NEWS RELEASE

SIMPONI® RECEIVES CHMP POSITIVE OPINION FOR TREATMENT OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITIS

5/27/2016

SIMPONI® RECEIVES CHMP POSITIVE OPINION FOR TREATMENT OF POLYARTICULAR JUVENILE IDIOPATHIC ARTHRITISSIMPONI Recommended for Sixth Indication in Europe and First in Pediatric Population

LEIDEN, Netherlands, May 27, 2016 /PRNewswire/ -- 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 subcutaneous SIMPONI® (golimumab) in combination with methotrexate (MTX) for the treatment of polyarticular juvenile idiopathic arthritis (pJIA) in children with a body weight of at least 40 kg, who have responded inadequately to previous therapy with MTX.

Based on the CHMP's positive opinion, a final decision from the European Commission is expected in the coming months. If approved, SIMPONI will become available for the treatment of patients with active pJIA, the most common type of arthritis in children under the age of 17 in which the predominant symptoms are persistent joint pain, swelling and stiffness. It is estimated that nearly 60,000 Europeans are affected by juvenile idiopathic arthritis.[1]

"Despite advances in biologic treatments in rheumatologic disease, there remains a need for effective and well-tolerated therapeutics for patients with polyarticular juvenile idiopathic arthritis, a complex and debilitating inflammatory arthritis," said Alberto Martini, M.D., Professor of Paediatrics at the University of Genoa, Founder and Chairman of the Pediatric Rheumatology International Trial Organization (PRINTO). "On behalf of PRINTO and the pediatric rheumatology community, we applaud the Committee for Medicinal Products for Human Use of the European Medicines Agency on today's recommendation of SIMPONI for the treatment of polyarticular juvenile idiopathic arthritis."

The CHMP adopted the opinion based on a review of data from the Phase 3 GO KIDS trial, a Janssen-sponsored program conducted in collaboration with MSD (known as Merck in the United States and Canada), that evaluated the efficacy and safety of SIMPONI in 173 children (2 to 17 years of age) with pJIA and active arthritis in at least five joints that had poor response to MTX. Part 1 of the study consisted of a 16-week open-label phase, in which enrolled patients received SIMPONI 30 mg/m^2 (maximum 50 mg) subcutaneously every four weeks and MTX. The 154 patients who achieved an American College of Rheumatology (ACR) Pediatric (Ped) 30 response at week 16 entered Part 2 of the study, the randomised withdrawal phase, and received SIMPONI 30 mg/m^2 (maximum 50 mg) and MTX or placebo and MTX every four weeks.

The primary endpoint, the proportion of patients who achieved ACR Ped 30 response at week 16 and who did not experience a flare between week 16 and week 48, did not reach statistical significance, as the majority of patients did not experience a flare between week 16 and week 48 (59 percent in the SIMPONI and MTX and 53 percent in the placebo and MTX groups, respectively; P=0.41). However, pre-specified subgroup analyses of the primary endpoint by baseline CRP (=1 mg/dL vs <1 mg/dL) demonstrated higher flare rates in placebo and MTX compared to golimumab and MTX treated subjects among subjects with baseline CRP =1 mg/dL (87 percent vs 40 percent, p=0.0068). In this study, the type and frequency of adverse events reported were generally similar to those seen in adult RA studies.

"We commend the European Medicines Agency, the Pediatric Rheumatology International Trial Organization and the Pediatric Rheumatology Collaborative Study Group, for a concerted and collaborative review of data and supportive analyses from the SIMPONI Phase 3 GO KIDS study to arrive at today's positive opinion," said Newman Yeilding, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "We believe the totality of data from the GO KIDS study supports the efficacy and safety of SIMPONI in the treatment of polyarticular juvenile idiopathic arthritis and look forward to the European Commission's decision."

About Polyarticular Juvenile Idiopathic Arthritis

Polyarticular juvenile idiopathic arthritis, also known as juvenile rheumatoid arthritis, is a type of arthritis characterised by persistent joint pain, swelling and stiffness.[2] The disease can cause serious health complications, such as growth problems and eye inflammation.[3] The European League Against Rheumatism (EULAR) defines seven subcategories of pJIA, with most forms more common in females than males.[4] While the cause of pJIA is unknown, heredity and environment are both thought to be factors.[3]

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 more than 85 countries for rheumatologic

indications including rheumatoid arthritis (RA), ankylosing spondylitis and psoriatic arthritis. In the European Union (EU), 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. In September 2013, SIMPONI received European Commission approval for the treatment of moderately to severely active ulcerative colitis in adults. In June 2015, SIMPONI received European Commission approval for the treatment of adults with severe, active non radiographic axial spondyloarthritis with objective signs of inflammation. 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. Cases of leukaemia have been reported in patients treated with SIMPONI. 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. Malignancies, some fatal, have been reported among children, adolescents and young adults (up to 22 years of age) treated with TNF-blocking agents (initiation of therapy = 18 years of age) in the post marketing setting.

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.

Melanoma has been reported in patients treated with TNF-blocking agents, including SIMPONI. Merkel cell carcinoma has been reported in patients treated with other TNF-blocking agents.

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 11.0 percent in control-treated patients). In the controlled periods of pivotal trials, 5.4% of golimumab-treated patients had injection site reactions compared with 2.0% in control 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:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000992/human_med_001053.jsp&mid=WC0b01ac058001d124

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at **www.janssen.com**. Follow us on Twitter at **https://twitter.com/JanssenGlobal.**

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development including expected availability. 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 known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Biologic B.V., any of the other Janssen Pharmaceutical Companies or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; competition, including technological advances, new products and patents attained by competitors; challenges to patents; manufacturing difficulties or delays; product efficacy or safety

concerns resulting in product recalls or regulatory action; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended January 3, 2016, including in Exhibit 99 thereto, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at **www.sec.gov**, **www.jnj.com** or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

References

[1] Thierry S, Fautrel B, Lemelle I, Guillemin F. Prevalence and incidence of juvenile idiopathic arthritis: a systematic review. Joint Bone Spine. 2014 Mar;81(2):112-7. doi: 10.1016/j.jbspin.2013.09.003.

[2] Sherry, D. (2016, March 3). Juvenile Idiopathic Arthritis. Medscape. **http://emedicine.medscape.com/article/1007276-overview** Accessed May 12, 2016.

[3] Juvenile rheumatoid arthritis. The Mayo Clinic website. **http://www.mayoclinic.org/diseases-conditions/juvenile-rheumatoid-arthritis/basics/definition/con-20014378**. Accessed May 12, 2016.

[4] Musculoskeletal Health in Europe Report v5.0. The European League Against Rheumatism website. **http://eular.org/myUploadData/files/EU_eumusc.net_Report_final.pdf** Accessed May 12, 2016.

Media Contact

Brian Kenney

Office: +1 215-628-7010

Mobile: +1 215-620-0111

bkenney1@its.jnj.com

Investor Contact

Lesley Fishman

Johnson & Johnson

Office: +1 732-524-3922