Johnson & Johnson

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SIMPONI® Receives CHMP Positive Opinion For Treatment Of Ulcerative Colitis

SIMPONI Recommended for Approval in Adult Patients with Moderately to Severely Active Ulcerative Colitis

Leiden, The Netherlands, July 26, 2013 - Janssen Biologics B.V. ("Janssen") announced today that the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the use of SIMPONI® (golimumab) for the treatment of adult patients with moderately to severely active ulcerative colitis (UC) who have had an inadequate response to conventional therapy or who are intolerant to or have medical contraindications for such therapies.

Based on the CHMP's positive opinion, a final decision from the European Commission is expected during the third quarter of 2013. If approved, SIMPONI will become available for patients living with moderately to severely active UC. SIMPONI will be the only biologic therapy available for this patient population that is administered subcutaneously every four weeks following an induction regimen. UC is a chronic inflammatory bowel disease (IBD) marked by inflammation and ulceration of the colonic mucosa, which may lead to bloody stools, severe diarrhea and frequent abdominal pain.

"The CHMP positive opinion is an important milestone as we look to bring SIMPONI to patients living with moderately to severely active ulcerative colitis who may benefit from this anti-TNF-alpha therapy," said Jerome A. Boscia, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "Adults living with this inflammatory bowel disease who remain uncontrolled on steroids or immunomodulators have limited treatment options today, and SIMPONI would represent a new, subcutaneous therapeutic option. We look forward to the European Commission's decision in the coming weeks."

The CHMP adopted the opinion based on a review of data from two pivotal studies in the Program of Ulcerative Colitis Research Studies Utilizing an Investigational Treatment (PURSUIT), which 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, azathioprine, corticosteroids and/or 5-aminosalicylate, or were corticosteroid dependent. Study participants were naïve to treatment with tumor necrosis factor (TNF) inhibitors, 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 (Mayo endoscopy score of 0 or 1). Overall, 1,065 patients were treated in the study; 761 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 (Mayo endoscopy score of 0 or 1 at both weeks 30 and 54).

About Ulcerative Colitis

Ulcerative colitis (UC), a chronic inflammatory bowel disease (IBD) affecting 2.5 million individuals worldwide,[2] 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.[2] Between 25 and 40 percent of people living with UC will require surgery at some point in their life.[3] UC is a chronic disease, which no cure. Although progress has been made in IBD research, researchers do not know what causes this disease.[2]

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 70 countries for rheumatologic indications, including the European Union (EU), where SIMPONI received European Commission approval in October 2009 for the treatment of moderate-to-severe, active RA in combination with methotrexate, for

the treatment of active and progressive psoriatic arthritis alone or in combination with methotrexate and for the treatment of severe, active ankylosing spondylitis. SIMPONI is available either through the SmartJect® autoinjector/prefilled pen or a prefilled syringe as a subcutaneously administered injection. For more information about SIMPONI in the EU, visit www.SIMPONI.eu.

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

In Europe, Russia and Turkey, Janssen Biotech, Inc. licenses distribution rights to SIMPONI to Schering-Plough (Ireland) Company, a subsidiary of Merck & Co., Inc.

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.

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

Important Safety Information (EU)

In the European Union, SIMPONI is contraindicated in patients with active tuberculosis, severe infections such as sepsis, opportunistic infections, in patients with moderate or severe heart failure (NYHA Class III/IV), as well as in patients who are hypersensitive to SIMPONI or any of its excipients. Serious infections, including sepsis, pneumonia, tuberculosis (TB), invasive fungal and other opportunistic infections have been observed with the use of TNF antagonists including SIMPONI. Some of these infections have been fatal. SIMPONI should not be given to patients with a clinically important, active infection. Caution should be exercised when considering the use of SIMPONI in patients with a chronic infection or a history of recurrent infection. Patients must be monitored closely for infections including TB before, during and after treatment with SIMPONI. If a patient develops a new serious infection or sepsis, SIMPONI therapy should be discontinued and appropriate antimicrobial therapy should be initiated until the infection is controlled. Patients should be advised of, and avoid exposure to, potential risk factors for infection as appropriate. For patients who have resided in or traveled to regions where invasive fungal infections such as histoplasmosis, coccidioidomycosis, or blastomycosis are endemic, the benefits and risks of SIMPONI treatment should be carefully considered before initiation of SIMPONI therapy. All patients must be evaluated for the risk of TB, including latent TB, prior to initiation of SIMPONI. If active TB is diagnosed, SIMPONI must not be initiated. If latent TB is suspected, a physician with expertise in the treatment of TB should be consulted. The benefit/risk balance should be very carefully considered for the following: treatment of latent TB infection must be initiated prior to therapy with SIMPONI. Antituberculosis therapy prior to initiating SIMPONI should also be considered in patients who have several or highly significant risk factors for tuberculosis infection and have a negative test for latent tuberculosis. Patients receiving SIMPONI should be monitored closely for signs and symptoms of active tuberculosis during and after treatment, including patients who tested negative for latent tuberculosis infections.

The use of TNF blocking agents including SIMPONI has been associated with reactivation of hepatitis B virus (HBV) in patients who are chronic carriers of the virus. Some of these cases have been fatal. Patients should be tested for HBV infection before initiating treatment with Simponi. Carriers of HBV who require treatment with Simponi should be closely monitored during treatment with, and for several months following discontinuation of SIMPONI. In patients who develop HBV reactivation, SIMPONI should be discontinued.

