



The first and only sphingosine 1-phosphate (S1P) receptor modulator approved for the treatment of moderately to severely active ulcerative colitis (UC) in adults<sup>1</sup>

## ANOTHER DAY IS DAWNING IN THE CONTROL OF UC

Significantly higher clinical remission rates vs placebo in the pivotal trial: 18% (79/429) vs 6% (13/216) at Week 10 ( $p < 0.0001$ ) and 37% (85/230) vs 19% (42/227) at Week 52 ( $p < 0.0001$ )<sup>1</sup>



### Demonstrated Safety Profile<sup>1a</sup>

Studied in 4 clinical trials with over 1370 ZEPOSIA-treated patients across multiple indications



<sup>a</sup>ZEPOSIA has been studied across multiple indications in 4 clinical trials, including TRUE NORTH (NCT02435992), a multicenter, randomized, double-blind, placebo-controlled phase 3 clinical trial; TOUCHSTONE (NCT01647516), a randomized, double-blind, placebo-controlled phase 2 clinical trial; and SUNBEAM (NCT02294058) and RADIANCE (NCT02047734), 2 multicenter, randomized, double-blind, double-dummy, active treatment-controlled phase 3 clinical trials. 496 patients receiving the 0.92-mg dose of ZEPOSIA during induction in TRUE NORTH or TOUCHSTONE and 882 patients receiving the 0.92-mg dose of ZEPOSIA in SUNBEAM or RADIANCE were assessed in the safety analysis.<sup>1</sup>

**Study Design:** 2 multicenter, randomized, double-blind, placebo-controlled studies in adult patients with moderately to severely active UC, UC Study 1 (induction 10 weeks, N=645) and UC Study 2 (maintenance 42 weeks, N=457). To enter UC Study 2, patients had to have received ZEPOSIA in either UC Study 1 or in an open-label arm and be in clinical response at Week 10.<sup>1</sup>

Clinical Remission Is Defined as: RBS=0, SFS=0 or 1 (and a decrease of  $\geq 1$  point from the baseline of SFS), and endoscopy subscore 0 or 1 without friability.<sup>1</sup>

### INDICATIONS

ZEPOSIA<sup>®</sup> (ozanimod) is indicated for the treatment of:

1. Relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults.
2. Moderately to severely active ulcerative colitis (UC) in adults.

