



The first and only sphingosine 1-phosphate (S1P) receptor modulator approved for the treatment of moderately to severely active ulcerative colitis (UC) in adults¹

ANOTHER DAY IS DAWNING IN THE CONTROL OF UC

Now many of your patients can choose another path forward before biologics.^{1a} ZEPOSIA delivers:



Lasting Remission¹

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 ($p < 0.0001$)

^aZEPOSIA 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).¹

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.²

Efficacy analysis by prior TNFi therapy was prespecified, but not powered to detect a difference in the treatment effect in these subgroups.³

Clinical Trial: 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 ulcerative colitis, defined as a Mayo score of 6 to 12 at baseline.¹

Primary Endpoint of Clinical Remission Is Defined as: rectal bleeding subscore (RBS)=0, stool frequency subscore (SFS) 0 or 1 (and a decrease of ≥ 1 point from baseline SFS), and endoscopy subscore 0 or 1 without friability.¹

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.¹

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, for a total of 52 weeks of treatment.¹



INDICATION

ZEPOSIA[®] (ozanimod) is indicated for the treatment of moderately to severely active ulcerative colitis (UC) in adults.

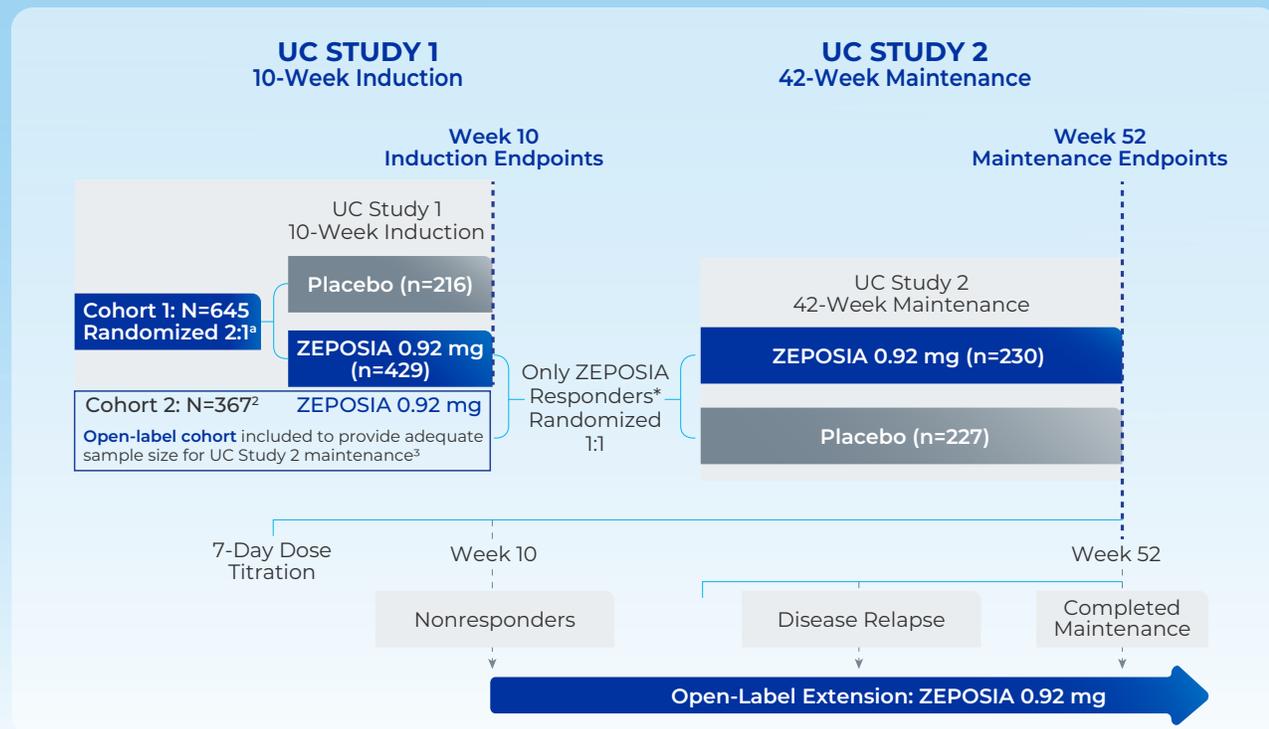
IMPORTANT SAFETY INFORMATION

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 a presence of Mobitz type II second 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^{1,4-6}



