Meet Becky, **63**—progressing RMS patient, mother, and nature lover.*

MAYZENT® (siponimod) 1 mg • 2 mg tablets

"MAYZENT® HELPS ME TO DELAY DISABILITY PROGRESSION, AND THAT GIVES ME HOPE."

MAYZENT IS THE FIRST AND ONLY ORAL DMT studied and proven to delay disability progression in a more progressed RMS population, including active SPMS.[1,2†]

SEE HOW MAYZENT HELPS PATIENTS LIKE BECKY WITH PROGRESSING RMS

DMT=disease-modifying therapy; EDSS=Expanded Disability Status Scale; MS=multiple sclerosis; RMS=relapsing MS; SPMS=secondary progressive MS.
*Becky has been an actual MAYZENT patient with RMS since 2019. Individual results may vary. Becky was compensated for her time.
†Patients in *EXPAND* had a mean EDSS score of 5.4.[3]

INDICATION

MAYZENT® (siponimod) 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

- Patients with a CYP2C9*3/*3 genotype
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- Presence of Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, unless patient has a functioning pacemaker

Please see additional Important Safety Information on pages 10-11 and accompanying full Prescribing Information.

MANY PATIENTS WITH RMS, LIKE BECKY, EXPERIENCE DISEASE PROGRESSION[4]

It's never too early to stay ahead of RMS progression[5,6]

Recognition and timely intervention may help delay disability progression over time.[5,6]

Disability steadily accumulates over time, and daily activities can be increasingly compromised[7]

SPMS can present as early as EDSS score of 3.0[8]

Disease progression may be ongoing, even when patients appear stable[9]

BECKY'S NEUROLOGIST NOTICED SUBTLE SIGNS OF RMS PROGRESSION.
Are you noticing progression in your RMS patients?

IMPORTANT SAFETY INFORMATION (CONT)

Infections: MAYZENT may increase risk of infections with some that are serious in nature. Life-threatening and rare fatal infections have occurred.

Before starting MAYZENT, review a recent complete blood count (CBC) (ie, within 6 months or after discontinuation of prior therapy). Delay initiation of treatment in patients with severe active infections until resolved. Employ effective treatments and monitor patients with symptoms of infection while on therapy. Consider discontinuing treatment if patient develops a serious infection.

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"Pay attention to physical and mental changes—everything you notice matters."

It's important to understand any physical or mental changes in your progressing RMS patients

BECKY, 63 YEARS OLD
Mother and nature lover

PATIENT HISTORY

- **20 years** since MS diagnosis. Initially presented with bilateral foot numbness that spread up her legs
- **2 therapies since diagnosis**
- **Relapses** are less frequent, but last MRI revealed 1 new GdE lesion and an increase in T2 lesion volume
- **Experienced** cognitive and physical issues; she has trouble with memory, which makes her feel slow both physically and mentally
- **Initiated treatment** 2 years ago

BECKY'S NEUROLOGIST TOOK ACTION AGAINST PROGRESSING RMS.
Is it time to consider MAYZENT® for your patients?

GdE=gadolinium-enhancing; HCP=health care professional; MRI=magnetic resonance imaging.

IMPORTANT SAFETY INFORMATION (CONT)

Infections (cont): Cases of fatal cryptococcal meningitis (CM) were reported in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator. Rare cases of CM have occurred with MAYZENT. If CM is suspected, MAYZENT should be suspended until cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated.

