



## **News Release**

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## **Results of Novel Clinical Study of Guselkumab and Golimumab Combination Therapy Show Adults with Moderately to Severely Active Ulcerative Colitis Maintained Higher Rates of Clinical, Histologic, and Endoscopic Remission at Week 38**

*The rate of clinical remission was 47.9 percent in patients who received combination induction therapy with guselkumab and golimumab compared with either treatment alone (31.0 percent and 20.8 percent, respectively) at 38 weeks<sup>1</sup>*

**SPRING HOUSE, PENNSYLVANIA, October 10, 2022** – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced data from an ongoing analysis of a Phase 2a clinical trial showing adults with moderately to severely active ulcerative colitis (UC) who received 12 weeks of combination induction therapy with guselkumab and golimumab, followed by a transition to guselkumab alone for maintenance, achieved a clinical remission rate<sup>a</sup> (based on the modified Mayo score [mMayo])<sup>b</sup> at week 38 of 47.9 percent, a higher rate than induction and maintenance treatment with either guselkumab alone (31.0 percent) or golimumab alone (20.8 percent).<sup>1,2</sup> Patients had comparable rates of adverse events (AEs) across the treatment groups.<sup>1</sup> Guselkumab alone, or the combination

of guselkumab and golimumab are under clinical investigation and not approved for the treatment of adults with UC in the U.S.

The VEGA study is the first randomized controlled trial to evaluate the efficacy and safety of combination therapy with an interleukin (IL)-23p19 subunit antagonist (guselkumab) and a tumor necrosis factor-alpha (TNF $\alpha$ ) antagonist (golimumab) in UC.<sup>3,4</sup> Detailed results were presented today as an oral presentation (OP087) at the United European Gastroenterology (UEG) Week 2022 congress taking place in-person in Vienna, Austria and virtually from October 8-11.<sup>1</sup>

“Exploring combinations of advanced therapies is an important step in continuing to innovate for the many patients living with ulcerative colitis,” said Bruce E. Sands, M.D., M.S., Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at Mount Sinai, Professor of Medicine at the Icahn School of Medicine at Mount Sinai, and VEGA Steering Committee member.<sup>c</sup> “These new data from the VEGA trial build upon and affirm our initial 12-week findings showing the potential clinical benefit of combining guselkumab and golimumab in treating adults with moderately to severely active ulcerative colitis.”

In the VEGA study, patients with moderately to severely active UC were randomized (1:1:1) to receive combination therapy with guselkumab and golimumab, guselkumab monotherapy, or golimumab monotherapy.<sup>1</sup> After endpoints were evaluated at week 12, patients in the monotherapy groups continued their initially assigned treatment, while patients randomized to the combination therapy group transitioned to guselkumab alone as a maintenance therapy.<sup>1</sup> Patients remained blinded and received their respective therapies through the final efficacy assessment at week 38. Clinical remission<sup>a,d</sup> was assessed based on the modified Mayo score (mMayo),<sup>b</sup> as well as the total Mayo score.<sup>e</sup> Symptomatic remission,<sup>f</sup> endoscopic improvement,<sup>g</sup> endoscopic remission,<sup>h</sup> histologic remission,<sup>i</sup> and composite histologic-endoscopic endpoints<sup>g,i</sup> were also assessed at week 38 in an exploratory analysis.<sup>1</sup> Safety was evaluated through week 50 (16 weeks after the final dose of study intervention at week 34).<sup>1</sup>

Patients who received combination therapy with guselkumab and golimumab followed by maintenance treatment with guselkumab achieved clinical remission<sup>a</sup> (mMayo<sup>b</sup>) at week 38 (47.9 percent [34/71]) versus 31.0 percent (22/71) and 20.8 percent (15/72) of patients who received guselkumab or golimumab alone, respectively (nominal  $p < 0.05$ ).<sup>1</sup>

Rates of clinical remission<sup>d</sup> as defined by the total Mayo score<sup>e</sup> at week 38 were similar to those based on the mMayo,<sup>a,b</sup> with 43.7 percent (31/71) in the combination therapy followed by guselkumab group achieving this endpoint, compared to either the guselkumab or golimumab monotherapy groups, (31.0 percent [22/71] and 22.2 percent [16/72], respectively).<sup>1</sup>

Also, patients receiving combination therapy followed by guselkumab had the following outcomes at week 38:<sup>1</sup>

- Endoscopic improvement<sup>g</sup> and the composite histologic-endoscopic endpoint<sup>g,i</sup> were higher in patients who received combination therapy followed by treatment with guselkumab compared to patients who received guselkumab or golimumab alone.
- Endoscopic remission<sup>h</sup> and histologic remission<sup>i</sup> were higher in patients who received combination therapy followed by treatment with guselkumab compared to patients who received golimumab alone.