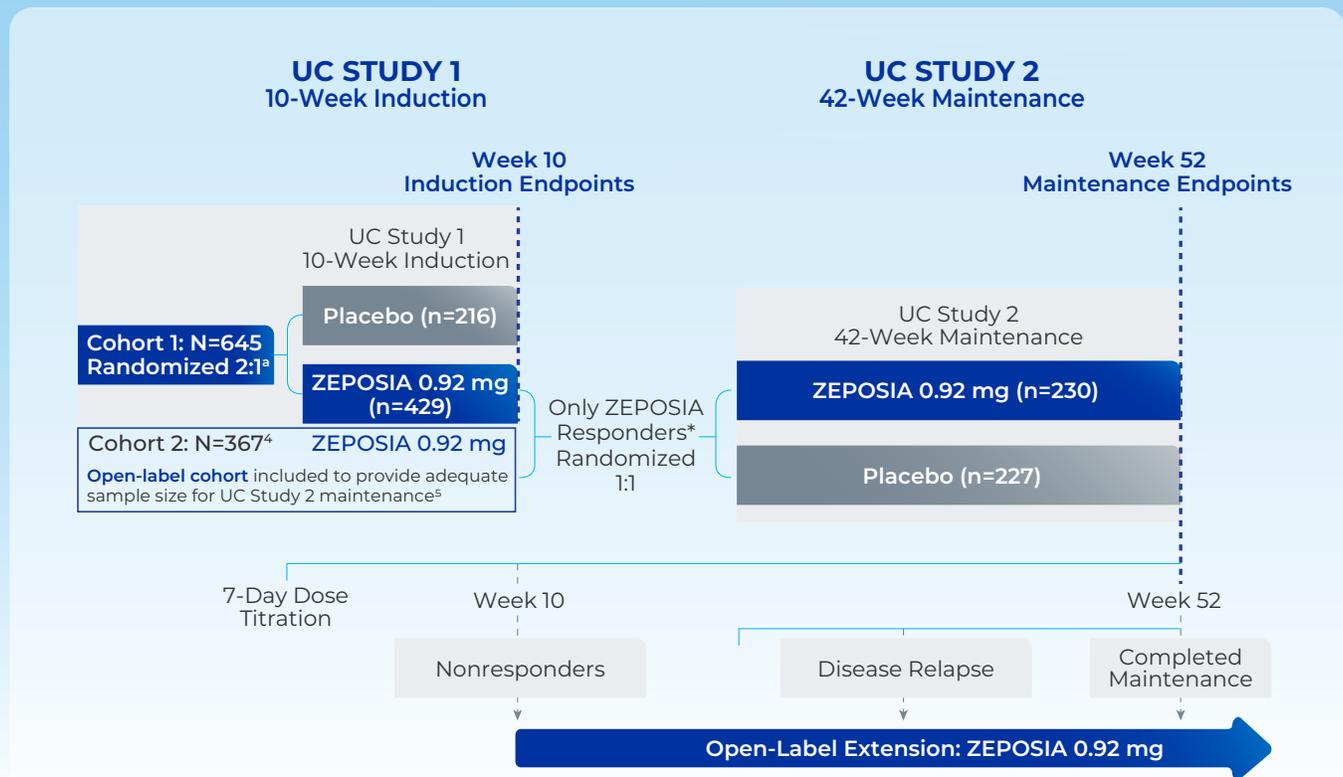
### IMPORTANT SAFETY INFORMATION

#### Contraindications:

- Patients who in the last 6 months, experienced myocardial infarction, unstable angina, stroke, transient ischemic attack (TIA), decompensated heart failure requiring hospitalization, or Class III/IV heart failure or have the presence of Mobitz type II second-degree or third degree atrioventricular (AV) block, sick sinus syndrome, or sino-atrial block, unless the patient has a functioning pacemaker
- Patients with severe untreated sleep apnea
- Patients taking a monoamine oxidase (MAO) inhibitor

**Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.**

# TRUE NORTH Study Design<sup>1,4,5</sup>



**Study Design:** The efficacy and safety of ZEPOSIA were evaluated in 2 multicenter, randomized, double-blind, placebo-controlled clinical studies (UC Study 1 [induction] and UC Study 2 [maintenance]) in adult patients with moderately to severely active UC, defined as a Mayo score of 6 to 12 at baseline.<sup>1</sup>

- Clinical remission is defined as: rectal bleeding subscore=0, stool frequency subscore (SFS) 0 or 1 (and a decrease of  $\geq 1$  point from baseline SFS), and endoscopy subscore 0 or 1 without friability<sup>1</sup>
- \*Clinical response is defined as a reduction from baseline in the 3-component Mayo score of  $\geq 2$  points and  $\geq 35\%$ , and a reduction from baseline in the RBS of  $\geq 1$  point or an absolute RBS of 0 or 1<sup>1</sup>

<sup>a</sup>Patients in cohort 1 were stratified by prior TNFi use and corticosteroid use prior to randomization.<sup>4</sup>

## IMPORTANT SAFETY INFORMATION (cont'd)

**Infections:** ZEPOSIA may increase the susceptibility to infections. Life-threatening and rare fatal infections have occurred in patients receiving ZEPOSIA. Obtain a recent (i.e., within 6 months or after discontinuation of prior MS or UC therapy) complete blood count (CBC) including lymphocyte count before initiation of ZEPOSIA. Delay initiation of ZEPOSIA in patients with an active infection until the infection is resolved. Consider interruption of treatment with ZEPOSIA if a patient develops a serious infection. Continue monitoring for infections up to 3 months after discontinuing ZEPOSIA

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.