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.¹

- *Clinical response is defined as a reduction from baseline in the 3-component Mayo score of ≥ 2 points and $\geq 35\%$, and a reduction from baseline in the RBS of ≥ 1 point or an absolute RBS of 0 or 1¹

^aPatients in cohort 1 were stratified by prior TNFi use and corticosteroid use prior to randomization.⁴

Key exclusion criteria^{1,6}

- 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^{1,4,6}

- Moderately to severely active UC (Mayo score of 6 to 12)
 - With endoscopy subscore ≥ 2
 - With RBS ≥ 1
 - With SFS ≥ 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)

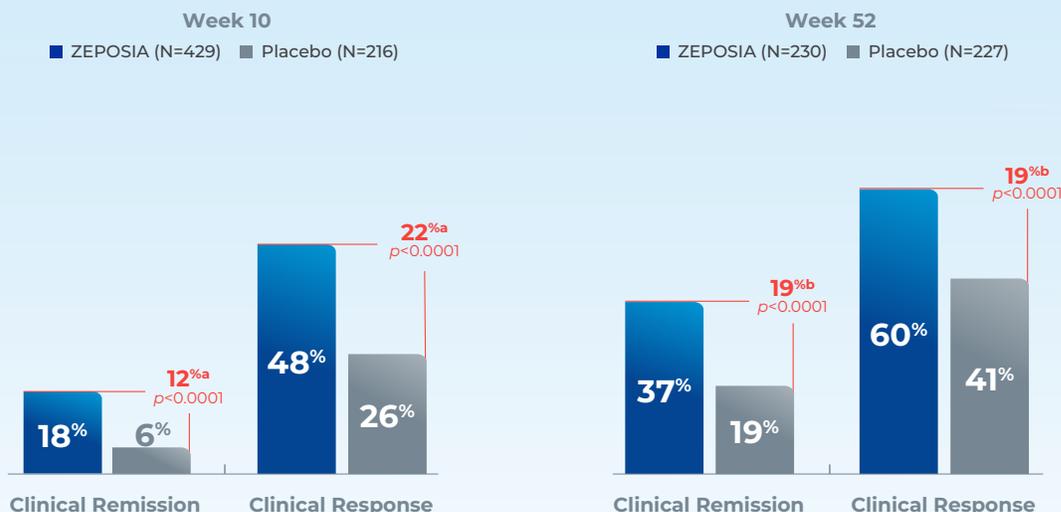
Infections: ZEPOSIA may increase the susceptibility to infections. Life-threatening and rare fatal infections have occurred in patients receiving ZEPOSIA.

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



Proven Control With ZEPOSIA—Rapid Clinical Response at Week 10 With Lasting Clinical Remission at Week 52¹

Clinical Remission (Primary Endpoint) and Clinical Response (Key Secondary Endpoint) at Weeks 10 and 52 (% of Patients)¹



- Clinical remission is defined as: rectal bleeding score (RBS)=0, stool frequency score (SFS) 0 or 1 (and a decrease of ≥ 1 point from baseline SFS), and endoscopy subscore 0 or 1 without friability¹
- Clinical response is defined as a reduction from baseline in the 3-component Mayo score of ≥ 2 points and $\geq 35\%$, and a reduction from baseline in the RBS of ≥ 1 point or an absolute RBS of 0 or 1¹

^aTreatment difference (adjusted for stratification factors of prior TNFi exposure and corticosteroid use at baseline).¹

^bTreatment difference (adjusted for stratification factors of clinical remission and concomitant corticosteroid use at Week 10).¹

IMPORTANT SAFETY INFORMATION (cont'd)