Patients receiving combination therapy followed by maintenance treatment with guselkumab and patients receiving treatment only with guselkumab monotherapy achieved the same rate of symptomatic remission<sup>f</sup> of 69 percent at week 38, which was greater than the golimumab monotherapy group of 59.7 percent.<sup>1</sup>

Rates of AEs were comparable through week 50 of the study.<sup>1</sup> Respectively, the combination therapy followed by guselkumab, guselkumab alone, and golimumab alone groups had AE rates of 63.4, 64.8, and 76.4 percent and infection rates of 31.0, 23.9, and 31.9 percent.<sup>1</sup> All groups had the same serious AE rates of 5.6

percent and the same serious infection rates of 2.8 percent.<sup>1</sup> Overall, 13.1 percent of patients discontinued their treatment prior to the final dose of study intervention.<sup>1</sup>

“The 38-week VEGA data suggest the potential that guselkumab and golimumab combination therapy has in patients with moderately to severely active ulcerative colitis for whom previous conventional treatments have inadequately managed their disease or improved their well-being,” said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. “We thank the patients who participated in the VEGA study, as their contribution helps us get closer to our goal of developing therapies that will bring meaningful improvements to patients with ulcerative colitis.”

Janssen [previously announced](#) the 12-week data of patient outcomes from the VEGA study at the 17th Congress of the European Crohn's and Colitis Organisation on February 19, 2022.<sup>2</sup>

**Editor’s Notes:**

- a. Clinical remission (based on the mMayo) is defined as a stool frequency subscore of 0 or 1, where the stool frequency subscore has not increased from baseline, a rectal bleeding subscore of 0, and an endoscopy subscore of 0 or 1 with no friability present on endoscopy.<sup>1</sup>
- b. Modified Mayo score consists of three of the four components of the full Mayo score: stool frequency, rectal bleeding, and endoscopic score. The physician global assessment score is not included.<sup>5</sup>
- c. Dr. Sands is a paid consultant for Janssen. He has not been compensated for any media work.
- d. Clinical remission is defined as a Mayo score  $\leq 2$ , with no individual subscore  $> 1$ .<sup>1</sup>
- e. The total Mayo score is the sum of four subscores – stool frequency, rectal bleeding, physician's global assessment, and endoscopy findings – that are scored from normal (0) to severe (3).<sup>3</sup>

- f. Symptomatic remission is defined as Mayo stool frequency subscore of 0 or 1, where the stool frequency subscore has not increased from baseline, and a rectal bleeding subscore of 0.<sup>1</sup>
- g. Endoscopic improvement is defined as an endoscopy subscore of 0 or 1 with no friability present on the endoscopy.<sup>1</sup>
- h. Endoscopic remission is defined as an endoscopy subscore of 0.<sup>1</sup>
- i. Histologic remission is defined as absence of neutrophils from the mucosa (both lamina propria and epithelium), no crypt destruction, and no erosions, ulcerations or granulation tissue according to the Geboes grading system.<sup>1</sup>

### **About VEGA (NCT03662542; EudraCT 2018-001510-15)**

VEGA was a randomized, double-blind, active-controlled, parallel group, global multicenter Phase 2a proof-of-concept study evaluating the efficacy and safety of combination induction therapy with guselkumab and golimumab, followed by a transition to guselkumab monotherapy for maintenance, in patients with moderately to severely active UC as defined by a Mayo score of 6 to 12 inclusive and an endoscopy subscore of 2 or greater as determined by central read.<sup>3,4</sup>