## TRUE NORTH Inclusion and Exclusion Study Criteria

### Key exclusion criteria<sup>1,6</sup>

- Clinically relevant cardiovascular conditions or other relevant diseases that could impact the implementation or interpretation of the trial, or put the patient at risk
- History of uveitis or unknown macular edema
- Concomitant use of biologics or immunomodulators
- Pregnant or lactating women

### Key inclusion criteria<sup>1,4,6</sup>

- Moderately to severely active UC (Mayo score of 6 to 12)
  - With endoscopy subscore  $\geq 2$
  - With RBS  $\geq 1$
  - With SFS  $\geq 1$
- An inadequate response or intolerance to any of the following: oral aminosalicylates, corticosteroids, immunomodulators, or a biologic
- Patients were required to be on stable doses of oral aminosalicylates and/or corticosteroids (prednisone daily dose up to 20 mg equivalent or budesonide extended-release tablets)

## IMPORTANT SAFETY INFORMATION (cont'd)

### Infections: (cont'd)

- Herpes zoster was reported as an adverse reaction in ZEPOSIA-treated patients. Herpes simplex encephalitis and varicella zoster meningitis have been reported with sphingosine 1-phosphate (S1P) receptor modulators. Patients without a healthcare professional-confirmed history of varicella (chickenpox), or without documentation of a full course of vaccination against varicella zoster virus (VZV), should be tested for antibodies to VZV before initiating ZEPOSIA. A full course of vaccination for antibody-negative patients with varicella vaccine is recommended prior to commencing treatment with ZEPOSIA

## ZEPOSIA Offers Patients a Demonstrated Safety Profile<sup>1</sup>

### Adverse Reactions With an Incidence of at Least 2% in ZEPOSIA-Treated Patients and at Least 1% Greater Than Placebo in Patients With Ulcerative Colitis (Pooled UC Study 1 and Study 3)<sup>1</sup>

Induction (UC Study 1 and Study 3) <sup>a</sup>		
Adverse Reaction	ZEPOSIA 0.92 mg (n=496) <sup>d,e</sup>	Placebo (n=281) <sup>e</sup>
Upper Respiratory Infection <sup>b</sup>	5%	4%
Liver Test Increased <sup>c</sup>	5%	0%
Headache	4%	3%
Pyrexia	3%	2%
Nausea	3%	2%
Arthralgia	3%	1%

<sup>a</sup>Additional data from the induction period of a randomized, double-blind, placebo-controlled study (UC Study 3/TOUCHSTONE) included 67 patients who received ZEPOSIA 0.92 mg once daily.<sup>1</sup>

<sup>b</sup>Includes the following terms: streptococcal pharyngitis, pharyngotonsillitis, bacterial pharyngitis, nasopharyngitis, upper respiratory tract infection, pharyngitis, sinusitis, tonsillitis, viral upper respiratory tract infection, laryngitis, acute sinusitis, catarrh, chronic sinusitis, upper respiratory tract inflammation, chronic tonsillitis, viral pharyngitis, viral sinusitis, bacterial sinusitis, bacterial upper respiratory tract infection, viral labyrinthitis, laryngeal inflammation, and pharyngeal inflammation.<sup>1</sup>

<sup>c</sup>Includes the following terms: gamma-glutamyl transferase increased, alanine aminotransferase increased, aspartate aminotransferase increased, hepatic enzyme increased, hyperbilirubinemia, liver function test increased, blood alkaline phosphatase increased, transaminases increased.<sup>1</sup>

<sup>d</sup>ZEPOSIA was initiated with a 7-day titration.<sup>1</sup>

<sup>e</sup>Percentages were calculated as the sum of each individual study percentage multiplied by its Cochran-Mantel-Haenszel weight.<sup>1</sup>

### Adverse Reactions With an Incidence of at Least 4% in ZEPOSIA-Treated Patients and at Least 1% Greater Than Placebo in Patients With Ulcerative Colitis (UC Study 2)<sup>1</sup>

Maintenance (UC Study 2)		
Adverse Reaction	ZEPOSIA 0.92 mg (n=230)	Placebo (n=227)
Liver Test Increased <sup>f</sup>	11%	2%
Headache	5%	<1%

