean NE T2 lesions per year vs Aubagio of 82% (0.72 vs 4.00) in ASCLEPIOS I and 85% (0.64 vs 4.16) in ASCLEPIOS II

Negative binomial regression model.

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 subcutaneous 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 data from ASCLEPIOS I and II: KESIMPTA provided **early and continued relapse reduction** over the study period[8,9]

- Cumulative ARR by time interval (KESIMPTA n=946, Aubagio n=936). Reduction in ARR seen in the first 3 months and time intervals over 2 years:
  - Month 0 to 3: 0.236 vs 0.373
  - Month 0 to 27: 0.123 vs 0.258
  - **No conclusions can be drawn**

Post hoc study design: ARR by time intervals was analyzed from the pooled pivotal trials. The ARR (95% CI) was estimated separately for each time interval by fitting a negative binomial regression model adjusted for treatment as factor.

Additional key clinical end point: Reduced risk in 3-month CDP vs Aubagio of 34% (10.9% vs 15.0%) in pooled populations from ASCLEPIOS I and II.[1†]

CI, confidence interval; DMT, disease-modifying therapy; EDSS, Expanded Disability Status Scale; NE, new or enlarging.

*At 96 weeks.

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

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.

Please see additional Important Safety Information on the following pages.
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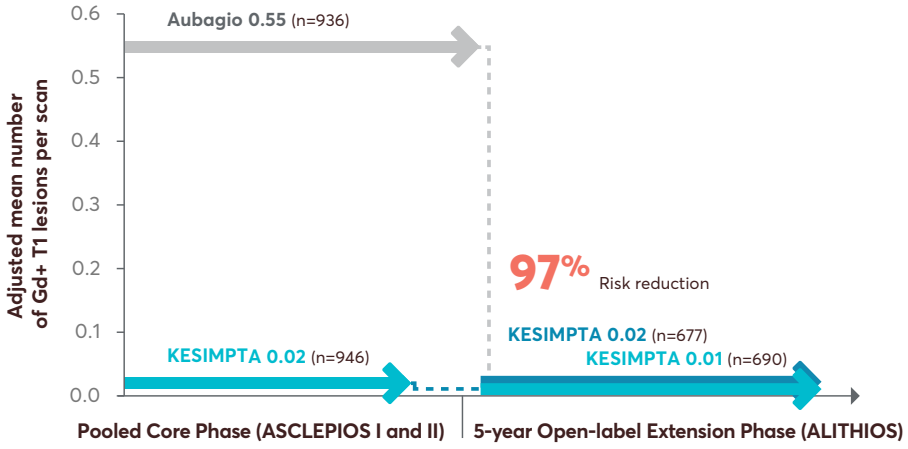
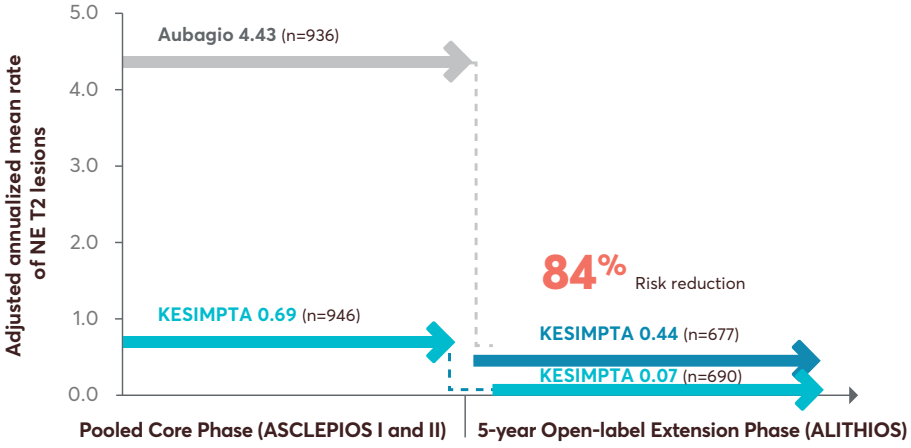
Long-term MRI lesion activity in patients who remained on KESIMPTA and those who switched from Aubagio to KESIMPTA[10]

Gd+ T1 lesions over time



NE T2 lesions over time



Limitations: This analysis represents chance findings. The open-label extension study was not blinded, not controlled, and included inherent self-selection bias for remaining in the trial. **No conclusions of statistical or clinical significance can be drawn.**

ALITHIOS study design: ALITHIOS (N=1703) was an open-label, umbrella extension, Phase 3b, single-arm study evaluating long-term (up to 5 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. Of these, 1145 patients were still receiving KESIMPTA at 5 years. A long-term safety analysis was conducted to evaluate IgM/IgG levels and their association with serious infection. 1416 patients were still receiving KESIMPTA at 5 years.[10-14]

HELP REDUCE MRI ACTIVITY NOW: TAKE THE 1ST STEP WITH KESIMPTA

IgG, immunoglobulin G; IgM, immunoglobulin M; SC, subcutaneous.