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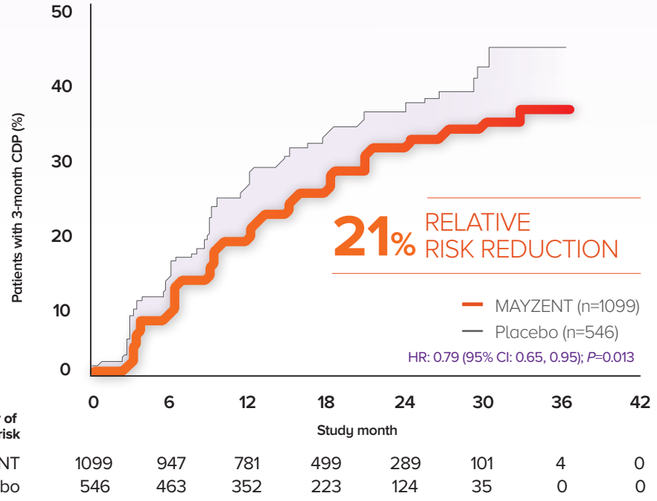
“Every bit of delayed disability progression counts.”

MAYZENT® was proven to delay disability progression in the *EXPAND* core study[3]

MAYZENT demonstrated a 21% relative risk reduction in time to 3-month CDP vs placebo.[1,3]

PRIMARY END POINT[1]

TIME TO 3-MONTH CDP VS PLACEBO[1]



Number of patients at risk								
MAYZENT	1099	947	781	499	289	101	4	0
Placebo	546	463	352	223	124	35	0	0

- The proportion of patients with 3-month CDP for MAYZENT was 26% vs 32% for placebo[3]
- CDP was defined as a ≥1-point increase from baseline in EDSS score (0.5-point increase for patients with a baseline EDSS score of ≥5.5) sustained for 3 months[1]
- Although MAYZENT had a significant effect on CDP in patients with active SPMS (relapse in the 2 years prior to study entry), its effect in patients with nonactive SPMS was not statistically significant[1]

Trial design: *EXPAND* was a randomized, double-blind, parallel-group, placebo-controlled, time-to-event study in 1651 patients with SPMS who had evidence of disability progression in the prior 2 years, no evidence of relapse in 3 months prior to study enrollment, and an EDSS score of 3.0-6.5 at study entry. The primary end point of the study was the time to 3-month CDP, defined as at least a 1-point increase from baseline in EDSS (0.5-point increase for patients with baseline EDSS of 5.5 or higher) sustained for 3 months. Key secondary end points were time to 3-month confirmed worsening by ≥20% from baseline on the T25-FW test and the change from baseline in T2 lesion volume.[1]

CDP=confirmed disability progression; CI=confidence interval; HR=hazard ratio; T25-FW=timed 25-foot walk.

IMPORTANT SAFETY INFORMATION (CONT)

Infections (cont): No cases of progressive multifocal leukoencephalopathy (PML) were reported in MAYZENT clinical trials; however, they have been observed in patients treated with another sphingosine 1-phosphate (S1P) receptor modulator and other multiple sclerosis (MS) therapies. If PML is suspected, MAYZENT should be discontinued.

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KEY SECONDARY END POINT RESULTS*

T25-FW TEST

Time to 3-month confirmed deterioration by ≥20% on the T25-FW test was not statistically significant vs placebo (*P*=NS)[1]

CNS TISSUE MEASURE

T2 LESION VOLUME

Reduced the expansion of T2 lesion volume at 12 and 24 months vs placebo (adjusted mean; $P<0.01^{\dagger}$)[1]

- Change from baseline in T2 lesion volume: 184 mm^3 for patients on MAYZENT vs 879 mm^3 for placebo[1]

†Nominal *P* value, not corrected for multiple comparisons.

*
- In *EXPAND*, a prespecified hierarchical analysis consisted of the primary end point and these 2 key secondary end points[1]
- The T25-FW test key end point was not significant; therefore, the T2 lesion volume key secondary end point was considered nominal[1,3]
- The remaining end points were not corrected for multiple comparisons[1]

BECKY IS RELIEVED KNOWING THAT MAYZENT CAN HELP.
How could MAYZENT help your patients with progressing RMS and aSPMS?

aSPMS=active secondary progressive MS; CNS=central nervous system; NS=not significant.

