



## **Simponi™ (Golimumab) Receives European Approval as One-Monthly Subcutaneous Anti-TNF for Treatment of Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis With Novel Smartject™ Autoinjector**

**HORSHAM, Pa. and KENILWORTH, N.J., October 6, 2009** - Centocor Ortho Biotech Inc. and Schering-Plough Corporation (NYSE: SGP) announced today that the European Commission has approved SIMPONI™ (golimumab) as a one-monthly, subcutaneous therapy for the treatment of moderate-to-severe, active rheumatoid arthritis (RA), active and progressive psoriatic arthritis (PsA) and severe, active ankylosing spondylitis (AS).

In the European Union, SIMPONI is approved as a 50 mg subcutaneous injection once a month and is indicated:

- In combination with methotrexate, for the treatment of moderate-to-severe, active RA in adult patients when the response to disease-modifying anti-rheumatic drug (DMARD) therapy, including methotrexate, has been inadequate. SIMPONI has also been shown to improve physical function in this patient population.
- Alone or in combination with methotrexate, for the treatment of active and progressive PsA in adult patients when the response to previous DMARD therapy has been inadequate. SIMPONI has also been shown to improve physical function in this patient population.
- For the treatment of severe, active AS in adult patients who have responded inadequately to conventional therapy.

Centocor Ortho Biotech Inc. developed and discovered SIMPONI and has exclusive marketing rights to the product in the United States. Following regulatory approvals, Schering-Plough will assume exclusive marketing rights outside the United States except in Japan, Indonesia and Taiwan, where SIMPONI will be co-marketed by Mitsubishi Tanabe Pharma Corporation and Janssen Pharmaceutical Kabushiki Kaisha; Hong Kong, where SIMPONI will be exclusively marketed by Janssen-Cilag; and China, where SIMPONI will be exclusively marketed by Xian-Janssen. Centocor Ortho Biotech, Janssen-Cilag and Xian-Janssen are wholly-owned subsidiaries of Johnson & Johnson.

"With this approval, Schering-Plough can now bring SIMPONI, one of the five stars in our development pipeline, to market in Europe," said Thomas P. Koestler, Ph.D., executive vice president and president, Schering-Plough Research Institute. "Offering once-monthly subcutaneous dosing, SIMPONI will provide an important and convenient new treatment option to rheumatologists and their patients. SIMPONI expands upon our leading immunology franchise in meeting the needs of the rheumatology community."

"SIMPONI has been shown to significantly reduce the signs and symptoms and improve physical function of rheumatoid arthritis, ankylosing spondylitis and psoriatic arthritis, three debilitating rheumatic diseases," said Iain B. McInnes, MD, PhD, FRCP, Professor of Experimental Medicine, University of Glasgow, study investigator. "With this approval, rheumatologists and patients now have an effective once-monthly subcutaneous anti-TNF therapy for the treatment of these rheumatic diseases."

The Commission Decision follows a positive opinion adopted on June 25, 2009, by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and results in marketing authorization with unified labeling that is valid in the current EU 27 member states as well as in Iceland and Norway. In April 2009, SIMPONI™ (golimumab) was approved by the U.S. Food and Drug Administration (FDA) and Health Canada for the treatment of moderately to severely active RA, active PsA and active AS.

The efficacy and safety of SIMPONI have been studied in a comprehensive Phase 3 development program that included more than 2,000 patients living with moderately to severely active RA, active PsA and active AS. In Phase 3 rheumatoid arthritis trials, SIMPONI was shown to be effective regardless of prior treatment experience, which included patients inadequately responding to methotrexate and patients previously treated with anti-TNF agents.

### **About Rheumatoid Arthritis**

Rheumatoid arthritis is a chronic and debilitating disease that affects more than three million people in Europe. Signs and symptoms of RA include pain, stiffness and motion restriction in multiple joints. Because RA is a progressive disease, over time it can cause permanent joint deformity and severe disability. RA can occur at any age, but is most common in adults 30-50 years old and is two-to-three times more prevalent in women than in men. The cause of RA is unknown, although genetic factors may contribute to the disease.

### **About Psoriatic Arthritis**

Psoriatic arthritis is a chronic inflammatory arthropathy manifesting with joint pain and swelling that can lead to joint destruction and debilitation over time. The Arthritis Research Campaign estimates one in 50 people have psoriasis. Of these, about one in 14 will develop PsA. It is frequently associated with inflamed, scaly, red patches of skin psoriasis and psoriasis nail involvement. Symptoms may include stiffness and tenderness of the joints and surrounding tissue and reduced range of motion. Joints of the hands, wrists, knees, ankles, feet, lower back and neck are commonly affected. Psoriasis affects an estimated two to three percent of the world's population, and approximately one out of three patients affected by psoriasis may develop psoriatic arthritis. Both men and women are equally affected by psoriatic arthritis, most commonly between the ages of 30 and 50, in the peak of their productive years.

