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## **New Phase 3 Study Results Show Anti-Tnf Simponi® Induced Clinical Response in Adults with Moderately to Severely Active Ulcerative Colitis**

### **First Presentation of Phase 3 Data Shows Significant Improvements in Clinical Remission, Mucosal Healing and Quality of Life Measures after SIMPONI Induction Treatment**

**San Diego, Calif., May 21, 2012** - New study findings presented today show that subcutaneous induction regimens of the anti-tumor necrosis factor (TNF)-alpha therapy SIMPONI® (golimumab) induced clinical response in a majority of patients with moderately to severely active ulcerative colitis (UC) who had previously failed or were intolerant to conventional agents. Investigators presented data from the Janssen Research & Development, LLC, (Janssen)-sponsored Phase 3 study at Digestive Disease Week® (DDW®) during a late breaker session and reported that more than 50 percent of patients in each of two SIMPONI dosing groups achieved clinical response at week 6, the primary endpoint of the study, which was significantly more than those in clinical response after receiving placebo. Treatment with SIMPONI also resulted in significant induction of clinical remission and mucosal healing and improvement in health-related quality of life measures at week 6 compared with placebo.

"Therapeutic options for patients living with moderate to severe forms of ulcerative colitis who have failed or become intolerant to conventional treatments are quite limited today, which is particularly challenging in managing a disease that primarily affects a younger, active patient population," said the study's lead investigator, William Sandborn, MD, professor and chief of the Division of Gastroenterology at the University of California, San Diego (UCSD) School of Medicine, and director of the UCSD Inflammatory Bowel Disease Center. "These data are promising because treatment with two subcutaneous administrations of SIMPONI induced clinical response at week 6, and also improved patient outcomes in other important measures of disease activity-clinical remission, mucosal healing and quality of life. We look forward to presenting data from the SIMPONI maintenance therapy portion of the trial in the future."

In the Program of Ulcerative Colitis Research Studies Utilizing an Investigational Treatment (PURSUIT) trial, a significantly higher proportion of patients receiving induction treatment with subcutaneous administrations of SIMPONI 200 mg at week 0 and SIMPONI 100 mg at week 2 or SIMPONI 400 mg at week 0 and SIMPONI 200 mg at week 2 met the primary endpoint of clinical response at week 6 compared with the placebo [51.8 percent, 55.0 percent and 29.7 percent of patients achieving clinical response, respectively ( $P < 0.0001$ )]. Clinical response at week 6 was defined as a decrease in the Mayo score of at least 30 percent and 3 points compared to baseline score, with either a decrease from baseline in the rectal bleeding subscore of at least 1 or a rectal bleeding subscore of 0 or 1. The Mayo score is a 12-point clinical assessment and colonoscopy-based measure of disease activity, which assesses improvement in symptoms based on rectal bleeding, endoscopic findings, stool frequency and a physician's global assessment.

Consistently significant results among the SIMPONI 200 mg/100 mg and SIMPONI 400 mg/200 mg groups were reported across all major secondary endpoints at week 6 compared with the placebo group, including clinical remission, defined as a Mayo score of 2 points or less [18.7 percent, 17.8 percent and 6.3 percent, ( $P < 0.0001$ )]; mucosal healing, defined as a Mayo endoscopy score of 0 or 1 [43.2 percent, 45.3 percent and 28.5 percent, ( $P = 0.0005$ )]; and a mean change from baseline in the Inflammatory Bowel Disease Questionnaire (IBDQ) score [(27.4 percent, 27.0 percent and 14.6 percent, ( $P < 0.0001$ )). The IBDQ is a 32-question survey that measures health-related quality of life in adult patients with IBD.

Through week 6, a similar proportion of patients in the combined SIMPONI groups (39.1 percent) and placebo group (38.2 percent) reported an adverse event (AE). Rates of serious AEs were 3.0 percent and 6.1 percent in the combined SIMPONI groups and placebo group, respectively. Injection site reactions were uncommon and comparable across SIMPONI groups. Malignancy rates were 0.0 percent, 0.3 percent and 0.3 percent in the SIMPONI 200 mg/100 mg, SIMPONI 400 mg/200 mg and placebo groups, respectively. One death resulting from postoperative complications following repeated surgeries for an ischiorectal abscess and a single case of demyelination were reported in the SIMPONI 400 mg/200 mg group. The safety of SIMPONI induction in the treatment of UC was consistent with the safety profile of SIMPONI in labeled rheumatologic indications.

#### **About the PURSUIT Trial**

PURSUIT is a Phase 3 multicenter, randomized, double-blind, placebo-controlled study designed to evaluate the safety and efficacy of subcutaneous SIMPONI in adults with moderately to severely active UC. All trial patients had failed to respond to or tolerate treatment with 6-mercaptopurine (6-MP), azathioprine (AZA), corticosteroids and/or 5-aminosalicylate (5-ASA), or were corticosteroid dependent. Study participants were naïve to treatment with TNF inhibitors and had a baseline Mayo score between 6 and 12 and endoscopic subscore greater than or equal to 2.