IMPORTANT SAFETY INFORMATION (CONT)

Infections (cont): Cases of herpes viral infection, including one case of reactivation of varicella zoster virus leading to varicella zoster meningitis, have been reported. Patients without a confirmed history of varicella zoster virus (VZV) or without vaccination should be tested for antibodies before starting MAYZENT. If VZV antibodies are not present or detected, then VZV immunization is recommended and MAYZENT should be initiated 4 weeks after vaccination.

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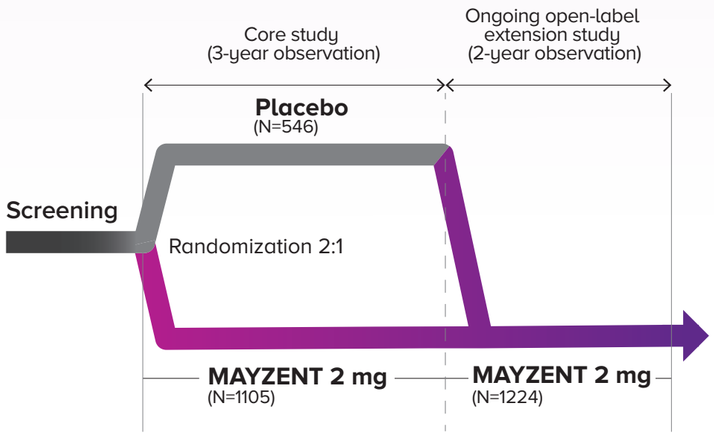
INTERIM ANALYSIS OF EXPLORATORY DATA UP TO 5 YEARS WITH MAYZENT®[10]

In the *EXPAND* open-label extension study[10]

The objective of the study is to evaluate the long-term safety and tolerability of MAYZENT. The extension study allows patients who completed the core part of the study to continue with MAYZENT, and aims to provide long-term safety data, as well as evaluate exploratory long-term data on efficacy measures.[10]

Of the 1224 patients who entered the extension study from the core study, 593 (72.2%) of MAYZENT patients (continuous MAYZENT group) and 285 (71.4%) of placebo patients (placebo-switch group) continued into the extension. The mean exposure to MAYZENT for all patients (core + extension) was 39.4 months. 18.5% of all study patients (core + extension) reached the 5-year MAYZENT treatment milestone at the time of this analysis.[10]

OPEN-LABEL EXTENSION STUDY DESIGN[10]



SELECT LONG-TERM EXPLORATORY END POINT[10,11]

- Time to 6-month CDP[10,11]*

This extension study end point differs from the core study and was predefined as exploratory in the extension protocol.[11]

*Additional long-term data that were collected but not listed: 6-month confirmed worsening of at least 20% from baseline in the T25-FW test, MRI parameters, Multiple Sclerosis Walking Scale-12, and EuroQoL, ARR, and SDMT.[10,11]
ARR=annualized relapse rate; SDMT=Symbol Digit Modalities Test.

IMPORTANT SAFETY INFORMATION (CONT)

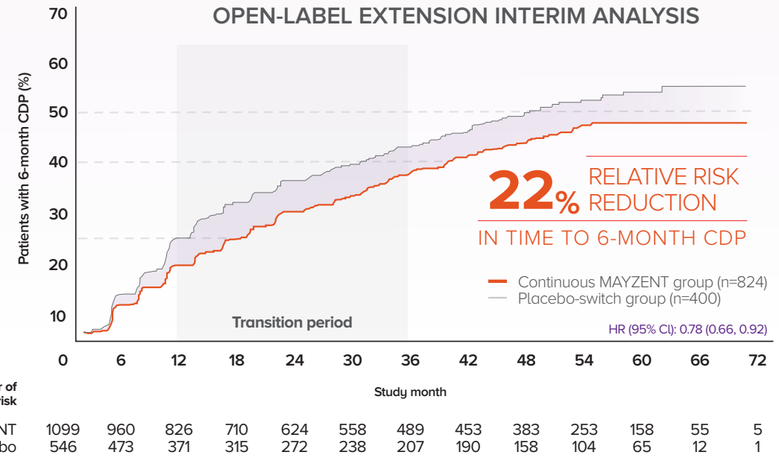
Infections (cont): Use of live vaccines should be avoided while taking MAYZENT and for 4 weeks after stopping treatment.