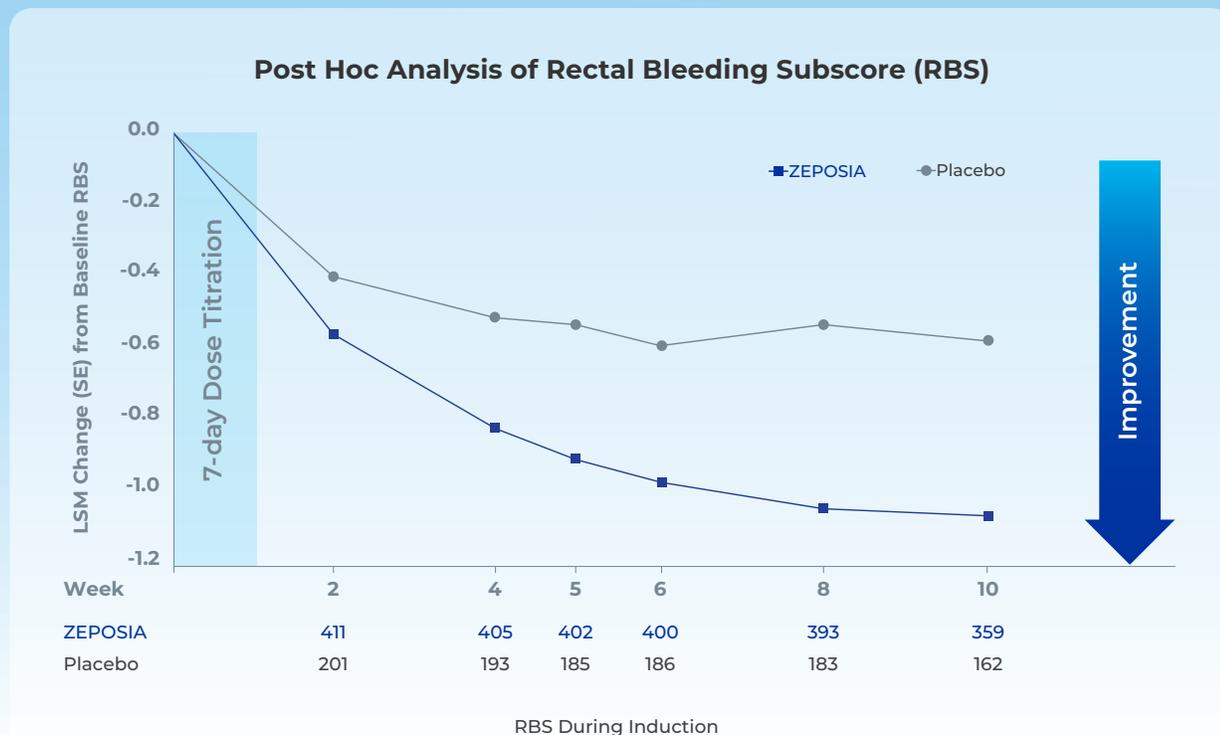
Infections: (cont'd) Obtain a recent (i.e., within 6 months or after discontinuation of prior UC therapy) complete blood count (CBC) including lymphocyte count before initiation of ZEPOSIA. Delay initiation of ZEPOSIA in patients with an active infection until the infection is resolved. Consider interruption of treatment with ZEPOSIA if a patient develops a serious infection. Continue monitoring for infections up to 3 months after discontinuing ZEPOSIA

- 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

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once-daily
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(ozanimod) | 0.92 mg capsules

Patients Treated With ZEPOSIA Observed a Decrease in Rectal Bleeding Subscore as Early as Week 2^a—1 Week After Completing the 7-Day Dose Titration^{1,7}



- Mean baseline RBS \pm SD: 1.7 ± 0.6 for ZEPOSIA (N=429) and 1.6 ± 0.6 for placebo (N=216)⁷
- Rectal Bleeding Subscore: 0=No blood seen, 1=Streaks of blood with stool less than half the time, 2=Obvious blood with stool most of the time, 3=Blood alone passes⁸

^aITT population, observed cases.

ITT=intention to treat; LSM=least squares mean; SD=standard deviation; SE=standard error.

IMPORTANT SAFETY INFORMATION (cont'd)

