News Release

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Results of Novel Clinical Study Show Adults with Moderately to Severely Active Ulcerative Colitis Achieved Higher Rates of Clinical Response, Clinical Remission, and Endoscopic Improvement at 12 Weeks with Guselkumab and Golimumab Combination Therapy Versus Either Monotherapy Alone

The VEGA Phase 2a proof-of-concept study shows 83.1 percent of patients who received combination therapy achieved the primary endpoint of clinical response and 36.6 percent of patients achieved clinical remission at week 12

The VEGA study represents a first-of-its-kind biologic combination assessment of an interleukin (IL)-23p19 subunit antagonist with a tumor necrosis factor-alpha (TNFα) antagonist in ulcerative colitis

SPRING HOUSE, PENNSYLVANIA, February 19, 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced data from a Phase 2a clinical trial that showed the combination of guselkumab, an interleukin (IL)-23p19 subunit antagonist, and golimumab, a tumor necrosis factor-alpha (TNFα) antagonist, induced higher rates of clinical response,[a] clinical remission,[b]

endoscopic improvement,[c] and a composite histologic-endoscopic endpoint[c,d] at 12 weeks than either treatment alone in adults with moderately to severely active ulcerative colitis (UC).[1] Rates of adverse events (AEs) were comparable among treatment groups.[1] Detailed results of the VEGA trial were presented today as an oral presentation (OP36) at the 17th Congress of the European Crohn's and Colitis Organisation (ECCO) taking place virtually from February 16-19.[1] Guselkumab as well as the combination of guselkumab and golimumab are not currently approved for the treatment of adults with UC in the U.S.

"There remains an unmet need for patients who are struggling with ulcerative colitis," said presenting study author Bruce E. Sands, M.D., M.S., Chief of the Dr. Henry D. Janowitz Division of Gastroenterology at the Icahn School of Medicine at Mount Sinai, and the Mount Sinai Hospital.[e] "The initial VEGA study results combining IL-23p19 and TNFα antagonists are encouraging as we continue the development of this potential treatment option for moderately to severely active ulcerative colitis."

VEGA 12-week study results show:[1]

- **Clinical response:**[a] A greater proportion of patients who received combination therapy of guselkumab and golimumab achieved the primary endpoint of clinical response[a] at week 12 (83.1 percent [59/71]) versus 74.6 percent (53/71) of patients who received guselkumab alone, or 61.1 percent (44/72) of those who received golimumab alone.[1]
- **Clinical remission:**[b] 36.6 percent (26/71) of patients in the combination group achieved clinical remission[b] based on the full Mayo score at week 12 versus 21.1 percent (15/71) and 22.2 percent (16/72) in the guselkumab and golimumab groups, respectively.[1] Additionally, 46.5 percent (33/71) of patients in the combination group achieved clinical remission[b] based on the modified Mayo score at week 12 versus 23.9 percent (17/71) and 25 percent (18/72) in the guselkumab and golimumab groups, respectively.[1]
- **Endoscopic outcomes**:
    - A higher proportion of patients who received combination therapy

achieved endoscopic improvement[c] (49.3 percent [35/71]) at week 12 compared with those who received either monotherapy (guselkumab: 29.6 percent [21/71]; golimumab: 25 percent [18/72]).[1]

- Percentages of patients with endoscopic normalization[f] were nearly double with combination therapy versus either monotherapy (combination therapy: 18.3 percent [13/71]; guselkumab: 8.5 percent [6/71]; golimumab: 9.7 percent [7/72]).[1]

- **Composite histologic-endoscopic outcomes:**
  - 40.8 percent (29/71) of patients in the combination group achieved the composite endpoint of histologic remission[d] and endoscopic improvement[c] versus 26.8 percent (19/71) and 15.3 percent (11/72) in the guselkumab and golimumab groups, respectively.[1]
  - Percentages of patients with both histologic remission[d] and endoscopic normalization[f] were double with combination therapy versus either monotherapy (combination therapy: 15.5 percent [11/71]; guselkumab: 7 percent [5/71]; golimumab: 4.2 percent [3/72]).[1]