Caution should be used when combining treatment (ie, anti-neoplastic, immune-modulating, or immunosuppressive therapies) due to additive immune system effects.

Please see additional Important Safety Information on pages 10-11 and accompanying full Prescribing Information.

Selected efficacy assessment up to 5 years was consistent with the core study[3,10†‡]

TIME TO 6-MONTH CDP IN CONTINUOUS MAYZENT GROUP VS PLACEBO-SWITCH GROUP[10]



Number of patients at risk	0	6	12	18	24	30	36	42	48	54	60	66	72
MAYZENT	1099	960	826	710	624	558	489	453	383	253	158	55	5
Placebo	546	473	371	315	272	238	207	190	158	104	65	12	1

In this analysis, patients who started in the MAYZENT treatment arm experienced a greater reduction in the risk of disability progression vs patients who switched to MAYZENT later.[10]

This exploratory analysis represents a chance finding. No conclusions of statistical or clinical significance can be drawn. Consider interim analysis open-label extension study limitations when interpreting data. The open-label extension study is not blinded, not controlled, and includes inherent self-selection bias for remaining in the trial.

†6-month CDP was an exploratory end point of efficacy measurement in the *EXPAND* extension study.[11]
‡3-month CDP was not evaluated as part of the long-term extension study.

IMPORTANT SAFETY INFORMATION (CONT)

Macular Edema: In most cases, macular edema occurred within 4 months of therapy. Patients with history of uveitis or diabetes are at an increased risk. Before starting treatment, an ophthalmic evaluation of the fundus, including the macula, is recommended and at any time if there is a change in vision. The use of MAYZENT in patients with macular edema has not been evaluated; the potential risks and benefits to the individual patient should be considered.

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"It's all about listening to your body and mind—and doing what's best."

Demonstrated safety profile in the *EXPAND* core study[1]

Adverse events that occurred in ≥5% of patients taking MAYZENT® and at a rate of ≥1% higher than in patients receiving placebo.[1]

PROPORTION OF PATIENTS WITH ADVERSE EVENTS[1]

	MAYZENT 2 mg (n=1099)	Placebo (n=546)
Headache	15%	14%
Hypertension	13%	9%
Transaminase levels increased	11%	3%
Falls	11%	10%
Peripheral edema	8%	4%
Nausea	7%	4%
Dizziness	7%	5%
Diarrhea	6%	4%
Bradycardia	6%	3%
Pain in extremity	6%	4%

In the core study, the most common adverse events (incidence ≥10%) were headache (15%), hypertension (13%), and transaminase increases (11%).[1]

Treatment discontinuation rates due to adverse events were similar across treatment arms.[1]

- 8.5% of patients taking MAYZENT discontinued treatment due to adverse events vs 5.1% with placebo[1]

KNOWING WHAT SOME OF THE POTENTIAL SIDE EFFECTS ARE MAKES BECKY FEEL MORE COMFORTABLE.
What does the demonstrated safety profile of MAYZENT mean for your patients?

IMPORTANT SAFETY INFORMATION (CONT)

Bradyarrhythmia and Atrioventricular Conduction Delays: Prior to initiation of MAYZENT, an ECG should be obtained to determine if preexisting cardiac conduction abnormalities are present. In all patients, a dose titration is recommended for initiation of MAYZENT treatment to help reduce cardiac effects.