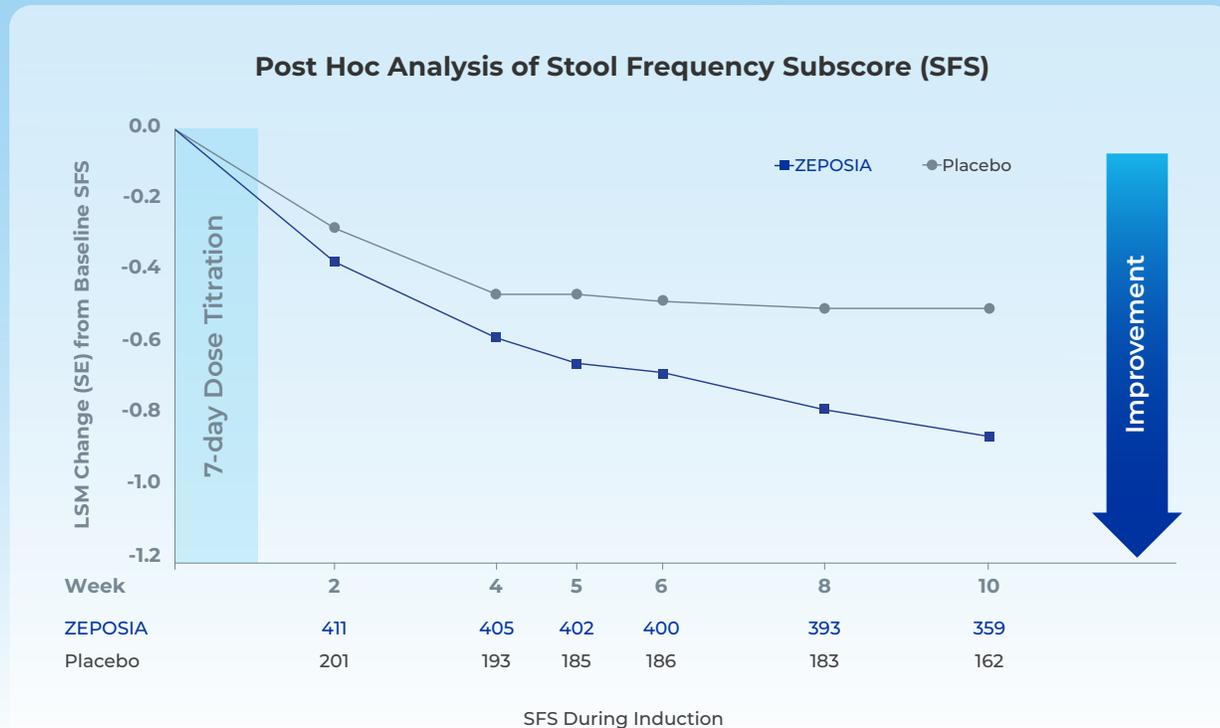
Infections (cont'd):

- 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
- 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. PML has been reported in patients treated with S1P receptor modulators and other 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

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Patients Treated With ZEPOSIA Observed a Decrease in Stool Frequency Subscore as Early as Week 2^a—1 Week After Completing the 7-Day Dose Titration^{1,7}



- Mean baseline SFS \pm SD: 2.4 ± 0.7 for ZEPOSIA (N=429) and 2.4 ± 0.7 for placebo (N=216)⁷
- SFS: 0=Normal number of stools, 1=1-2 more than normal, 2=3-4 more than normal, 3= \geq 5 more than normal⁸

^aITT population, observed cases.

ITT=intention to treat; LSM=least squares mean; SD=standard deviation; SE=standard error.

IMPORTANT SAFETY INFORMATION (cont'd)

Infections (cont'd):

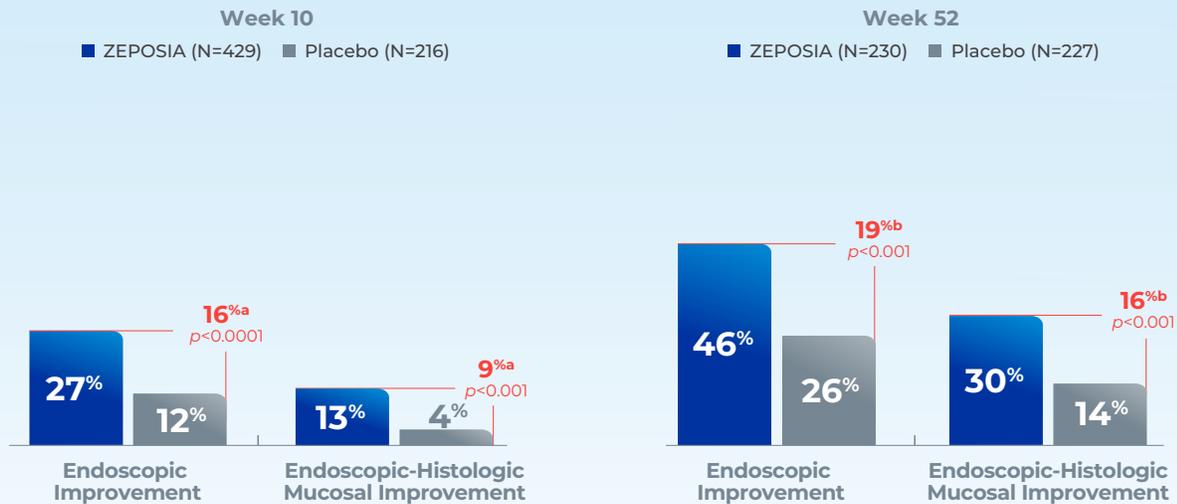
- In the UC clinical studies, patients who received ZEPOSIA were not to receive concomitant treatment with antineoplastic, non-corticosteroid immunosuppressive, or immune-modulating therapies used for treatment of UC. Concomitant use of ZEPOSIA with any of these therapies would be expected to increase 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
- 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