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.

Kesimpta® (ofatumumab) 20 mg injection

Efficacy in recently diagnosed treatment-naïve patients on KESIMPTA vs Aubagio[15]

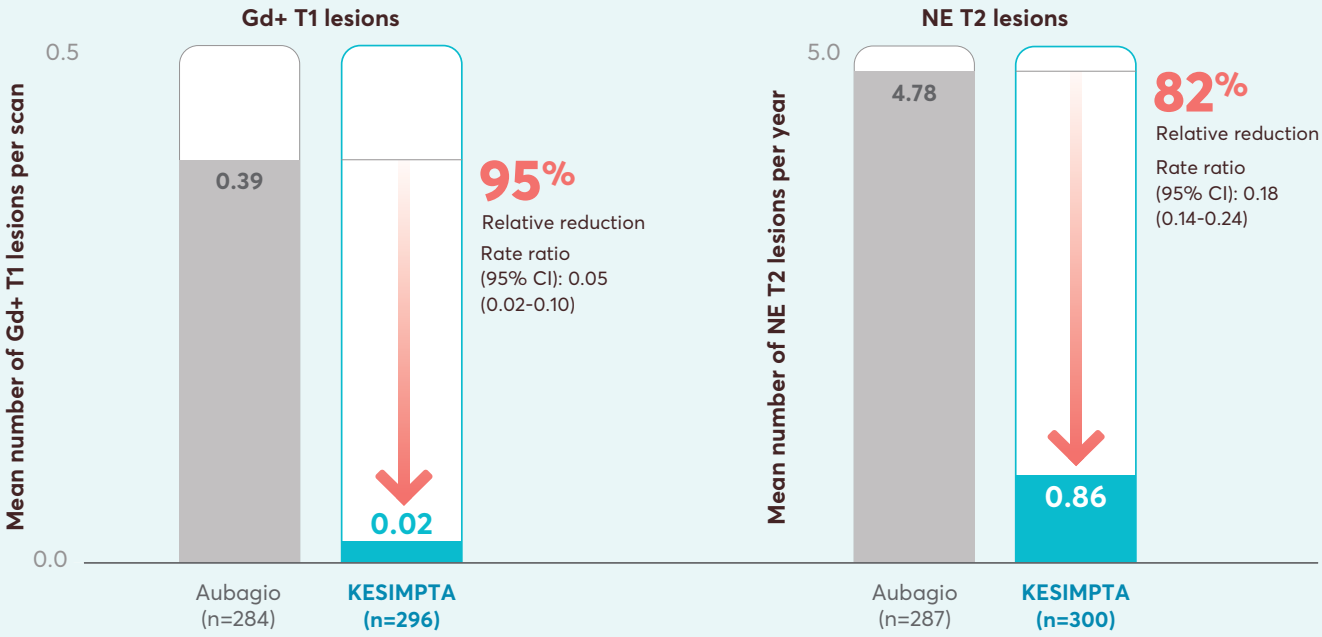
ARR 0.09 in the recently diagnosed treatment-naïve patient population

0.09

Primary end point: relative reduction in annualized relapses vs Aubagio of 50% (0.09 vs 0.18; 95% CI: 0.50 [0.33-0.74])*

MRI lesion activity in recently diagnosed treatment-naïve patients on first-line KESIMPTA vs Aubagio

Reductions in MRI lesion activity vs Aubagio*



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.

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).

No conclusions can be drawn.

*Negative binomial regression model.