MAYZENT was not studied in patients who had:

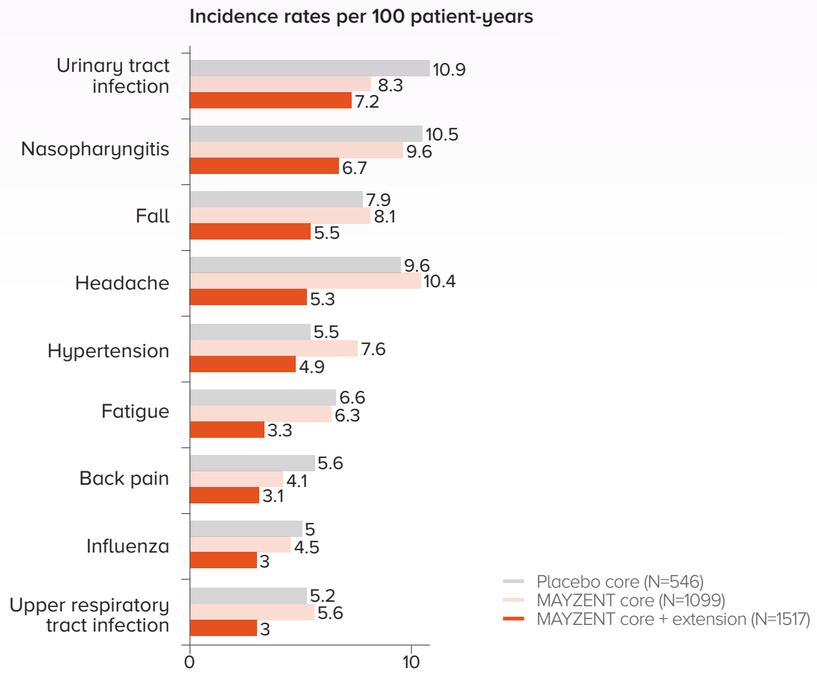
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, or decompensated heart failure requiring hospitalization

Please see additional Important Safety Information on pages 10-11 and accompanying full Prescribing Information.

The safety profile of MAYZENT remained consistent with the core study up to 5 years[10]

Adverse events that occurred in ≥3% of patients taking MAYZENT in the core and extension studies (analysis results were consistent with core study per listed criteria).[10]

PROPORTION OF PATIENTS WITH ADVERSE EVENTS[10]



IMPORTANT SAFETY INFORMATION (CONT)

Bradyarrhythmia and Atrioventricular Conduction Delays (cont):

- New York Heart Association Class II-IV heart failure
- Cardiac conduction or rhythm disorders, including complete left bundle branch block, sinus arrest or sino-atrial block, symptomatic bradycardia, sick sinus syndrome, Mobitz type II second-degree AV-block or higher-grade AV-block (either history or observed at screening), unless patient has a functioning pacemaker

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Indication and Important Safety Information

INDICATION

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IMPORTANT SAFETY INFORMATION

Contraindications

- Patients with a CYP2C9*3/*3 genotype
- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, decompensated heart failure requiring hospitalization, or Class III/IV heart failure
- Presence of Mobitz type II second-degree, third-degree atrioventricular block, or sick sinus syndrome, unless patient has a functioning pacemaker

Infections: MAYZENT may increase risk of infections with some that are serious in nature. Life-threatening and rare fatal infections have occurred.

Before starting MAYZENT, review a recent complete blood count (CBC) (ie, within 6 months or after discontinuation of prior therapy). Delay initiation of treatment in patients with severe active infections until resolved. Employ effective treatments and monitor patients with symptoms of infection while on therapy. Consider discontinuing treatment if patient develops a serious infection.

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Use of live vaccines should be avoided while taking MAYZENT and for 4 weeks after stopping treatment.

Caution should be used when combining treatment (ie, anti-neoplastic, immune-modulating, or immunosuppressive therapies) due to additive immune system effects.

Macular Edema: In most cases, macular edema occurred within 4 months of therapy. Patients with history of uveitis or diabetes are at an increased risk. Before starting treatment, an ophthalmic evaluation of the fundus, including the macula, is recommended and at any time if there is a change in vision. The use of MAYZENT in patients with macular edema has not been evaluated; the potential risks and benefits to the individual patient should be considered.