<sup>f</sup>Includes the following terms: gamma-glutamyl transferase increased, alanine aminotransferase increased, aspartate aminotransferase increased, hepatic enzyme increased, hyperbilirubinemia, blood bilirubin increased, liver function test increased, blood alkaline phosphatase increased.<sup>1</sup>

## IMPORTANT SAFETY INFORMATION (cont'd)

### Infections: (cont'd)

- Cases of fatal cryptococcal meningitis (CM) were reported in patients treated with another S1P receptor modulator. If CM is suspected, ZEPOSIA should be suspended until cryptococcal infection has been excluded. If CM is diagnosed, appropriate treatment should be initiated

Please see additional Important Safety Information throughout and the full [Prescribing Information](#) and [Medication Guide](#).



# ZEPOSIA: Low Discontinuation Rates Due to TEAEs That Are Comparable to Placebo<sup>1,4,7</sup>

## Overall Discontinuation Rates<sup>4,7</sup>

**UC Study 1—Induction:**  
6% for ZEPOSIA | 11% for Placebo

**UC Study 2—Maintenance:**  
20% for ZEPOSIA | 45% for Placebo

### Discontinuation Rates Due to Treatment Emergent Adverse Events (TEAEs)<sup>4,7</sup>

**Induction**  
**3.3%** vs 3.2%  
for placebo  
ZEPOSIA

**Maintenance**  
**1.3%** vs 2.6%  
for placebo  
ZEPOSIA

- 1 case of macular edema was reported during the maintenance phase in one person with preexisting risk factors at baseline; it resolved after discontinuation of treatment<sup>1,7</sup>
- Overall, the discontinuation rate because of elevations in hepatic enzymes was 0.4% in patients treated with ZEPOSIA 0.92 mg and none in patients who received placebo in the controlled UC studies<sup>1</sup>

## IMPORTANT SAFETY INFORMATION (cont'd)

### Infections: (cont'd)

- Progressive Multifocal Leukoencephalopathy (PML) is an opportunistic viral infection of the brain that typically occurs in patients who are immunocompromised, and that usually leads to death or severe disability. No cases of PML were identified in active-controlled MS clinical trials with ZEPOSIA. PML has been reported in patients treated with S1P receptor modulators and other MS and UC therapies and has been associated with some risk factors. If PML is suspected, withhold ZEPOSIA and perform an appropriate diagnostic evaluation. If confirmed, treatment with ZEPOSIA should be discontinued
- In the MS and UC clinical studies, patients who received ZEPOSIA were not to receive concomitant treatment with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies used for treatment of MS and UC. Concomitant use of ZEPOSIA with any of these therapies would be expected to increase the risk of immunosuppression. When switching to ZEPOSIA from immunosuppressive medications, consider the duration of their effects and their mode of action to avoid unintended additive immunosuppressive effects

Please see additional Important Safety Information throughout and the full [Prescribing Information](#) and [Medication Guide](#).



## Rates of Serious Infection Were Low and Comparable to Placebo in Clinical Trials<sup>1</sup>

Rates of Serious Infection in Clinical Trials<sup>1</sup>

Infection	Induction <sup>a</sup>		Maintenance	
	ZEPOSIA 0.92 mg (n=496)	Placebo (n=281)	ZEPOSIA 0.92 mg (n=230)	Placebo (n=227)
Overall Rate of Infection	9.9%	10.7%	23%	12%
Serious Infections	0.8%	0.4%	0.9%	1.8%
Herpes Zoster	0.4%	0%	2.2%	0.4%

- Malignancies, such as melanoma, basal cell carcinoma, breast cancer, seminoma, cervical carcinoma, and adenocarcinomas, including rectal adenocarcinoma, were reported with ZEPOSIA in controlled trials of multiple sclerosis and UC. An increased risk of cutaneous malignancies has been reported with another SIP receptor modulator<sup>1</sup>

<sup>a</sup>Additional data from the induction period of a randomized, double-blind, placebo-controlled study (UC Study 3/TOUCHSTONE) included 67 patients who received ZEPOSIA 0.92 mg once daily.