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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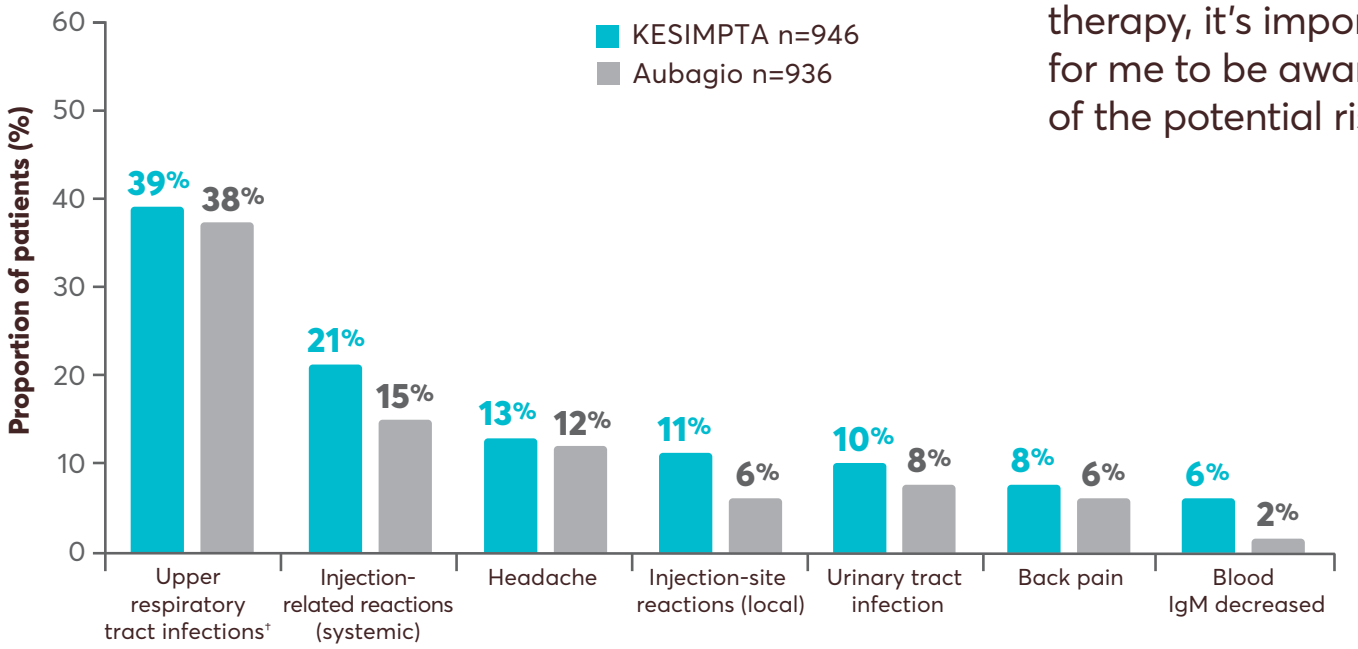
A demonstrated safety profile comparable to Aubagio, an oral therapy[1]

"Before I start any therapy, it's important for me to be aware of the potential risks.*

Safety across pooled ASCLEPIOS I and II studies



(≥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%).[16]

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 lower limit of normal (LLN).[1]

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

*Individual results may vary.
†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: 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. 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,

Kesimpta® (ofatumumab) 20 mg injection

KESIMPTA has an established safety profile demonstrated over 5 years[14]

SCAN NOW FOR COVID-19 SAFETY EVIDENCE

Select adverse events	ASCLEPIOS core KESIMPTA group (N=946) n (%)	Core + extension KESIMPTA group (N=1969) n (%)
Patients with at least one AE	791 (83.61)	1771 (89.9)
Patients with at least one SAE	86 (9.10)	289 (14.7)
AEs leading to KESIMPTA discontinuation	54 (5.70)	139* (7.1)
Infections and infestations	488 (51.58)	1334 (67.75)
Serious infections	24 (2.54)	106 (5.38)
Serious infections (excluding COVID-19)	24 (2.54)	61 (3.09)
Injection-related systemic reactions	195 (20.61)	508 (25.79)
Injection-site reactions	103 (10.88)	243 (12.34)
Malignancies	5 (0.53)	21 (1.06)
Deaths	0	9† (0.46)

- No new safety signals were identified
- The most common AEs were infections (COVID-19 [30.3%], nasopharyngitis [19%], URTI [12.8%], and UTI [12.7%]). Most (90.3%) infections resolved without discontinuing KESIMPTA® treatment
- The nature and frequency of the most common AEs were comparable with those reported in ASCLEPIOS I and II[11]
- In the overall population, the proportion of patients with AEs leading to discontinuation (7.1%) was consistent with those observed in the pivotal trials (5.7%) with KESIMPTA
- Serious infections occurred in 5.38% of the overall safety population over 5 years
- EAIRs for malignancies did not increase over time in the overall KESIMPTA population‡

GIVE YOUR PATIENTS CONFIDENCE WITH EVIDENCE ON LONG-TERM SAFETY WITH KESIMPTA

AE, adverse event; EAIR, exposure-adjusted incidence rate per 100 patient years; PT, preferred term; SAE, serious adverse event; URTI, upper respiratory tract infection; UTI, urinary tract infection.