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- In the last 6 months, experienced myocardial infarction, unstable angina, stroke, TIA, or decompensated heart failure requiring hospitalization
- New York Heart Association Class II-IV heart failure
- Cardiac conduction or rhythm disorders, including complete left bundle branch block, sinus arrest or sino-atrial block, symptomatic bradycardia, sick sinus syndrome, Mobitz type II second-degree AV-block or higher-grade AV-block (either history or observed at screening), unless patient has a functioning pacemaker
- Significant QT prolongation (QTc greater than 500 msec)
- Arrhythmias requiring treatment with Class Ia or Class III anti-arrhythmic drugs

Reinitiation of treatment (initial dose titration, monitoring effects on heart rate and AV conduction [ie, ECG]) should apply if ≥4 consecutive daily doses are missed.

Respiratory Effects: MAYZENT may cause a decline in pulmonary function. Spirometric evaluation of respiratory function should be performed during therapy if clinically warranted.

IMPORTANT SAFETY INFORMATION (CONT)

Liver Injury: Elevation of transaminases may occur in patients taking MAYZENT. Before starting treatment, obtain liver transaminase and bilirubin levels. Closely monitor patients with severe hepatic impairment. Patients who develop symptoms suggestive of hepatic dysfunction should have liver enzymes checked, and MAYZENT should be discontinued if significant liver injury is confirmed.

Cutaneous Malignancies: Long-term use of S1P modulators, including MAYZENT, have been associated with an increased risk of basal cell carcinoma (BCC). Cases of other cutaneous malignancies, including melanoma and squamous cell carcinoma, have also been reported in patients treated with MAYZENT and in patients treated with another S1P modulator.

Periodic skin examination is recommended. Monitor for suspicious skin lesions and promptly evaluate any that are observed. Exposure to sunlight and ultraviolet light should be limited by wearing protective clothing and using a sunscreen with high protection factor. Concomitant phototherapy with UV-B radiation or PUVA-photochemotherapy is not recommended.

Increased Blood Pressure: Increase in systolic and diastolic pressure was observed about 1 month after initiation of treatment and persisted with continued treatment. During therapy, blood pressure should be monitored and managed appropriately.

Fetal Risk: Based on animal studies, MAYZENT may cause fetal harm. Women of childbearing potential should use effective contraception to avoid pregnancy during and for 10 days after stopping MAYZENT therapy.

Posterior Reversible Encephalopathy Syndrome (PRES): Rare cases of PRES have been reported in patients receiving a sphingosine 1-phosphate (S1P) receptor modulator. Such events have not been reported for patients treated with MAYZENT in clinical trials. If patients develop any unexpected neurological or psychiatric symptoms, a prompt evaluation should be considered. If PRES is suspected, MAYZENT should be discontinued.

Unintended Additive Immunosuppressive Effects From Prior Treatment or After Stopping MAYZENT: When switching from drugs with prolonged immune effects, the half-life and mode of action of these drugs must be considered to avoid unintended additive immunosuppressive effects.

Initiating treatment with MAYZENT after treatment with alemtuzumab is not recommended.

After stopping MAYZENT therapy, siponimod remains in the blood for up to 10 days. Starting other therapies during this interval will result in concomitant exposure to siponimod.

Lymphocyte counts returned to the normal range in 90% of patients within 10 days of stopping therapy. However, residual pharmacodynamic effects, such as lowering effects on peripheral lymphocyte count, may persist for up to 3-4 weeks after the last dose. Use of immunosuppressants within this period may lead to an additive effect on the immune system, and therefore, caution should be applied 3-4 weeks after the last dose of MAYZENT.

Severe Increase in Disability After Stopping MAYZENT: Severe exacerbation of disease, including disease rebound, has been rarely reported after discontinuation of an S1P receptor modulator. The possibility of severe exacerbation of disease should be considered after stopping MAYZENT treatment, thus patients should be monitored upon discontinuation.