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



ZEPOSIA Demonstrated Mucosal Healing Defined by Significant Endoscopic-Histologic Mucosal Improvement¹

Key Secondary Endpoints: Endoscopic Improvement and Endoscopic-Histologic Mucosal Improvement (EHMI) at Weeks 10 and 52 (% of Patients)¹



- Endoscopic improvement is defined as a Mayo endoscopy subscore of 0 or 1 without friability¹
- Endoscopic-histologic mucosal improvement is defined as both Mayo endoscopy subscore of 0 or 1 without friability and histologic improvement of colonic tissue (defined as no neutrophils in the epithelial crypts or lamina propria and no increase in eosinophils, no crypt destruction, and no erosions, ulcerations, or granulation tissue, ie, Geboes <2.0)¹
- The relationship of endoscopic-histologic mucosal improvement, as defined in UC Study 1 and UC Study 2 (Weeks 10 and 52), to disease progression and long-term outcomes, was not evaluated¹

^aTreatment difference (adjusted for stratification factors of prior TNFi exposure and corticosteroid use at baseline).¹

^bTreatment difference (adjusted for stratification factors of clinical remission and concomitant corticosteroid use at Week 10).¹

IMPORTANT SAFETY INFORMATION (cont'd)

Bradycardia 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:

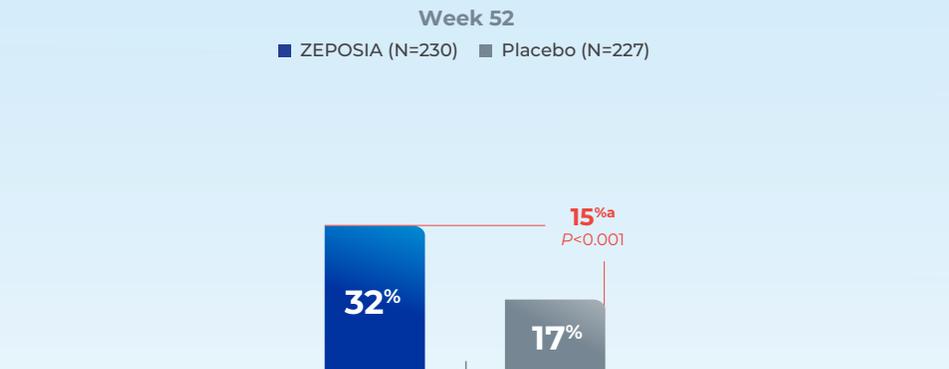
- with significant QT prolongation
- with arrhythmias requiring treatment with Class 1a or III anti-arrhythmic drugs
- with ischemic heart disease, heart failure, history of cardiac arrest or myocardial infarction, cerebrovascular disease, and uncontrolled hypertension
- with a history of Mobitz type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

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once-daily
ZEPOSIA[®]
(ozanimod) | 0.92 mg capsules

ZEPOSIA: Control Is Possible Without the Use of Corticosteroids¹

Key Secondary Endpoint: Corticosteroid-Free Clinical Remission (% of Patients)¹



- Corticosteroid-free remission is defined as clinical remission at Week 52 while off corticosteroids for ≥ 12 weeks¹
- Clinical remission is defined as: rectal bleeding subscore=0, stool frequency subscore (SFS) 0 or 1 (and a decrease from baseline in the SFS of ≥ 1 point), and endoscopy subscore=0 or 1 without friability¹