No conclusions of clinical outcomes can be drawn.

*AEs related to reduced IgM levels is the most common reason for treatment discontinuation (n=71 [3.6%]).

†PT for these 9 cases include: sudden death (n=1), completed suicide (n=1), COVID-19 and COVID-19 pneumonia (n=2), COVID-19 (n=2), intestinal metastasis (n=1), pneumonia and septic shock (n=1), and pneumothorax (n=1).

‡EAIRs per 100 patient years are defined as the number of patients with a particular event during 100 years of exposure to a treatment, estimated by Poisson regression in which patients were censored at time of first event.

IMPORTANT SAFETY INFORMATION (cont)

Injection-Related Reactions and Hypersensitivity Reactions (cont)**:** rash, urticaria, erythema, bronchospasm, throat irritation, oropharyngeal pain, dyspnea, pharyngeal or laryngeal edema, flushing, hypotension, dizziness, nausea, and tachycardia. 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

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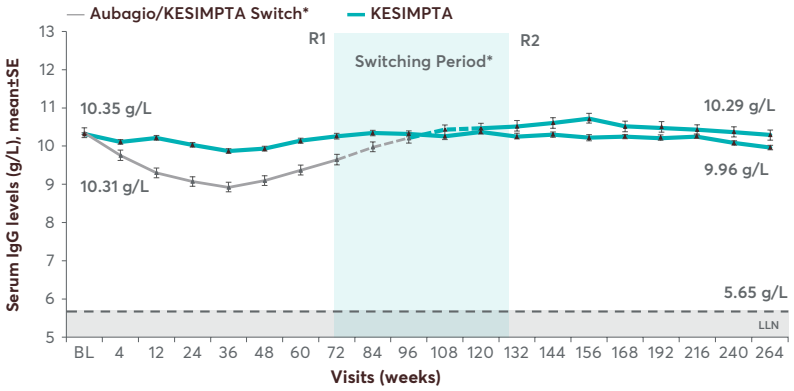
In the extension study analysis,

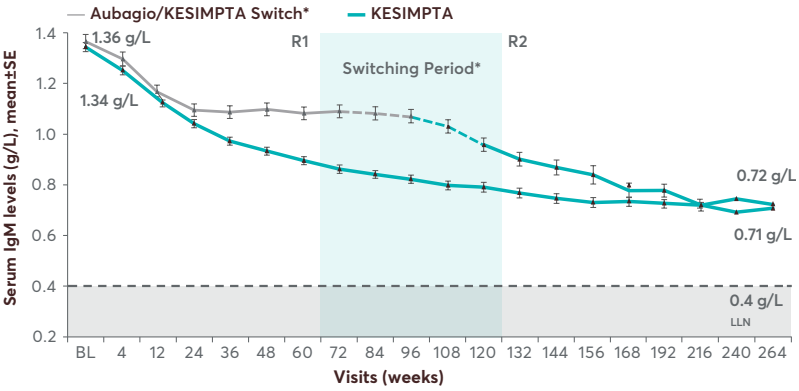
Patients on KESIMPTA maintained stable mean IgG levels for up to 5 years; mean IgM levels declined but remained above LLN[14]

IgG levels with KESIMPTA over 5 years



Average IgG levels remained within the reference range (patients aged >18 years): 5.65-17.65 g/L.[17]

IgM levels with KESIMPTA over 5 years



Average IgM levels remained within the reference range (patients aged >18 years): 0.4-2.3 g/L.[17]

In the extension analysis, the overall incidence of serious infections was low

Low incidence of serious infection (<2 per 100 PY): 5.38% of patients (n=106) experienced ≥1 serious infection within 1 month prior and until 1 month after any series of drops in IgG/IgM below LLN. Infections included herpes zoster, upper respiratory tract infection, urinary tract infection, COVID-19, bronchitis, pneumonia, pyelonephritis chronic, and COVID-19 pneumonia.

KESIMPTA has the potential for an increased risk of infections, including serious bacterial, fungal, and new or reactivated viral infections; some of these infections have been fatal in patients treated with anti-CD20 antibodies.