Study participants were naïve to TNF $\alpha$ , IL-12/23, and IL-23p19 antagonists and had to be refractory or intolerant to conventional therapy (e.g. immunosuppressants and/or corticosteroids).<sup>1</sup> Participants were randomly assigned 1:1:1 to receive guselkumab monotherapy dosed at 200 milligrams (mg) intravenously (IV) at weeks 0, 4, and 8 followed by 100 mg every 8 weeks (q8w) subcutaneous (SC) (n=71); golimumab SC monotherapy dosed at 200 mg at week 0 followed by 100 mg SC at weeks 2, 6, and 10 followed by 100 mg every 4 weeks SC monotherapy (n=72); or a combination of 200 mg IV guselkumab plus 200 mg SC golimumab at week 0, 100 mg SC golimumab at weeks 2, 6, and 10, and 200 mg IV guselkumab at weeks 4 and 8 (n=71) followed by 100 mg guselkumab SC q8w thereafter.<sup>1</sup> After week 12, participants in the monotherapy groups continued their initially assigned treatment, while patients randomized to the combination group transitioned to guselkumab 100 mg SC q8w as a maintenance therapy.<sup>1</sup> The

participants received their respective therapies through week 34 with final efficacy assessments at week 38.<sup>1</sup>

The primary endpoint was clinical response at week 12, defined as a decrease from baseline in the Mayo score by 30 percent or more and 3 or more points, with either a decrease in rectal bleeding subscore of 1 or more or rectal bleeding subscore of 0 or 1. The trial's major secondary endpoint was clinical remission at week 12, defined as Mayo score less than or equal to 2, with no individual subscore more than 1. No adjustments were made for multiple comparisons.<sup>2,3</sup> Other key endpoints evaluated at week 12 were clinical remission (based on components of the mMayo score), symptomatic remission, endoscopic improvement, endoscopic remission, histologic remission, composite histologic-endoscopic endpoints, and biomarker outcomes.<sup>1</sup>

### **About Ulcerative Colitis**

Inflammatory bowel disease (IBD), which includes Crohn's disease and UC, affect as many as 1.6 million people in the United States.<sup>6</sup> UC is a chronic disease of the large intestine, also known as the colon, in which the lining of the colon becomes inflamed and develops tiny open sores, or ulcers, that produce pus and mucus.<sup>7</sup> It is the result of the immune system's overactive response.<sup>7</sup> Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss, and fatigue.<sup>8</sup>

### **About guselkumab**

Developed by Janssen, guselkumab (which is marketed under the brand name TREMFYA®) is the first approved fully human monoclonal antibody that selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor.<sup>9</sup> TREMFYA is approved in the U.S., Canada, Japan, and a number of other countries worldwide for the treatment of adults with moderate to severe plaque psoriasis (PsO) who may benefit from taking injections or pills (systemic therapy) or phototherapy (treatment using ultraviolet light), and for the treatment of adult patients with active psoriatic arthritis (PsA).<sup>9</sup> It is also approved in the EU for the

treatment of moderate to severe plaque PsO in adults who are candidates for systemic therapy and for the treatment of active PsA in adult patients who have had an inadequate response or who have been intolerant to a prior disease-modifying antirheumatic drug therapy.<sup>9</sup>

The Janssen Pharmaceutical Companies of Johnson & Johnson maintain exclusive worldwide marketing rights to TREMFYA®.

### **IMPORTANT SAFETY INFORMATION**

**What is the most important information I should know about TREMFYA®? TREMFYA® is a prescription medicine that may cause serious side effects, including:**

- **Serious Allergic Reactions.** Stop using TREMFYA® and get emergency medical help right away if you develop any of the following symptoms of a serious allergic reaction:
  - fainting, dizziness, feeling lightheaded (low blood pressure)
  - swelling of your face, eyelids, lips, mouth, tongue or throat
  - trouble breathing or throat tightness
  - chest tightness
  - skin rash, hives
  - itching
- **Infections.** TREMFYA® may lower the ability of your immune system to fight infections and may increase your risk of infections. Your healthcare provider should check you for infections and tuberculosis (TB) before starting treatment with TREMFYA® and may treat you for TB before you begin treatment with TREMFYA® if you have a history of TB or have active TB. Your healthcare provider should watch you closely for signs and symptoms of TB during and after treatment with TREMFYA®.

Tell your healthcare provider right away if you have an infection or have symptoms of an infection, including:

  - fever, sweats, or chills
  - muscle aches

- weight loss
- cough
- warm, red, or painful skin or sores on your body different from your psoriasis
- diarrhea or stomach pain
- shortness of breath
- blood in your phlegm (mucus)
- burning when you urinate or urinating more often than normal

**Do not take TREMFYA®** if you have had a serious allergic reaction to guselkumab or any of the ingredients in TREMFYA®.