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Infections: (cont'd)

- Use of live attenuated vaccines should be avoided during and for 3 months after treatment with ZEPOSIA. If live attenuated vaccine immunizations are required, administer at least 1 month prior to initiation of ZEPOSIA

## Serious Infections and Malignancies Across All UC Trials With ZEPOSIA<sup>®</sup>

	ZEPOSIA 0.92 mg (n=1158) PY=1922.5 <sup>a</sup>		Placebo (n=508) PY=249.2 <sup>a</sup>	
	% (n)	IR, per 100 PY <sup>b</sup>	% (n)	IR, per 100 PY <sup>b</sup>
Any Infection	29.1 (337)	22.81	14.0 (71)	31.43
Any Serious Infection	2.2 (25)	1.32	1.4 (7)	2.84
Malignancies	1.0 (12)	0.63	0.4 (2)	0.81

- Safety outcomes were analyzed using descriptive statistics on pooled data from all controlled and uncontrolled UC trials: participants from 32-week TOUCHSTONE trial<sup>c</sup> (phase 2), 52-week TRUE NORTH trial (phase 3), and the respective open-label extension trials<sup>8</sup>
- Median treatment duration in weeks for ZEPOSIA 0.92 mg and placebo was 65.79 and 17.21, respectively<sup>8</sup>
- TEAEs identified in the pooled data from all controlled and uncontrolled UC trials were consistent with the controlled UC trials<sup>8</sup>

<sup>a</sup>Total patient-years equals the sum of the number of years on study contributed by each patient from time of first dose per treatment group in the pool to last date on study per treatment group in the pool. The algorithm for the last date on study is dependent on patient disposition and whether the patient enrolled into an extension study.<sup>8</sup>

<sup>b</sup>Incidence rate per 100 patient-years, calculated as number of patients/PY x 100 for specific SOC category or PT subcategory. Analysis was based on the treatment group to which a patient was assigned when the event occurred, including patients who were re-randomized to placebo.<sup>8</sup>

<sup>c</sup>TOUCHSTONE patients randomized to ZEPOSIA 0.46 mg unapproved dose were only analyzed upon entering TOUCHSTONE OLE and receiving daily ZEPOSIA 0.92 mg.<sup>8</sup> IR=incidence rate; OLE=open-label extension; PT=preferred term; PY=patient years; SIP=sphingosine 1-phosphate; SOC=system organ class.

### IMPORTANT SAFETY INFORMATION (cont'd)

**Bradyarrhythmia and Atrioventricular Conduction Delays:** Since initiation of ZEPOSIA may result in a transient decrease in heart rate and atrioventricular conduction delays, dose titration is recommended to help reduce cardiac effects. Initiation of ZEPOSIA without dose escalation may result in greater decreases in heart rate. If treatment with ZEPOSIA is considered, advice from a cardiologist should be sought for those individuals:

- with significant QT prolongation
- with arrhythmias requiring treatment with Class 1a or III anti-arrhythmic drugs
- with ischemic heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, and uncontrolled hypertension
- with a history of Mobitz type II second-degree or higher AV block, sick sinus syndrome, or sino-atrial heart block

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.



# Getting Patients Started on ZEPOSIA

## Screening for All Patients Prior to First Dose—Within the Last 6 Months<sup>1</sup>

- ✓ Obtain blood work
  - Complete blood count (CBC), including lymphocyte count (within the last 6 months or after discontinuation of prior UC therapy)
  - Transaminase and total bilirubin levels
- ✓ Obtain an electrocardiogram (ECG) to determine whether **preexisting** conduction abnormalities are present<sup>a</sup>

## Screening Only for Select Patients Prior to First Dose<sup>1</sup>

- With a history of uveitis, macular edema, or diabetes mellitus—ophthalmic evaluation of the fundus, including the macula<sup>b</sup>
- Without documentation of history of varicella-zoster virus (VZV)/chicken pox, or documentation of a full course of vaccination, test for antibodies<sup>c</sup>
  - If live *attenuated* immunizations are required, administer at least 1 month prior to initiation