Most patients (98%) had IgG levels above the LLN for up to 5 years. From the patients (2%) whose IgG levels dropped below the LLN, 3 experienced serious infections, all of which resolved[14]

BL, baseline; Ig, immunoglobulin; PY, patient years; SE, standard error.
*Switching period refers to the patients started with Aubagio and not applicable to the patients treated with KESIMPTA in the core period; for Aubagio/KESIMPTA group, data from first dose of Aubagio until last dose of KESIMPTA plus 100 days/analyses cutoff dates have been used.

IMPORTANT SAFETY INFORMATION (cont)

Injection-Related Reactions and Hypersensitivity Reactions (cont)**:** reactions with KESIMPTA should be instructed to seek immediate medical attention. If local injection-related reactions occur, symptomatic treatment is recommended.

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).

Kesimpta® (ofatumumab) 20 mg injection

KESIMPTA is the first and only SC B-cell RMS treatment that is self-administered once monthly—at home or on the go[1,18*]

When the patient is ready to administer

1 MINUTE A MONTH[2†]

In a real-world survey[19,20‡]

~90%

of patients found the KESIMPTA® Pen easy and simple to use

B-cell administration times[1,2,21,22]

1 min† vs 1 to 4 hour infusion

KESIMPTA | **Briumvi® (ublituximab-xiiy)** | **Ocrevus® (ocrelizumab)**

This chart is only intended to show administration times. **No conclusions of comparative efficacy and safety should be drawn**. KESIMPTA is administered in 1 minute a month subcutaneously. Ocrevus and Briumvi are administered twice yearly via infusion. Please refer to the product's specific prescribing information for complete dosing and administration instructions.

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†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 subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA.[1,2]

‡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 characteristics of overall ease of use and ease of monthly dosing schedule. 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.[19,20]

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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Right dose. Right frequency. Right route of administration.

The KESIMPTA Phase 2 trial determined that once-monthly frequency in a low SC dose was comparably effective, with fewer side effects, vs higher SC doses. The 20 mg dose was chosen through dose modeling based on B-cell depletion results and Phase 2 data.[23,24*]

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

- The Sensoready Pen can be kept at room temperature (up to 86°F) for up to a week[†]
- No premedication is required prior to treatment[‡]
- No monitoring is required after administration[‡]

In two real-world persistence studies[25,26§]

KESIMPTA vs platform injectables	**75%** of patients on KESIMPTA remained on treatment at 1 year	vs	**43%** of those on platform injectables
KESIMPTA vs orals	**82%** of patients taking KESIMPTA remained on treatment at 1 year	vs	**68%** of those on orals

Persistence was defined as the number of days from the index date until discontinuation or a switch to a new DMT. It was measured during the post index period, which included the index date. Discontinuation was defined as a >60-day gap in therapy (injectables) or >90-day gap (orals) of the index medication, defined as a gap between the last supply date (based on expected duration of treatment or days' supply) and the next claim date for the index therapy.[25,26]

*MIRROR was a Phase 2b multicenter, randomized, double-blind, placebo-controlled, dose ranging study of subcutaneous KESIMPTA (N=232). Primary end point was new Gd+ T1 lesions at week 12. Secondary end points included new Gd+ T1 lesions at week 24 and new and/or newly enlarging T2 lesions. Other clinical end points included EDSS, Multiple Sclerosis Functional Composite (MSFC), and Modified Fatigue Impact Scale (MFIS) scores.[23]

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‡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]

§Study 1: retrospective cohort study of adult RMS patients treated with KESIMPTA (n=333) vs platform injectables (n=333) (glatiramer acetate, interferon beta-1a/1b, and peginterferon beta-1a).[25]

Study 2: retrospective cohort study of adult RMS patients treated with KESIMPTA (n=576) or oral DMTs (n=576) (dimethyl fumarate, fingolimod, teriflunomide, cladribine, siponimod, ozanimod, diroximel fumarate, monomethyl fumarate, and ponesimod).[26]

Both studies were conducted from August 2020 to November 2021, utilizing the IQVIA PharMetrics® Plus database. Patients were indexed on first observed therapy and followed until discontinuation, switch, or 12 months post index for persistent patients. Propensity score matching was used to balance the baseline demographic, clinical, and RMS characteristics, as well as use of prior DMT between cohorts.[25,26]

Analyses using claims data are dependent on the accuracy and specificity of information provided. Early discontinuation may be overestimated if treatment occurred outside the purview of the claims data source. Caution should be exercised in making any direct comparisons due to differences between DMTs.[25,26]

IQVIA PharMetrics® Plus is a longitudinal health plan database of medical and pharmacy claims in the United States.

