



New SIMPONI(TM) Data Show Long-Term Efficacy in Treatment of Rheumatoid Arthritis

Patients with Active Rheumatoid Arthritis Receiving SIMPONI Demonstrated Sustained Improvements in Signs and Symptoms Through One Year

PHILADELPHIA, Oct 19, 2009 /PRNewswire via COMTEX News Network/ -- New long-term data from two pivotal, Phase 3 clinical trials showed that patients with active rheumatoid arthritis (RA) receiving SIMPONI(TM) (golimumab) every four weeks achieved sustained improvements in signs and symptoms and physical function response through one year. These new data were presented today at the 2009 American College of Rheumatology (ACR) Annual Scientific Meeting.

"New data demonstrate sustained efficacy of golimumab dosed every four weeks in patients with RA who were previously treated with anti-TNF agents," said Dr. Jonathan Kay, Professor of Medicine and Director of Clinical Research in the Rheumatology Division at the University of Massachusetts Medical School in Worcester, Massachusetts and lead study investigator.

Findings from the *G*olimumab *A*fter *F*ormer anti-TNF Therapy *E*valuated in *R*A (*GO-AFTER*) study demonstrated that patients with RA previously treated with adalimumab, etanercept or infliximab responded to, and maintained response to, SIMPONI through one year. At week 52, 63 percent of patients receiving SIMPONI 50 mg achieved at least a 20 percent improvement in arthritis signs and symptoms as measured by American College of Rheumatology (ACR 20) response, and 41 percent achieved a 50 percent improvement in arthritis signs and symptoms as measured by ACR 50 response.

SIMPONI-treated patients who had discontinued previous anti-TNF treatment for any reason sustained improvements in physical function, as measured by the Health Assessment Questionnaire (HAQ). At week 52, patients receiving SIMPONI 50 mg maintained a clinically relevant improvement (decrease in HAQ score of at least 0.25) from baseline. Similar results were previously reported at week 24. HAQ assesses the degree of difficulty a person has in accomplishing tasks in eight functional areas (dressing, arising, eating, walking, hygiene, reaching, gripping and other activities of daily living). The data also showed that 81 percent and 61 percent of patients receiving SIMPONI 50 mg reported improvements from baseline in the number of tender and swollen joints, respectively.

Results from the *G*olimumab *F*OR subjects *W*ith *A*ctive *R*A *D*espite Methotrexate (*GO-FORWARD*) study showed the efficacy of SIMPONI in patients with active RA despite prior treatment with methotrexate. At week 52, 64 percent of patients taking SIMPONI 50 mg plus methotrexate achieved ACR 20 response, and 25 percent achieved a 70 percent improvement in arthritis signs and symptoms as measured by ACR 70 response. There was no clear evidence of improved ACR response with the higher SIMPONI dose group (100 mg). Importantly, investigators also reported that 48 percent of patients receiving SIMPONI 50 mg plus methotrexate achieved a low level of disease activity as measured by Disease Activity Score 28 (DAS 28) C-reactive protein (CRP) <2.6, which measures tender and swollen joints, inflammation and overall disease activity including measurement of serum CRP levels.

"These data show that patients receiving golimumab, a once-monthly anti-TNF therapy, sustained clinical response through one year," said Dr. Mark Genovese, Division Co-Chief of Immunology and Rheumatology at Stanford University and study investigator.

In April 2009, the U.S. Food and Drug Administration (FDA) and Health Canada approved SIMPONI 50 mg as a once-monthly subcutaneous injection for the treatment of moderately to severely active RA, active psoriatic arthritis (PsA) and active ankylosing spondylitis. In October 2009, the European Commission approved SIMPONI as a once-monthly, subcutaneous injection for the treatment of moderate to severe, active RA, active and progressive PsA and severe, active ankylosing spondylitis.