^aTreatment difference (adjusted for stratification factors of clinical remission and concomitant corticosteroid use at Week 10)¹

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

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

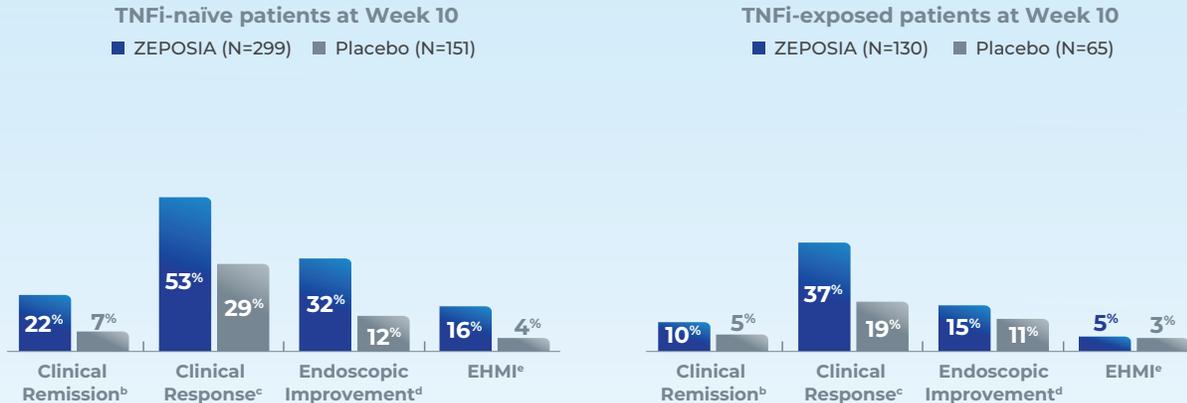
Increased Blood Pressure: Increase in systolic pressure was observed after about 3 months of treatment and persisted throughout treatment. Blood pressure should be monitored during treatment and managed appropriately. Certain foods that may contain very high amounts of tyramine could cause severe hypertension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

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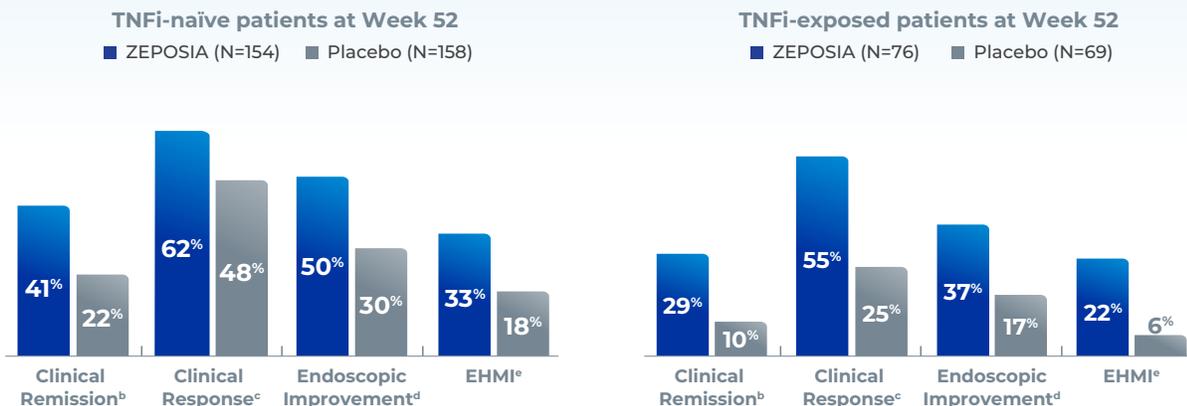
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Efficacy Across TNFi Subgroups With Improved Disease Control Observed in TNFi-Naïve Patients at Weeks 10 and 52^{1a}

Prespecified Subgroup Analysis (% of Patients)¹



Prespecified Subgroup Analysis (% of Patients)¹



^{1a}Efficacy analysis by prior TNFi therapy was prespecified, but not powered to detect a difference in the treatment effect in these subgroups.³

^bClinical remission is defined as RBS=0, SFS 0 or 1 (and a decrease of ≥ 1 point from baseline SFS), and endoscopy subscore 0 or 1 without friability.¹

