



## Health Canada Approves Simponi™ (Golimumab) For Treatment Of Rheumatoid Arthritis, Psoriatic Arthritis And Ankylosing Spondylitis

### Canadian Approval Is World's First Regulatory Approval for SIMPONI

HORSHAM, Pa. and KENILWORTH, N.J., April 13, 2009 - Centocor Ortho Biotech, Inc. and Schering-Plough Corporation (NYSE: SGP) today announced that Health Canada has granted approval of SIMPONI™ (golimumab) as a once-monthly, subcutaneous therapy for the treatment of moderately to severely active rheumatoid arthritis (RA), active psoriatic arthritis (PsA) and active ankylosing spondylitis (AS). With this approval in Canada, SIMPONI, in combination with methotrexate (MTX), is indicated for reducing the signs and symptoms in adult patients with moderately to severely active RA; reducing signs and symptoms in adult patients with moderately to severely active PsA, alone or in combination with MTX; and reducing signs and symptoms in adult patients with active AS who have had an inadequate response to conventional therapies. SIMPONI is the first biologic therapy to be approved concurrently in three distinct rheumatologic diseases. Schering-Plough anticipates that the medication will become available in Canada in the second half of 2009.

"This first approval marks a major milestone in the clinical development program for SIMPONI," said Jerome A. Boscia, M.D., senior vice president, Clinical R&D, Centocor Research & Development, Inc. "More importantly, the approval of SIMPONI expands the therapeutic options for physicians and offers patients an effective new medication that can be self-administered once monthly."

"This is the first approval for SIMPONI, one of the five stars in our late-stage pipeline," said Thomas P. Koestler, Ph.D., executive vice president, Schering-Plough Corporation 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 our leading immunology franchise in meeting the needs of the rheumatology community."

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.

In March 2008, Centocor Ortho Biotech Inc. and Schering-Plough Corporation announced that a Marketing Authorization Application (MAA) had been submitted to the European Medicines Agency (EMA) requesting the approval of golimumab as a monthly subcutaneous treatment for adults with RA, PsA and AS.

In June 2008, Centocor Ortho Biotech Inc. announced that a Biologics License Application (BLA) had been submitted to the U.S. Food and Drug Administration (FDA) requesting the approval of golimumab as a monthly subcutaneous treatment for adults with active forms of RA, PsA and AS.

The approval of SIMPONI in Canada is based on data from five pivotal clinical trials: GO-BEFORE, GO-FORWARD, GO-AFTER, GO-REVEAL and GO-RAISE. Each trial found SIMPONI to be effective in reducing the signs and symptoms of RA, PsA and AS.

#### **About Rheumatoid Arthritis**

RA is a chronic and debilitating disease that affects approximately 4 million people in Canada. 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. 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 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. It typically begins in the late teens and early twenties, 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, ankylosing spondylitis 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. The first once-monthly subcutaneous anti-TNF-alpha therapy, SIMPONI is approved in Canada for the treatment of moderately to severely active rheumatoid arthritis, active psoriatic arthritis and active ankylosing spondylitis, and is available either through the SIMPONI SmartJect auto injector or a prefilled syringe. SIMPONI is also being studied as an intravenous infusion therapy for the treatment of rheumatoid arthritis.

In Canada, SIMPONI is approved for:

- In combination with methotrexate (MTX), reducing signs and symptoms in adult patients with moderately to severely active rheumatoid arthritis.
- Reducing signs and symptoms in adult patients with moderately to severely active psoriatic arthritis, alone or in combination with MTX. SIMPONI can be used in combination with MTX in patients who do not respond adequately to MTX alone.
- Reducing signs and symptoms in adult patients with active ankylosing spondylitis who have had an inadequate response to conventional therapies.

## Important Safety Information

SIMPONI is contraindicated in patients with severe infections such as sepsis, tuberculosis and opportunistic infections and in patients who are hypersensitive to golimumab, latex or any of the 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 (chronic or localized). 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 while on or after treatment with SIMPONI. If a patient develops a serious infection or sepsis, SIMPONI therapy should be discontinued. 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, including latent tuberculosis, prior to initiation of SIMPONI. 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 has been associated with reactivation of hepatitis B virus in patients who are chronic carriers of the virus. 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.

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. Caution should be exercised when considering TNF-blocking therapy for patients with a history of malignancy or when considering continuing treatment in patients who develop malignancy.

Worsening congestive heart failure (CHF) and new onset CHF have been reported with TNF blockers. Cases of CHF in patients with known cardiovascular risk factors have been observed with SIMPONI. SIMPONI should be used with caution in patients with heart failure and should be discontinued if new or worsening symptoms of heart failure appear. TNF-blocking agents, including SIMPONI, have been associated in rare cases with demyelinating disease. 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. Treatment with SIMPONI may result in the formation of auto-antibodies and, rarely, in the development of a lupus-like syndrome. 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 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.

#### **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 Item 1A. "Risk Factors" in Schering-Plough's 2008 10-K, filed February 27, 2009.

SIMPONI™ is the trademark of Centocor Ortho Biotech Inc. used under license by Schering-Plough Canada Inc.