About the GO-AFTER Trial

GO-AFTER is the first placebo-controlled, double-blind, Phase 3 registration trial that demonstrates the efficacy and safety of an anti-TNF-alpha agent in patients previously treated with other anti-TNFs. The trial included patients with active RA of 8.65 years mean duration. Discontinuation of previous anti-TNF-alpha therapy was to occur at least eight to 12 weeks prior to enrollment in the study. At baseline, 66 percent of patients were receiving methotrexate; five percent and eight percent of patients were receiving sulfasalazine and hydroxychloroquine, respectively. Patients continued to receive stable doses of methotrexate, sulfasalazine and/or hydroxychloroquine if receiving them at baseline. At week 16, patients with less than a 20 percent improvement in tender and swollen joint counts were entered into a double-blinded early escape. Those who did not achieve ACR 20 response at week 16 while taking placebo were given SIMPONI 50 mg every four weeks. Those who qualified

for early escape and had been taking SIMPONI 50 mg were given SIMPONI 100 mg and those who had been receiving SIMPONI 100 mg continued to receive that dosing.

At least one adverse event was reported in 76 percent of patients receiving SIMPONI 50 mg or SIMPONI 100 mg with 13 and eight percent of patients, respectively, experiencing a serious adverse event. Serious infections were reported in four percent of patients receiving SIMPONI 50 mg and three percent of patients taking SIMPONI 100 mg, and injection site reactions were reported in one percent and two percent of patients, respectively.

About the GO-FORWARD Trial

GO-FORWARD, a Phase 3, multi-center clinical trial, includes adult patients with active RA and more than four tender and swollen joints, despite methotrexate therapy. Patients were randomly assigned to receive SIMPONI (50 or 100 mg) plus methotrexate, SIMPONI 100 mg plus placebo or placebo plus methotrexate at weeks 0, 4, 8, 12, 16 and 20. At week 16, patients with at least a 20 percent response (ACR 20) were entered into an early escape and patients who had been receiving placebo plus methotrexate received SIMPONI 50 mg plus methotrexate; methotrexate was added to the SIMPONI 100 mg with placebo group, the group receiving SIMPONI 50 mg plus methotrexate was given SIMPONI 100 mg and the SIMPONI 100 mg plus methotrexate group was not changed. The patients continued receiving treatment through 52 weeks.

Serious adverse events were reported in 11, 17, 14 and 18 percent of patients in each group, respectively, and two, six, two and eight percent of patients, in each group respectively, experienced a serious infection. From week 24 through week 52, nine serious infections were reported; three in patients receiving SIMPONI 50 mg plus methotrexate, four in patients receiving SIMPONI 100 mg plus placebo and two in patients taking SIMPONI 100 mg plus methotrexate. There were also four malignancies reported between week 24 and week 52; two patients receiving SIMPONI 50 mg plus methotrexate were diagnosed with squamous and basal cell cancer and breast cancer, respectively, and two patients receiving SIMPONI 100 mg plus methotrexate were diagnosed with basal cell cancer and breast cancer, respectively.

About Rheumatoid Arthritis

Rheumatoid arthritis is characterized by persistent and progressive joint inflammation, causing pain, stiffness and functional disability. The Arthritis Foundation estimates that approximately 1.3 million people in the United States are affected by RA. For more information, visit the [Arthritis Foundation](#).

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 for the treatment of RA, PsA and ankylosing spondylitis in the United States, Europe and Canada, and is available either through the SIMPONI SmartJect autoinjector or a prefilled syringe. For more information about SIMPONI, visit www.SIMPONI.com.

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.

Important Safety Information

SIMPONI 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. 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

Tell your doctor about all the medications you take or if you are scheduled to or recently received a vaccine.

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 may 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
- skin or eyes look yellow
- little or no appetite
- vomiting
- muscle aches
- dark urine
- clay-colored bowel movements
- fevers
- chills
- stomach discomfort

- skin rash

If you take SIMPONI or other TNF blockers, your risk for developing lymphoma or other cancers may increase. You should tell your doctor if you have had or develop lymphoma or other cancers.

Heart failure can occur or get worse in people who use TNF blockers like SIMPONI. Your doctor will monitor you closely 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 can have nervous system problems such as multiple sclerosis. 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.

Liver problems can happen in people using TNF blockers. 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. 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.

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. Common side effects of SIMPONI include: upper respiratory tract infection, nausea, abnormal liver tests, redness at site of injection, high blood pressure, bronchitis, dizziness, sinus infection, flu, runny nose, fever, cold sores, numbness or tingling.

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.

The Full Prescribing Information and Medication Guide for SIMPONI will be available at 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. For more information about Centocor Ortho Biotech, visit www.CentocorOrthoBiotech.com. 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 healthcare reforms and governmental laws and regulations; and trends toward healthcare 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, 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

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