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SIMPONI® (Golimumab) Receives FDA Approval For Ulcerative Colitis

First and Only Subcutaneous Biologic Treatment Approved to Induce and Maintain Clinical Response and Improve Endoscopic Appearance of the Mucosa During Induction

Horsham, PA., May 15, 2013 -- Janssen Biotech, Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved SIMPONI® (golimumab) for the treatment of moderately to severely active ulcerative colitis (UC) in adult patients who have demonstrated corticosteroid dependence or who have had an inadequate response to or failed to tolerate oral aminosalicylates, oral corticosteroids, azathioprine, or 6-mercaptopurine. SIMPONI is the first and only subcutaneously administered anti-tumor necrosis factor (TNF)-alpha therapy approved to induce and maintain clinical response and improve endoscopic appearance of the mucosa during induction. In addition, SIMPONI is indicated to induce clinical remission and achieve and sustain clinical remission in induction responders. As many as 700,000 people in the United States are affected by UC[1], a chronic inflammatory bowel disease (IBD) marked by inflammation and ulceration of the innermost lining of the colon.

"The FDA approval of SIMPONI brings an important, new subcutaneous therapeutic option to adults living with moderate to severe ulcerative colitis, a disease where treatment options have been limited," said William Sandborn, MD, professor and chief of the Division of Gastroenterology at the University of California, San Diego (UCSD) School of Medicine, director of the UCSD Inflammatory Bowel Disease Center, and lead study investigator. "SIMPONI has demonstrated significant benefits in the treatment of ulcerative colitis, a chronic inflammatory bowel disease, and represents a meaningful addition to the treatment armamentaria for gastroenterologists."

For the treatment of UC, the SIMPONI dose regimen consists of 200 mg subcutaneously injected at week 0, followed by 100 mg at week 2 and then 100 mg every 4 weeks, thereafter.

The approval is supported by data from the Program of Ulcerative Colitis Research Studies Utilizing an Investigational Treatment (PURSUIT) clinical trials, evaluating patients with moderately to severely active UC who had previously failed or were intolerant to conventional treatments. Significantly greater proportions of patients who received SIMPONI 200 mg/100 mg achieved clinical response, clinical remission and improvement of the endoscopic appearance of the mucosa at week 6 compared with patients receiving placebo. Through week 54, significantly greater proportions of patients in the SIMPONI 100 mg group maintained clinical response compared with the placebo group. The proportion of patients in clinical response following SIMPONI induction treatment who went on to demonstrate clinical remission at both weeks 30 and 54, without demonstrating a loss of response at any time point through week 54, were significantly greater in the SIMPONI 100 mg group compared with the placebo group.

"The approval of SIMPONI for the treatment of UC is a notable milestone for adults living with this chronic, devastating disease for which there is no cure," said Cindy Guzzo, M.D., Vice President, Medical Affairs, Janssen Biotech, Inc. "As leaders in the treatment of IBD for more than a decade, we are proud to offer a new subcutaneous treatment option to patients and healthcare providers where unmet need continues to exist."

SIMPONI is also approved by the FDA for the treatment of moderately to severely active rheumatoid arthritis (RA) with the medicine methotrexate, active psoriatic arthritis alone or with the medicine methotrexate and active ankylosing spondylitis.

About PURSUIT The Program of Ulcerative Colitis Research Studies Utilizing an Investigational Treatment (PURSUIT) included Phase 3 multicenter, randomized, double-blind, placebo-controlled studies designed to evaluate the safety and efficacy of subcutaneous induction and every-four-week maintenance regimens of 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 naive to treatment with TNF inhibitors and had a baseline Mayo score between 6 and 12 and an endoscopic subscore of 2 or more. 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.

The induction trial (PURSUIT-SC) had an adaptive design with a Phase 2 dose-finding portion followed by a Phase 3 dose-confirming component. The primary endpoint was clinical response at week 6. Secondary endpoints at week 6 included clinical remission and mucosal healing (improvement of endoscopic appearance of mucosa) - Mayo endoscopy score of 0 or 1. Overall, 1,065 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 be randomized in the Phase 3 PURSUIT-Maintenance study. The primary endpoint in this study was maintenance of clinical response through week 54, and secondary endpoints included clinical remission and mucosal healing (improvement of endoscopic appearance of mucosa) - Mayo endoscopy score of 0 or 1 - at both weeks 30 and 54.

The safety results of SIMPONI observed in the PURSUIT studies were consistent with the known safety profile of SIMPONI in labeled rheumatologic indications. For more information regarding the safety profile for SIMPONI, please see "Important Safety Information" below.

About Ulcerative Colitis

Ulcerative colitis (UC), a chronic inflammatory bowel disease (IBD) affecting as many as 700,000 individuals in the United States 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.[1] Tiny open sores, or ulcers, form on the surface of the lining, where they bleed and produce pus and mucus.[1] Symptoms of the disease may lead to loss of appetite, subsequent weight loss and fatigue.[1] On average, people are diagnosed with UC in their mid-30s, but the disease can occur at any age. As many as 30 percent of people living with UC will require surgery at some point in their life.[2] 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.[3]

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 for the treatment of moderately to severely active rheumatoid arthritis (RA) with the medicine methotrexate, active psoriatic arthritis alone or with the medicine methotrexate, active ankylosing spondylitis and moderately to severely active ulcerative colitis. For more information about SIMPONI visit www.SIMPONI.com.

Janssen Biotech, Inc. discovered and developed SIMPONI.

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. 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.

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-Barre 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, 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.

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, or call 1-800-FDA-1088.

About Janssen Biotech, Inc.

Janssen Biotech, Inc. redefines the standard of care in immunology, oncology, urology and nephrology. Built upon a rich legacy of innovative firsts, Janssen Biotech has delivered on the promise of new treatments and ways to improve the health of individuals with serious disease. Beyond its innovative medicines, Janssen Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates and health care professionals have access to the latest treatment information, support services and quality care. For more information on Janssen Biotech, Inc. or its products, visit www.janssenbiotech.com.

Janssen Biotech is one of the Janssen Pharmaceutical Companies of Johnson & Johnson which are dedicated to addressing

and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we work together to bring innovative ideas, products, services and solutions to people throughout the world. Follow us on Twitter at www.twitter.com/JanssenUS.

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2. Crohn's & Colitis Foundation of America. Colitis Treatment Options. Available at: http://www.ccfa.org/what-are-crohns-and-colitis/what-is-ulcerative-colitis/colitis-treatment-options.html. Accessed March 18, 2013.
3. World IBD Day. About Us. Available at: http://www.ibdday.bvsalud.org/. Accessed March 18, 2013.