Evaluate current and prior medications before initiation of treatment<sup>1</sup>



### BMS Support Provided at the Homes of Eligible Patients<sup>d</sup>

- Blood work
- ECG with cardiologist overread
- Macular edema screening with licensed eye clinician overread
- VZV antibody testing

## The full Prescribing Information for ZEPOSIA does not require routine lab monitoring unless clinically indicated

<sup>a</sup>In patients with certain preexisting conditions, advice from a cardiologist should be sought—see Warnings and Precautions in Prescribing Information.<sup>1</sup>

<sup>b</sup>Patients with a history of uveitis and patients with a history of diabetes mellitus are at increased risk of macular edema during ZEPOSIA therapy.<sup>1</sup>

The incidence of macular edema is also increased in patients with a history of uveitis. In addition to the examination of the fundus, including the macula, prior to treatment, patients with diabetes mellitus or a history of uveitis should have regular follow-up examinations.<sup>1</sup>

<sup>c</sup>VZV vaccination of antibody-negative patients is recommended prior to commencing treatment.<sup>1</sup>

<sup>d</sup>Home visits for initial routine medical tests are not available to people enrolled in Medicare, Medicaid, or other federal or state healthcare programs, or to people living in Rhode Island.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Liver Injury:** Elevations of aminotransferases may occur in patients receiving ZEPOSIA. Obtain liver function tests, if not recently available (i.e., within 6 months), before initiation of ZEPOSIA. Patients who develop symptoms suggestive of hepatic dysfunction should have hepatic enzymes checked and ZEPOSIA should be discontinued if significant liver injury is confirmed. Caution should be exercised when using ZEPOSIA in patients with history of significant liver disease

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.



# Another Day Starts With a Once-Daily Oral Administration<sup>1</sup>



## The ZEPOSIA Starter Pack is designed to make the titration instructions easier to follow<sup>1</sup>

- Initiate ZEPOSIA with a 7-day titration schedule. After initial titration, the recommended once-daily dosage of ZEPOSIA is 0.92 mg taken orally, starting on Day 8.<sup>1</sup>
  - An up-titration schedule should be used to reach the maintenance dose, as a transient decrease in heart rate and atrioventricular (AV) conduction delays may occur<sup>1</sup>
  - ZEPOSIA can be taken with or without food<sup>1</sup>

## Recommended Dosage<sup>1</sup>

**ZEPOSIA 7-Day Titration Schedule<sup>1</sup>** | **DAYS 1-4** 0.23 mg > **DAYS 5-7** 0.46 mg > **DAY 8** 0.92 mg

## Additional dosing considerations<sup>1</sup>

- If a dose of ZEPOSIA is missed during the first 2 weeks of treatment, reinitiate treatment using the titration regimen<sup>1</sup>
- If a dose of ZEPOSIA is missed after the first 2 weeks of treatment, continue with the treatment as planned<sup>1</sup>

**References:** **1.** ZEPOSIA. Prescribing Information. Bristol-Myers Squibb Company; 2021. **2.** Data on File. OZA 027. Princeton, NJ: Bristol Myers Squibb. **3.** Data on File. OZA 025. Princeton, NJ: Bristol Myers Squibb. **4.** Sandborn WJ, D'Haens G, Wolf DC, et al. Ozanimod as induction therapy in moderate-to-severe ulcerative colitis: results from the phase 3, randomized, double-blind, placebo-controlled TRUE NORTH Study. Oral Presentation at: UEG Week; October 11-13, 2020. Presentation LB02. **5.** Data on File. OZA 022. Princeton, NJ: Bristol Myers Squibb. **6.** ClinicalTrials.gov. Safety and efficacy trial of RPC 1063 for moderate to severe ulcerative colitis. Updated March 2, 2021. Accessed June 2021. www.clinicaltrials.gov/show/NCT02435992. **7.** Danese S, Furfaro F, Vetrano S. Targeting SIP in inflammatory bowel disease: new avenues for modulating intestinal leukocyte migration. *J Crohns Colitis*. 2018;12(suppl 2):S678-S686. **8.** D'Haens G, Colombel JF, Lichtenstein GR, et al. Safety of ozanimod in patients with moderately to severely active ulcerative colitis over time: pooled analysis from phase 2, phase 3, and open-label extension trials. Oral presentation at: DDW 2021 Virtual Digestive Disease Week; May 21-23, 2021.