### **About Ankylosing Spondylitis**

Ankylosing spondylitis is a painful and progressive form of spinal arthritis, and symptoms of inflammatory back pain often first present in people under the age of 35 years. On the European continent, it is estimated that prevalence ranges from 0.2 to one percent of the entire population. It typically begins in the late teens and early 20s, and in severe cases can result in fusing of the spinal vertebrae and cause structural damage to hips and other joints. Often misdiagnosed as "just back pain" or undifferentiated arthritis, AS is a systemic inflammatory disease that, in addition to its effect on the spine, can affect internal organs, peripheral joints and vision.

### **About SIMPONI**

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 the first once monthly subcutaneous therapy approved in the U.S., European Union and Canada for the treatment of three rheumatic conditions: rheumatoid arthritis, psoriatic arthritis and ankylosing spondylitis. The approved dose for SIMPONI in the U.S., European Union and Canada is a 50 mg subcutaneous injection given once a month either through the SIMPONI SmartJect™ auto injector or a prefilled syringe.

### **Important Safety Information**

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, 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 should be monitored for signs and symptoms of infection before, during and after treatment with SIMPONI. If a patient develops a serious infection or sepsis, SIMPONI therapy should be discontinued and appropriate antimicrobial therapy should be initiated. 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. Patients must be evaluated for the risk of tuberculosis (TB), including latent tuberculosis, prior to initiation of SIMPONI. If active TB is diagnosed, SIMPONI must not be initiated. If latent TB is suspected then the benefit/risk balance should be considered for the following: treatment of latent tuberculosis infection should 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 in patients who are chronic carriers of the virus. Some of these cases have been fatal. Chronic carriers of hepatitis B should be appropriately evaluated and monitored prior to the initiation of, 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, 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.

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.

Patients treated with SIMPONI may receive concurrent vaccinations, except for live vaccines. Non-serious allergic reactions associated with SIMPONI occurred in clinical trials, and included urticaria, bronchospasm, and hypersensitivity. 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. All patients should be monitored for anaphylactic or other serious allergic reactions.

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. In case of severe reaction(s) SIMPONI should be discontinued.

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.

The most common adverse drug reaction reported from clinical trials through week 16 was upper respiratory tract infection (7.2 percent of SIMPONI-treated patients compared with 5.8 percent in control-treated patients). In controlled Phase 3 trials through Week 16 in RA, PsA and AS, 5.8 percent of SIMPONI treated patients had injection site reactions compared with 2.2 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.

**For complete EU prescribing information, please visit [www.emea.europa.eu](http://www.emea.europa.eu). For the Full U.S. Prescribing Information and Medication Guide, please visit [www.SIMPONI.com](http://www.SIMPONI.com).**

#### **About Centocor Ortho Biotech, Inc.**

Centocor Ortho Biotech Inc. redefines the standard of care in immunology, nephrology, and oncology. The company was created when Ortho Biotech Inc. merged into Centocor, Inc., and Centocor, Inc. was renamed Centocor Ortho Biotech Inc. Built upon a pioneering history, Centocor Ortho Biotech Inc. harnesses innovations in large-molecule and small-molecule research to create important new therapeutic options. Beyond its innovative medicines, Centocor Ortho Biotech is at the forefront of developing education and public policy initiatives to ensure patients and their families, caregivers, advocates, and healthcare professionals have access to the latest treatment information, support services, and quality care. Centocor Ortho Biotech is a wholly-owned subsidiary of Johnson & Johnson.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 Centocor Ortho Biotech Inc. and/or Johnson & Johnson's expectations and projections. Risks and uncertainties include general industry conditions and competition; economic conditions, such as interest rate and currency exchange rate fluctuations; technological advances and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; domestic and foreign health care reforms and governmental laws and regulations; and trends toward health care cost containment. 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 28, 2008. Copies of this Form 10-K, as well as subsequent 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. Neither Centocor Ortho Biotech Inc. nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)

#### **About Schering-Plough**

Schering-Plough is an innovation-driven, science-centered global health care company. Through its own biopharmaceutical research and collaborations with partners, Schering-Plough creates therapies that help save and improve lives around the world. The company applies its research-and-development platform to human prescription and consumer products as well as to animal health products. Schering-Plough's vision is to "Earn Trust, Every Day" with the doctors, patients, customers and other stakeholders served by its colleagues around the world. The company is based in Kenilworth, N.J., and its Web site is [www.schering-plough.com](http://www.schering-plough.com).

SCHERING-PLOUGH DISCLOSURE NOTICE: The information in this press release includes certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, including statements relating to the potential market for SIMPONI. Forward-looking statements relate to expectations or forecasts of future events. Schering-Plough does not assume the obligation to update any forward-looking statement. Many factors could cause actual results to differ materially from Schering-Plough's forward-looking statements, including market forces, economic factors, product availability, patent and other intellectual property protection, current and future branded, generic or over-the-counter competition, the regulatory process, and any developments following regulatory approval, among other uncertainties. For further details about these and other factors that may impact the forward-looking statements, see Schering-Plough's Securities and Exchange Commission filings, including Part II, Item 1A. "Risk Factors" in the Company's second quarter 2009 10-Q, filed July 24, 2009.

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