**Before using TREMFYA®, tell your healthcare provider about all of your medical conditions, including if you:**

- have any of the conditions or symptoms listed in the section "**What is the most important information I should know about TREMFYA®?**"
- have an infection that does not go away or that keeps coming back.
- have TB or have been in close contact with someone with TB.
- have recently received or are scheduled to receive an immunization (vaccine). You should avoid receiving live vaccines during treatment with TREMFYA®.
- are pregnant or plan to become pregnant. It is not known if TREMFYA® can harm your unborn baby.
- are breastfeeding or plan to breastfeed. It is not known if TREMFYA® passes into your breast milk.

**Tell your healthcare provider about all the medicines you take**, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

**What are the possible side effects of TREMFYA®?**

**TREMFYA® may cause serious side effects. See "What is the most important information I should know about TREMFYA®?"**

**The most common side effects of TREMFYA® include:** upper respiratory infections, headache, injection site reactions, joint pain (arthralgia), diarrhea, stomach flu (gastroenteritis), fungal skin infections, herpes simplex infections, and bronchitis.

These are not all the possible side effects of TREMFYA®. Call your doctor for medical advice about side effects.

Use TREMFYA® exactly as your healthcare provider tells you to use it.

**Please read the full [Prescribing Information](#), including [Medication Guide](#) for TREMFYA®, and discuss any questions that you have with your doctor.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

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### **About golimumab<sup>10</sup>**

- Golimumab (marketed as SIMPONI®) is a prescription medicine for adults with:
- Moderate to severe rheumatoid arthritis (RA), with the medicine methotrexate (MTX)
- Active PsA, alone or with the medicine MTX
- Active ankylosing spondylitis
- Moderately to severely active UC when certain other UC medicines have not worked well enough or cannot be tolerated, or if it is necessary to continue taking steroid medicines

## **IMPORTANT SAFETY INFORMATION**

### **SERIOUS INFECTIONS**

**SIMPONI® (golimumab) is a prescription medicine. SIMPONI® can lower your ability to fight infections. There are reports of serious infections caused by bacteria, fungi, or viruses that have spread throughout the body, including tuberculosis (TB) and histoplasmosis. Some of these infections have been fatal. Your doctor will test you for TB before starting SIMPONI® and will monitor you for signs of TB during treatment. Tell your doctor if you have been in close contact with people with TB. Tell your doctor if you have been in a region (such as the Ohio and Mississippi River Valleys and the Southwest) where certain fungal infections like histoplasmosis or coccidioidomycosis are common.**

You should not start SIMPONI® if you have any kind of infection. Tell your doctor if you are prone to or have a history of infections or have diabetes, HIV or a weak immune system. You should also tell your doctor if you are currently being treated for an infection or if you have or develop any signs of an infection such as:

- fever, sweat, or chills
- muscle aches
- cough
- shortness of breath
- blood in phlegm
- weight loss
- warm, red, or painful skin or sores on your body
- diarrhea or stomach pain
- burning when you urinate or urinate more than normal
- feel very tired

Your doctor will examine you for TB and perform a test to see if you have TB. If your doctor feels that you are at risk for TB, you may be treated with medicine for TB before you begin treatment with SIMPONI® and during treatment with

SIMPONI®. Even if your TB test is negative, your doctor should carefully monitor you for TB infections while you are taking SIMPONI®. People who had a negative TB skin test before receiving SIMPONI® have developed active TB. Tell your doctor if you have any of the following symptoms while taking or after taking SIMPONI®:

- cough that does not go away
- low grade fever
- weight loss
- loss of body fat and muscle (wasting)

## **CANCER**

### **Unusual cancers have been reported in children and teenage patients taking TNF-blocker medicines.**

For children and adults taking TNF blockers, including SIMPONI®, the chances for getting lymphoma or other cancers may increase. Hepatosplenic T-cell lymphoma, a rare and fatal lymphoma, has occurred mostly in teenage or young adult males with Crohn's disease or ulcerative colitis who were taking other TNF blockers with azathioprine or 6-mercaptopurine. You should tell your doctor if you have had or develop lymphoma or other cancers.

Some people treated with SIMPONI® have developed certain kinds of skin cancer. If any changes in the appearance of your skin or growths on your skin occur during or after your treatment with SIMPONI®, tell your doctor.