## IMPORTANT SAFETY INFORMATION (cont'd)

**Fetal Risk:** There are no adequate and well-controlled studies in pregnant women. Based on animal studies, ZEPOSIA may cause fetal harm. Women of childbearing potential should use effective contraception to avoid pregnancy during treatment and for 3 months after stopping ZEPOSIA

**Increased Blood Pressure:** Increase in systolic pressure was observed after about 3 months of treatment and persisted throughout treatment. Blood pressure should be monitored during treatment and managed appropriately. Certain foods that may contain very high amounts of tyramine could cause severe hypertension in patients taking ZEPOSIA. Patients should be advised to avoid foods containing a very large amount of tyramine while taking ZEPOSIA

Please see additional Important Safety Information throughout and the full Prescribing Information and Medication Guide.



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## IMPORTANT SAFETY INFORMATION (cont'd)

**Respiratory Effects:** ZEPOSIA may cause a decline in pulmonary function. Spirometric evaluation of respiratory function should be performed during therapy, if clinically indicated

**Macular edema:** S1P modulators have been associated with an increased risk of macular edema. Patients with a history of uveitis or diabetes mellitus are at increased risk. Patients with a history of these conditions should have an ophthalmic evaluation of the fundus, including the macula, prior to treatment initiation and regular follow-up examinations. An ophthalmic evaluation is recommended in all patients at any time if there is a change in vision. Continued use of ZEPOSIA in patients with macular edema has not been evaluated; potential benefits and risks for the individual patient should be considered if deciding whether ZEPOSIA should be discontinued

**Posterior Reversible Encephalopathy Syndrome (PRES):** Rare cases of PRES have been reported in patients receiving a S1P receptor modulator. If a ZEPOSIA-treated patient develops unexpected neurological or psychiatric symptoms or any symptom/sign suggestive of an increase in intracranial pressure, a complete physical and neurological examination should be conducted. Symptoms of PRES are usually reversible but may evolve into ischemic stroke or cerebral hemorrhage. Delay in diagnosis and treatment may lead to permanent neurological sequelae. If PRES is suspected, treatment with ZEPOSIA should be discontinued

**Unintended Additive Immunosuppressive Effects From Prior Immunosuppressive or Immune-Modulating Drugs:** 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 while at the same time minimizing risk of disease reactivation. Initiating treatment with ZEPOSIA after treatment with alemtuzumab is not recommended

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

**Immune System Effects After Stopping ZEPOSIA:** After discontinuing ZEPOSIA, the median time for lymphocyte counts to return to the normal range was 30 days with approximately 90% of patients in the normal range within 3 months. Use of immunosuppressants within this period may lead to an additive effect on the immune system, therefore caution should be applied when initiating other drugs 4 weeks after the last dose of ZEPOSIA

**Most Common Adverse Reactions** that occurred in the MS clinical trials of ZEPOSIA-treated patients ( $\geq 4\%$ ): upper respiratory infection, hepatic transaminase elevation, orthostatic hypotension, urinary tract infection, back pain, and hypertension



The first and only sphingosine 1-phosphate (S1P) receptor modulator approved for the treatment of moderately to severely active ulcerative colitis (UC) in adults<sup>1</sup>

## ANOTHER DAY IS DAWNING IN THE CONTROL OF UC

Now many of your patients can choose another path forward before biologics.<sup>1a</sup> ZEPOSIA delivers:



### Lasting Remission<sup>1</sup>

Significantly higher clinical remission rates vs placebo in the pivotal trial:  
18% (79/429) vs 6% (13/216) at Week 10 ( $p < 0.0001$ ) and 37% (85/230) vs 19% (42/227) at Week 52 ( $p < 0.0001$ )