Lymphomas have been observed in patients treated with TNF blocking agents, including SIMPONI. The incidence of non-lymphoma malignancies was similar to controls, and lymphoma is seen more often than in the general population. The potential role of TNF-blocking therapy in the development of malignancies is not known. Based on an exploratory clinical trial in patients with COPD using another anti-TNF agent, caution should be exercised when using any TNF-blocking therapy in COPD patients, as well as in patients with an increased risk for malignancy due to heavy smoking. Rare post-marketing cases of hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with other TNF-blocking agents. This rare type of T-cell lymphoma has a very aggressive disease course and is usually fatal.

It is not known if SIMPONI treatment influences the risk for developing dysplasia or colon cancer. All patients with ulcerative colitis who are at increased risk for dysplasia or colon carcinoma, or who had a prior history of dysplasia or colon carcinoma should be screened for dysplasia at regular intervals before therapy and throughout their disease course.

Worsening and new onset congestive heart failure (CHF) and increased mortality due to CHF have been reported with another TNF blocker. SIMPONI has not been studied in patients with CHF. SIMPONI should be used with caution in patients with mild heart failure and must be discontinued if new or worsening symptoms of heart failure appear.

TNF-blocking agents, including SIMPONI, have been associated in rare cases with new onset or exacerbation of demyelinating disorders, including multiple sclerosis. The benefits and risks of anti-TNF treatment should be carefully considered before initiation of SIMPONI therapy in patients with pre-existing or recent onset of demyelinating disorders.

There is limited safety experience of SIMPONI treatment in patients who have undergone surgical procedures, including

arthroplasty. A patient who requires surgery while on SIMPONI should be closely monitored for infections, and appropriate actions should be taken.

The possibility exists for TNF-blocking agents, including SIMPONI, to affect host defenses against infections and malignancies. Treatment with SIMPONI may result in the formation of auto-antibodies and, rarely, in the development of a lupus-like syndrome.

There have been postmarketing reports of pancytopenia, leukopenia, neutropenia, aplastic anemia, and thrombocytopenia in patients receiving TNF blockers. Cytopenias including pancytopenia, have been infrequently reported with SIMPONI in clinical trials. Discontinuation of SIMPONI should be considered in patients with significant hematologic abnormalities.

The concurrent administration of TNF-antagonists with anakinra or abatacept is not recommended. Concurrent administration has been associated with increased infections, including serious infections without increased clinical benefit. The concomitant use of Simponi with other biological therapeutics used to treat the same conditions as Simponi is not recommended because of the possibility of an increased risk of infection, and other potential pharmacological interactions. Patients should continue to be monitored when switching from one biologic to another.

Patients treated with SIMPONI may receive concurrent vaccinations, except for live vaccines. In postmarketing experience, serious systemic hypersensitivity reactions have been reported following Simponi administration. Allergic reactions may occur after first or subsequent administration of SIMPONI. If an anaphylactic reaction or other serious allergic reactions occur, administration of SIMPONI should be discontinued immediately and appropriate therapy initiated.

The needle cover on the syringe in the pre-filled pen is manufactured from dry natural rubber containing latex, and may cause allergic reactions in individuals sensitive to latex. SIMPONI also contains sorbitol; patients with rare hereditary problems of fructose intolerance should not take SIMPONI.

Patients should be given detailed instructions on how to administer SIMPONI. After proper training, patients may self inject if their physician determines that this is appropriate. The full amount of SIMPONI should be administered at all times. Mild injection site reactions commonly occur.

Women of childbearing potential must use adequate contraception to prevent pregnancy and continue its use for at least 6 months after the last SIMPONI treatment. Women must not breast feed during and for at least 6 months after SIMPONI treatment.

The most common adverse drug reaction reported from clinical trials through week 16 was upper respiratory tract infection (12.6 percent of SIMPONI-treated patients compared with 10.7 percent in control-treated patients). In controlled Phase 3 trials through Week 16 in RA, psoriatic arthritis and ankylosing spondylitis, 5.1 percent of SIMPONI treated patients had injection site reactions compared with 2.0 percent in control-treated patients. The majority of the injection site reactions were mild and moderate, and the most frequent manifestation was injection site erythema.

The SIMPONI Patient Alert Card provides safety information to the patient. It should be given and explained to all patients before treatment. Patients must show the Alert Card to any doctor involved in his/her treatment, during and up to 6 months after SIMPONI treatment.

For complete EU prescribing information, please visit www.emea.europa.eu.

About Janssen Biologics B.V. and Janssen Research & Development, LLC

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we develop innovative products, services and healthcare solutions to help people with serious diseases throughout the world. Beyond its innovative medicines, Janssen 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.

Janssen Biologics B.V. and Janssen Research & Development, LLC are two of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssen.com for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Biologics B.V., any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products

and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. A further list and description of these risks, uncertainties and other factors can be found in Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent 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 undertake to update any forward-looking statements as a result of new information or future events or developments.)

References:

1. World IBD Day. About Us. http://worldibdday.org/. Accessed April 8, 2013.
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