## **USE WITH OTHER DRUGS**

Tell your doctor about all the medications you take including ORENCIA® (abatacept), KINERET® (anakinra), ACTEMRA® (tocilizumab), RITUXAN® (rituximab), or another TNF blocker, or if you are scheduled to or recently received a vaccine. People taking SIMPONI® should not receive live vaccines or treatment with a weakened bacteria (such as BCG for bladder cancer).

## **HEPATITIS B INFECTION**

Reactivation of hepatitis B virus has been reported in patients who are carriers of this virus and are taking TNF-blocker medicines, such as SIMPONI®. Some of these

cases have been fatal. Your doctor should do blood tests before and after you start treatment with SIMPONI®. Tell your doctor if you know or think you may be a carrier of hepatitis B virus or if you experience signs of hepatitis B infection, such as:

- feel very tired
- dark urine
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- clay-colored bowel movements
- fevers
- chills
- stomach discomfort
- skin rash

## **HEART FAILURE**

**Heart failure can occur or get worse in people who use TNF blockers, including SIMPONI®.** If you develop new or worsening heart failure with SIMPONI®, you may need treatment in a hospital, and it may result in death. Your doctor will closely monitor you if you have heart failure. Tell your doctor right away if you get new or worsening symptoms of heart failure like shortness of breath, swelling of your lower legs or feet, or sudden weight gain.

## **NERVOUS SYSTEM PROBLEMS**

Rarely, people using TNF blockers, including SIMPONI®, can have nervous system problems such as multiple sclerosis or Guillain-Barré syndrome. Tell your doctor right away if you have symptoms like vision changes, weakness in your arms or legs, or numbness or tingling in any part of your body.

## **IMMUNE SYSTEM PROBLEMS**

Rarely, people using TNF blockers have developed lupus-like symptoms. Tell your

doctor if you have any symptoms such as a rash on your cheeks or other parts of the body, sensitivity to the sun, new joint or muscle pain, becoming very tired, chest pain or shortness of breath, swelling of the feet, ankles, and/or legs.

### **LIVER PROBLEMS**

Serious liver problems can happen in people using TNF blockers, including SIMPONI®. Contact your doctor immediately if you develop symptoms such as feeling very tired, skin or eyes look yellow, poor appetite or vomiting, or pain on the right side of your stomach.

### **BLOOD PROBLEMS**

Low blood counts have been seen with SIMPONI®. If this occurs, your body may not make enough blood cells to help fight infections or help stop bleeding. Your doctor will check your blood counts before and during treatment. Tell your doctor if you have signs such as fever, bruising, bleeding easily, or paleness.

### **OTHER CONSIDERATIONS TO TELL YOUR DOCTOR**

Tell your doctor if you are allergic to rubber or latex. The needle cover contains dry natural rubber.

Tell your doctor if you are pregnant, planning to become pregnant or are breastfeeding or have a baby and were using SIMPONI® during pregnancy. Tell your baby's doctor before your baby receives any vaccine because of an increased risk of infection for up to 6 months after birth.

### **ALLERGIC REACTIONS**

Allergic reactions can happen in people who use TNF-blocker medicines, including SIMPONI®. Tell your doctor if you have any symptoms of an allergic reaction while taking SIMPONI® such as hives, swollen face, breathing trouble, or chest pain. Some reactions can be serious and life-threatening.

**Common side effects of SIMPONI® include:** upper respiratory tract infection, reaction at site of injection, and viral infections.

## **PSORIASIS**

New or worse psoriasis symptoms may occur. Tell your doctor if you develop red scaly patches or raised bumps that are filled with pus.

**Please read the full [Prescribing Information](#) and [Medication Guide](#) for SIMPONI® and discuss any questions you have with your doctor.**

**You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.fda.gov/medwatch](http://www.fda.gov/medwatch), or call 1-800-FDA-1088.**

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## **About the Janssen Pharmaceutical Companies of Johnson & Johnson**

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular, Metabolism & Retina; Immunology; Infectious Diseases & Vaccines; Neuroscience; Oncology; and Pulmonary Hypertension.

Learn more at [www.janssen.com](http://www.janssen.com).

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Janssen Research & Development, LLC is part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

## **Cautions Concerning Forward-Looking Statements**

*This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding guselkumab and*

*golimumab product development. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at [www.sec.gov](http://www.sec.gov), [www.jnj.com](http://www.jnj.com) or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.*

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