### Demonstrated Safety Profile<sup>1b</sup>

Studied in 4 clinical trials with over 1370 ZEPOSIA-treated patients across multiple indications



### One Capsule, Once Daily<sup>1</sup>

Once-daily oral administration, with or without food

<sup>a</sup>ZEPOSIA demonstrated higher rates of clinical remission vs placebo in tumor necrosis factor inhibitor (TNFi)-naïve patients at Week 10 (22% [66/299] vs 7% [10/151]) and at Week 52 (41% [63/154] vs 22% [35/158], respectively).<sup>1</sup>

In UC Study 1 and UC Study 2, of the ZEPOSIA-treated patients who were TNFi-naïve, 288 and 145 were also biologic-naïve, respectively.<sup>2</sup> Efficacy analysis by prior TNFi therapy was prespecified, but not powered to detect a difference in the treatment effect in these subgroups.<sup>3</sup>

<sup>b</sup>ZEPOSIA has been studied across multiple indications in 4 clinical trials, including TRUE NORTH (NCT02435992), a multicenter, randomized, double-blind, placebo-controlled phase 3 clinical trial; TOUCHSTONE (NCT01647516), a randomized, double-blind, placebo-controlled phase 2 clinical trial; and SUNBEAM (NCT02294058) and RADIANCE (NCT02047734), 2 multicenter, randomized, double-blind, double-dummy, active treatment-controlled phase 3 clinical trials. 496 patients receiving the 0.92-mg dose of ZEPOSIA during induction in TRUE NORTH or TOUCHSTONE and 882 patients receiving the 0.92-mg dose of ZEPOSIA in SUNBEAM or RADIANCE were assessed in the safety analysis.<sup>1</sup>

**Clinical Trial:** The efficacy and safety of ZEPOSIA were evaluated in two multicenter, randomized, double-blind, placebo-controlled clinical studies [UC Study 1 (induction) and UC Study 2 (maintenance)] in adult patients with moderately to severely active ulcerative colitis, defined as a Mayo score of 6 to 12 at baseline.<sup>1</sup>

**Primary Endpoint of Clinical Remission Is Defined as:** rectal bleeding subscore (RBS)=0, stool frequency subscore (SFS) 0 or 1 (and a decrease of  $\geq 1$  point from baseline SFS), and endoscopy subscore 0 or 1 without friability.<sup>1</sup>

**UC Study 1 (10-week induction):** 645 patients were randomized 2:1 to either ZEPOSIA 0.92 mg given orally once daily or placebo for 10 weeks, beginning with a dosage titration. The trial included patients who had an inadequate response or were intolerant to any of the following: oral aminosalicylates, corticosteroids, immunomodulators, or a biologic. Patients were required to be on stable doses of oral aminosalicylates and/or corticosteroids.<sup>1</sup>

**UC Study 2 (42-week maintenance):** 457 patients who received ZEPOSIA in either UC Study 1 or in an open-label arm and achieved clinical response at Week 10 were re-randomized 1:1 and were treated with either ZEPOSIA 0.92 mg (n=230) or placebo (n=227) for 42 weeks (UC Study 2), for a total of 52 weeks of treatment.<sup>1</sup>

Learn more at [ZEPOSIAHCP.COM/UC](http://ZEPOSIAHCP.COM/UC)



once-daily  
**ZEPOSIA**<sup>®</sup>  
(ozanimod) | 0.92 mg capsules

### IMPORTANT SAFETY INFORMATION (cont'd)

#### Most Common Adverse Reactions (cont'd)

In the UC clinical trials, the most common adverse reactions that occurred in  $\geq 4\%$  of ZEPOSIA-treated patients and greater than in patients who received placebo were upper respiratory infection, liver test increased, and headache

Please see additional Important Safety Information throughout and the full **Prescribing Information and Medication Guide.**

Bristol Myers Squibb is committed to transparency. For information on the list price of ZEPOSIA as well as information regarding average out-of-pocket costs and assistance programs, please visit our pricing information page at [ZEPOSIA.com/ulcerative-colitis/cost](http://ZEPOSIA.com/ulcerative-colitis/cost).