^cClinical response is defined as a reduction from baseline in the 3-component Mayo score of ≥ 2 points and $\geq 35\%$, and a reduction from baseline in the RBS of >1 point or an absolute RBS of 0 or 1.¹

^dEndoscopic improvement is defined as a Mayo endoscopy subscore=0 or 1 without friability.¹

^eEndoscopic-histologic mucosal improvement is defined as both a Mayo endoscopy subscore of 0 or 1 without friability and histologic improvement of colonic tissue (defined as no neutrophils in the epithelial crypts or lamina propria and no increase in eosinophils, no crypt destruction, and no erosions, ulcerations, or granulation tissue, ie, Geboes <2.0).¹ EHMI=endoscopic-histologic mucosal improvement; TNFi=tumor necrosis factor inhibitor.

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

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



ZEPOSIA Offers Patients a Demonstrated Safety Profile¹

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)¹

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

^aAdditional 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.¹

^bIncludes 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.¹

^cIncludes 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.¹

^dZEPOSIA was initiated with a 7-day titration.¹

^ePercentages were calculated as the sum of each individual study percentage multiplied by its Cochran-Mantel-Haenszel weight.¹

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)¹

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

^fIncludes 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.¹

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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 Months¹

- ✓ 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^a

Screening Only for Select Patients Prior to First Dose¹

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

Evaluate current and prior medications before initiation of treatment¹



BMS Support Provided at the Homes of Eligible Patients^d

- 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

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

^bPatients with a history of uveitis and patients with a history of diabetes mellitus are at increased risk of macular edema during ZEPOSIA therapy.¹

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.¹

^cVZV vaccination of antibody-negative patients is recommended prior to commencing treatment.¹

^dHome 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)

Posterior Reversible Encephalopathy Syndrome (PRES): Rare cases of PRES have been reported in patients receiving a 5-HT_{2A} 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.

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



Another Day Starts With a Once-Daily Oral Administration¹



The ZEPOSIA Starter Pack is designed to make the titration instructions easier to follow¹

- 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 occur¹
- ZEPOSIA can be taken with or without food¹

Recommended Dosage¹

ZEPOSIA 7-Day Titration Schedule¹ | **DAYS 1-4** > **DAYS 5-7** > **DAY 8**
0.23 mg > **0.46 mg** > **0.92 mg**

Additional Dosing Considerations¹

- If a dose is missed during the first 2 weeks of treatment, reinstate the titration regimen¹
- If a dose is missed after the first 2 weeks of treatment, continue with the treatment as planned¹

IMPORTANT SAFETY INFORMATION (cont'd)

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

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

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. <https://clinicaltrials.gov/ct2/show/NCT02435992>. Accessed June 15, 2021. **7.** Osterman MT, Longman R, Sninsky C, et al. Rapid induction effects of ozanimod on clinical symptoms and inflammatory biomarkers in patients with moderately to severely active ulcerative colitis: results from the induction phase of True North. Oral presentation at: DDW 2021 Virtual Digestive Disease Week; May 21-23, 2021. **8.** Rubin DT, Ananthakrishnan AN, Siegel CA, et al. ACG Clinical Guideline: Ulcerative Colitis in Adults. *Am J Gastroenterol.* 2019;114(3):384-413.

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ANOTHER DAY IS DAWNING IN THE CONTROL OF UC

Now many of your patients can choose another path forward before biologics.^{1a} ZEPOSIA delivers:



Lasting Remission¹

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^{1b}

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



One Capsule, Once Daily¹

Once-daily oral administration, with or without food

^aZEPOSIA 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).¹

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.²

Efficacy analysis by prior TNFi therapy was prespecified, but not powered to detect a difference in the treatment effect in these subgroups.³

^bZEPOSIA 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 safety analysis.¹

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.¹

Primary Endpoint of Clinical Remission Is Defined as: rectal bleeding subscore (RBS)=0, stool frequency subscore (SFS) 0 or 1 (and a decrease of ≥ 1 point from baseline SFS), and endoscopy subscore 0 or 1 without friability.¹

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.¹

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.¹

Learn more at ZEPOSIAHCP.COM/UC



IMPORTANT SAFETY INFORMATION (cont'd)

Most Common Adverse Reactions: Most common adverse reactions (incidence $\geq 4\%$) are: liver test increased, upper respiratory infection, and headache

Use in Specific Populations: Hepatic Impairment: Use is not recommended

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.



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