The trial had an adaptive design with Phase 2 dose ranging followed by a confirmatory Phase 3 component. Patients were randomized to receive SIMPONI 100 mg/50 mg (prior to dose selection only), placebo or SIMPONI 200 mg/100 mg or 400 mg/200 mg at weeks 0 and 2. The primary endpoint was clinical response at week 6. Secondary endpoints at week 6 included clinical remission, mucosal healing and a change from baseline in IBDQ scores. Overall, 1065 patients were treated in the study; 774 of these patients were randomized into the Phase 3 component of the study. Patients responding to induction treatment with SIMPONI were eligible to continue in the Phase 3 PURSUIT maintenance study.

### **About Ulcerative Colitis**

Ulcerative colitis (UC), a chronic inflammatory bowel disease (IBD) affecting nearly 700,000 people in the U.S., is marked by the inflammation and ulceration of the colonic mucosa, or innermost lining, which may lead to bloody stools, severe diarrhea and frequent abdominal pain. Tiny open sores, or ulcers, form on the surface of the lining where they bleed and produce pus and mucus. Symptoms of the disease may lead to loss of appetite, subsequent weight loss and fatigue. On average people are diagnosed with UC in their mid-30s, but the disease can occur at any age.<sup>1</sup> Between 25 and 40 percent of people living with UC will require surgery at some point in their life.<sup>2</sup> UC is a chronic disease, and there is no cure. Although progress has been made in IBD research, researchers do not know what causes this disease.<sup>1</sup>

### **About DDW**

DDW is the largest international gathering of physicians, researchers and academics in the fields of gastroenterology, hepatology, endoscopy and gastrointestinal surgery. Jointly sponsored by the American Association for the Study of Liver Diseases, the American Gastroenterological Association (AGA) Institute, the American Society for Gastrointestinal Endoscopy and the Society for Surgery of the Alimentary Tract, DDW takes place May 19 - 22, 2012, at the San Diego Convention Center. The meeting showcases more than 5,000 abstracts and hundreds of lectures on the latest advances in GI research, medicine and technology. For more information, visit [www.ddw.org](http://www.ddw.org).

### **About SIMPONI® (golimumab)**

SIMPONI is a human monoclonal antibody that targets and neutralizes excess TNF-alpha, a protein that when overproduced in the body due to chronic inflammatory diseases can cause inflammation and damage to bones, cartilage and tissue. SIMPONI is approved in 52 countries for rheumatologic indications, including the United States where SIMPONI received FDA approval in April 2009 for the treatment of moderately to severely active RA with the medicine methotrexate, active psoriatic arthritis alone or with the medicine methotrexate and active ankylosing spondylitis, and is available either through the SmartJect® autoinjector or a prefilled syringe as a once-monthly subcutaneously administered injection. For more information about SIMPONI, visit [www.SIMPONI.com](http://www.SIMPONI.com).

SIMPONI is currently being investigated in Phase 3 studies as a subcutaneously administered treatment for moderately to severely active ulcerative colitis, active polyarticular juvenile idiopathic arthritis (JIA) and as an intravenous (I.V.) formulation for the treatment of moderately to severely active RA.

Janssen Biotech, Inc. discovered and developed SIMPONI and markets the product in the United States. Janssen pharmaceutical companies market SIMPONI in Canada, Central and South America, the Middle East, Africa and Asia Pacific.

In Japan, Indonesia and Taiwan, Janssen Biotech, Inc. licenses distribution rights to SIMPONI to Mitsubishi Tanabe Pharma Corporation and has retained co-marketing rights in those countries. In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to SIMPONI to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co., Inc.

The U.S. full prescribing information for SIMPONI® can be accessed at the following link:

<http://www.simpONI.com/sites/default/files/pdf/prescribing-information.pdf>

For further information about SIMPONI outside of the United States, please consult the relevant official product information applicable to that country location.

### **Important Safety Information**

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

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. You should tell your doctor if you have had or develop lymphoma or other cancers.

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.

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 can occur or get worse in people who use TNF blockers, including SIMPONI®. 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 or swelling of your lower legs or feet.

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.

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.

Low blood counts have been seen with people using TNF blockers, including 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.

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.

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

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.

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

Tell your doctor if you have any symptoms of an allergic reaction while taking SIMPONI® such as hives, swollen face, breathing trouble, 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.

Please read the 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.

**About Janssen Research & Development, LLC**

At Janssen Research & Development, LLC, we are united and energized by one mission-to discover and develop innovative medicines that ease patients' suffering, and solve the most important unmet medical needs of our time. As one of the Janssen Pharmaceutical Companies of Johnson & Johnson, our strategy is to identify the biggest unmet medical needs and match them with the best science, internal or external, to find solutions for patients worldwide. We leverage our world-class discovery and development expertise, and operational excellence, to bring innovative, effective treatments in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. For more information on Janssen R&D, visit <http://www.janssenrnd.com/>.

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