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.

Kesimpta® (ofatumumab) 20 mg injection

Once you decide, Alongside KESIMPTA delivers

HELP GET YOUR PATIENTS OFF TO A QUICK START

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

9 out of 10 patients with commercial insurance are covered, with ~70% having first-line coverage[27]*

$0 **copay.** Eligible commercial patients may pay as little as $0 with the KESIMPTA Access Card†

80% of patients with commercial insurance in the Bridge Program get KESIMPTA in **4 days or less**[28‡]

ALONGSIDE KESIMPTA OFFERS RESOURCES TAILORED TO FIT YOUR PATIENTS' NEEDS

*Coverage data are provided by MMIT and Data on File, current as of May 2024.[27]

†Limitations apply. Offer not valid under Medicare, Medicaid, or any other federal or state health insurance program. Patients with commercial insurance coverage for KESIMPTA may receive up to $18,000 in annual copay benefits. Patients with commercial insurance and an initial denial of coverage may receive up to 12 months of free product while coverage is pursued. Novartis reserves the right to rescind, revoke, or amend this program without notice. See complete Terms & Conditions at start.kesimpta.com.

‡Based on prescription data collected from April to September 2023.[28]

IMPORTANT SAFETY INFORMATION (cont)

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

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.

Please see additional Important Safety Information on the following pages.
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Experience with KESIMPTA keeps growing

>30,000

patients

were prescribed KESIMPTA to treat their RMS[29*]

>4,700

HCPs

have already prescribed KESIMPTA for their patients with RMS[29†]

~700

neurology centers and practices

with patients who were prescribed KESIMPTA to treat their RMS[30‡]

64%

of patients

starting KESIMPTA are either treatment naïve or on their first DMT prior to starting KESIMPTA[30§‖]

JOIN THE THOUSANDS OF NEUROLOGISTS JUST LIKE YOU, WHO CHOOSE KESIMPTA EARLY FOR THEIR RMS PATIENTS

HCP, health care provider.

*Based on Novartis contracted specialty pharmacy and copay claims from launch through September 30, 2023.[29]

†Based on patient Start Forms completed through September 15, 2023 as reported by Novartis patient specialty services and new-to-brand prescriptions (NBRx) reported by data-contracted specialty pharmacies.[29]

‡Based on Symphony Health Physician prescribing data and IQVIA Drug Distribution Data through March 2023, and IQVIA OneKey physician affiliation with practices who have prescribed at least 20 KESIMPTA prescriptions in the last 12 months.[30]

§Based on Symphony Health Anonymized Patient Level Data adjusted by IQVIA National Prescription Audit (NPA) and National Sales Perspectives and Novartis contracted specialty pharmacy and copay claims data for January and February 2023.[30]

‖Treatment naïve: 35%, first DMT: 29%.[30]

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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.

Kesimpta® (ofatumumab) 20 mg injection

The first and only self-administered SC B-cell RMS treatment[1,18]

Powerful efficacy*

Up to 98% reduction in mean Gd+ T1 MRI lesion activity vs Aubagio[1,8,9†]

Safety profile proven over 5 years

With stable IgG levels, and, while IgM levels declined, they remained above LLN through the study period[14]

Easy and simple to use pen[19,20‡]

- 1 minute a month when the patient is ready to administer—at home or on the go[1,2§‖]
- 80% of patients with commercial insurance in the Bridge Program get KESIMPTA® in 4 days or less[28¶]

>30,000 US patients have already been treated with KESIMPTA[29#]

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.

Start your early RMS patients on KESIMPTA today

*As evidenced by ARR, MRI (Gd+ T1 and T2 lesions), and 3- and 6-month CDP.[1]

†Reduction in Gd+ T1 lesions per scan vs Aubagio of 98% (0.01 vs 0.46) in ASCLEPIOS I and 94% (0.03 vs 0.52) in ASCLEPIOS II.[1]

‡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 characteristics of overall ease of use and ease of monthly dosing schedule. 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.[19,20]

§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 subcutaneous doses at weeks 0, 1, and 2. Please see Instructions for Use for more detailed instructions on preparation and administration of KESIMPTA.[1,2]

‖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]

¶Based on prescription data collected from April to September 2023.[28]

#Based on Novartis contracted specialty pharmacy and copay claims from launch through September 30, 2023.[29]

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Kesimpta® (ofatumumab) 20 mg injection

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