Most Common Adverse Reactions: Most common adverse reactions (>10%) are headache, hypertension, and transaminase increases.

Please see accompanying full Prescribing Information, including Medication Guide.

References: 1. Mayzent [prescribing information]. East Hanover, NJ: Novartis Pharmaceuticals Corp; March 2022. **2.** Data on file. First and only progressing RMS treatment. Novartis Pharmaceuticals Corp; October 2021. **3.** Kappos L, Bar-Or A, Cree BAC, et al; for the EXPAND Clinical Investigators. Siponimod versus placebo in secondary progressive multiple sclerosis (EXPAND): a double-blind, randomised, phase 3 study. *Lancet*. 2018;391(10127):1263-1273. **4.** Inojosa H, Proschmann U, Akgün K, Ziemssen T. A focus on secondary progressive multiple sclerosis (SPMS): challenges in diagnosis and definition. *J Neurol*. 2021;268:1210-1221. **5.** Fox RJ, Cohen JA. Multiple sclerosis: the importance of early recognition and treatment. *Cleve Clin J Med*. 2001;68(2):157-171. **6.** Gross HJ, Watson C. Characteristics, burden of illness, and physical functioning of patients with relapsing-remitting and secondary progressive multiple sclerosis: a cross-sectional US survey. *Neuropsychiatr Dis Treat*. 2017;13:1349-1357. **7.** Ziemssen T, Derfuss T, de Stefano N, et al. Optimizing treatment success in multiple sclerosis. *J Neurol*. 2016;263(6):1053-1065. **8.** Tremlett H, Zhao Y, Devonshire V. Natural history of secondary-progressive multiple sclerosis. *Mult Scler*. 2008;14:314-324. **9.** Lublin FD, Reingold SC, Cohen JA, et al. Defining the clinical course of multiple sclerosis. *Neurology*. 2014;83:278-286. **10.** Data on file. Long-term Efficacy and Safety of Siponimod in Patients with SPMS: EXPAND Extension Analysis up to 5 Years. Novartis Pharmaceuticals Corp; May 2020. **11.** Data on file. A multicenter, randomized, double-blind, parallel-group, placebo-controlled variable treatment duration study evaluating the efficacy and safety of Siponimod (BAF312) in patients with secondary progressive multiple sclerosis followed by extended treatment with open-label BAF312. Novartis Pharmaceuticals Corp; July 2020. **12.** Kurtzke JF. Rating neurologic impairment in multiple sclerosis: An expanded disability status scale (EDSS). *Neurology*. 1983;33(11):1444-1452. **13.** Data on file. US National Library of Medicine. ClinicalTrials.gov. SPMS Clinical Trial Search Results. Accessed February 11, 2022.

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“MAYZENT® HAS HELPED DELAY MY DISABILITY PROGRESSION, WHICH HAS GIVEN ME THE OPPORTUNITY TO DO MANY OF THE THINGS I WANT TO DO.”

—Becky, 63, real MAYZENT patient

For patients like Becky, with first signs of progression in RMS, including active SPMS,[1]

STAY AHEAD OF PROGRESSION—CHOOSE MAYZENT[1]

FIRST AND ONLY ORAL DMT studied and proven to delay disability progression in a more progressed RMS population, including active SPMS[1,2*]

- Disability progression was measured by the EDSS, which includes combined physical and cognitive functions, with significance in time to 3-month CDP in active SPMS[3,12,†]

DEMONSTRATED SAFETY PROFILE in the largest trial designed for this more progressed patient population in RMS[1,13]

SELECTED INTERIM ASSESSMENT UP TO 5 YEARS WAS CONSISTENT with the *EXPAND* core study, and patients who started in the MAYZENT treatment arm experienced a greater reduction in the risk of disability progression vs patients who switched to MAYZENT later[3,10‡]

*Patients in *EXPAND* had a mean EDSS score of 5.4.[3]
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NOVARTIS

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