News Release

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SIMPONI® RECEIVES EUROPEAN COMMISSION APPROVAL FOR TREATMENT OF NON-RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS

Approval Marks Fifth Indication for SIMPONI in Europe

Leiden, The Netherlands, June 26, 2015 – Janssen Biologics B.V. ("Janssen") announced today that the European Commission (EC) has approved SIMPONI® (golimumab) for the treatment of adults with severe active non-radiographic axial spondyloarthritis (nr-AxSpA) with objective signs of inflammation (OSI), as indicated by elevated C-reactive protein (CRP) and/or magnetic resonance imaging (MRI) evidence, who have had an inadequate response to or are intolerant to nonsteroidal anti-inflammatory drugs (NSAIDs). The EC approval follows a positive opinion issued by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in May 2015 recommending the use of SIMPONI for this indication. Nr-AxSpA is a form of spondyloarthritis—a chronic inflammatory disease affecting the spine—in which the predominant symptom is back pain and stiffness. It is estimated that 0.3 to 2.5 percent of the European population are affected by some type of spondyloarthritis.[1]

"The European Commission approval of SIMPONI for the treatment of severe active non-radiographic axial spondyloarthritis provides an important new therapeutic option for people living with this debilitating inflammatory disease," said Newman Yeilding, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "We are pleased to make SIMPONI available to patients and physicians in Europe in partnership with our MSD colleagues."

Data from the Phase 3 GO-AHEAD trial, a MSD- (known as Merck in the United States and Canada) sponsored program conducted in collaboration with Janssen, served as the basis for EC approval. The two-part study validated the efficacy and safety of SIMPONI compared with placebo in adults living with severe active nr-AxSpA. At week 16, a greater percentage of patients treated with SIMPONI than placebo (71.1 percent versus 40.0 percent, respectively; P< .0001) achieved an Assessment in Ankylosing Spondylitis (ASAS) 20 response, the primary endpoint of the study. ASAS 20 improvements were also seen in the OSI subpopulation (76.9 percent versus 37.5 percent, respectively; P< .0001). Similarly, major secondary endpoints at week 16 were attained in more SIMPONI-treated patients compared with placebo, as measured by ASAS 40 response, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) 50 response, ASAS partial remission and change from baseline in Spondyloarthritis Research Consortium of Canada (SPARCC) MRI Sacroiliac joints scoring.

In the GO-AHEAD study, adverse events occurred in 41 percent and 47 percent of patients receiving SIMPONI and placebo, respectively. There were no cases of serious infections, serious opportunistic infections, active tuberculosis, malignancies, serious systemic hypersensitivity reactions or death.

About GO-AHEAD

GO-AHEAD, a multicenter, randomized, double-blind, placebo-controlled Phase 3 study, evaluated the efficacy and safety of SIMPONI in adults 18 to 45 years of age with severe active nr-AxSpA. Patients had been diagnosed no more than five years prior with chronic back pain of at least three months' duration and were inadequately controlled with 30 days of

optimal daily doses of at least one NSAID or were intolerant to such therapy. In part one of the study, patients were randomised equally to receive SIMPONI 50 mg or placebo at weeks 0, 4, 8 and 12. Beginning at week 16—part two of the study—all patients began receiving open-label SIMPONI 50 mg every four weeks. Part two was 44 weeks in duration, with 36 weeks of treatment and an eight-week safety follow-up period.

About Spondyloarthritis

Spondyloarthritis refers to a family of chronic, inflammatory diseases that share common clinical features, including inflammation of the joints and the entheses (sites where ligaments and tendons attach to bones). AxSpA is a type of spondyloarthritis that mainly affects the spine and pelvic joints. The primary symptoms of AxSpA include pain and stiffness of the spine. The disease can eventually progress to spinal deformity and dysfunction. Unlike ankylosing spondylitis, which is another type of AxSpA, patients with nr-AxSpA may not present with traditional X-ray evidence of structural damage in sacroiliac joins the spine.[2]

About SIMPONI® (golimumab)

SIMPONI is a human monoclonal antibody that targets and neutralises excess tumor necrosis factor (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 85 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 rheumatoid arthritis 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. In September 2013, SIMPONI received European Commission approval for the treatment of moderately to severely active ulcerative colitis. SIMPONI is available either through the SmartJect® autoinjector/prefilled pen or a prefilled syringe as a subcutaneously administered injection.

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.

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., Janssen Research & Development, LLC and Janssen Biotech, Inc.
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., Janssen Research & Development, LLC and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssen.com for more information.

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