Symptomatic remission[g] (based on patient reports of rectal bleeding and stool frequency [SF]), histologic remission,[d] and biomarker normalization (calprotectin, C-reactive protein) rates at week 12 were also greater in the combination group.[1] Rates of key safety events were similar among treatment groups.[1] In the combination group, the guselkumab group, and the golimumab group, AEs occurred in 40.8 percent (29/71), 43.7 percent (31/71), and 52.8 percent (38/72), respectively.[1] Serious adverse events occurred in 1.4 percent (1/71), 2.8 percent (2/71), and 1.4 percent (1/72), respectively.[1] Infections were reported in 14.1 percent (10/71) in each of the combination and guselkumab groups and in 22.2 percent (16/72) of the golimumab group.[1] No deaths, malignancies, or tuberculosis cases were reported through week 12 of the study. One patient receiving combination therapy experienced concurrent serious infections of influenza and sepsis.[1]

"Results from the VEGA study, a first-of-its-kind assessment of an IL-23p19 subunit

antagonist combined with a TNFα antagonist in ulcerative colitis, allow us to further explore and identify the areas of unmet need that exist for patients," said Jan Wehkamp, M.D., Ph.D., Vice President, Gastroenterology Disease Area Leader, Janssen Research & Development, LLC. "We are encouraged about the insights we will gain for future combination studies, as they can help to inform our pursuit to redefine treatment paradigms for people living with immune-mediated conditions like ulcerative colitis."

The next step for Janssen in studying combination therapy in UC is the Phase 2b DUET-UC study, which is a one-year dose-ranging study comparing combination therapy with monotherapy.

Editor's Notes:

a. Primary endpoint of clinical response is defined as a decrease from baseline in the Mayo score ≥30 percent and ≥3 points, with either a decrease in rectal bleeding subscore ≥1 or rectal bleeding subscore of 0 or 1.[1]
b. Major secondary endpoint of clinical remission is based on the full Mayo score and is defined as Mayo score ≤2, with no individual subscore >1. Using the modified Mayo score, clinical remission is defined as a Mayo SF subscore of 0 or 1, where the SF 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 the endoscopy.[1]
c. Endoscopic improvement is defined as an endoscopy subscore of 0 or 1 with no friability present on the endoscopy.[1]
d. 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.[1]
e. Dr. Sands is a paid consultant for Janssen. He has not been compensated for any media work.
f. Endoscopic normalization is an endoscopy subscore of 0 with no friability present on the endoscopy.[1]
g. Symptomatic remission is defined as Mayo SF subscore of 0 or 1, where the SF

subscore has not increased from baseline, and a rectal bleeding subscore of 0.[1]

About VEGA (NCT03662542; EudraCT 2018-001510-15)[2,3]

VEGA is a randomized, double-blind, active-controlled, parallel group, global multicenter Phase 2a proof-of-concept study evaluating the efficacy and safety of combination therapy with guselkumab and golimumab 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.

Study participants were naïve to TNFα antagonists and had to be refractory or intolerant to conventional therapy (e.g., immunomodulators and/or corticosteroids). Participants were randomly assigned to receive guselkumab dosed at 200 mg intravenous (IV) at weeks 0, 4, and 8 (n=71); golimumab dosed at 200 mg subcutaneous (SC) at week 0, then 100 mg SC at weeks 2, 6, and 10 (n=72); or combination with guselkumab dosed at 200 mg IV plus golimumab dosed at 200 mg SC at week 0, golimumab dosed at 100 mg SC at weeks 2, 6, and 10, and guselkumab dosed at 200 mg IV at weeks 4 and 8 (n=71).

The primary endpoint was clinical response at week 12, defined as a decrease from baseline in the Mayo score ≥30 percent and ≥3 points, with either a decrease in rectal bleeding subscore ≥1 or rectal bleeding subscore of 0 or 1. The major secondary endpoint was clinical remission at week 12, defined as Mayo score ≤2, with no individual subscore >1. No adjustments were made for multiple comparisons. Other key endpoints evaluated at week 12 were clinical remission (based on components of the modified Mayo score), symptomatic remission, endoscopic improvement, endoscopic normalization, histologic remission, composite histologic-endoscopic endpoints, and biomarker outcomes.

About Ulcerative Colitis

In the United States, about one million people are affected by UC.[4] 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.[5] It is the result of an abnormal response by the body's immune system.[6] Symptoms vary, but may include loose and more urgent bowel movements, persistent diarrhea, abdominal pain, bloody stool, loss of appetite, weight loss, and fatigue.[6]

About guselkumab[7]

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.[7] 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).[7] 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.[7]

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, or call 1-800-FDA-1088.

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About golimumab[8]

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, 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, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension.

Learn more at 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 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, 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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