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Data at EULAR 2015 Showcase Commitment of Janssen to Advancing Innovative Treatments for Immune and Inflammatory Diseases

New data highlights efficacy and safety of
STELARA® (ustekinumab), SIMPONI® (golimumab), sirukumab and guselkumab

Beerse, Belgium, 2 June 2015 – The Janssen Pharmaceutical Companies* announced today that 17 Janssen Immunology abstracts in ankylosing spondylitis, rheumatoid arthritis, psoriatic arthritis and psoriasis, will be presented at the Annual European Congress of Rheumatology (EULAR), 10–13 June, in Rome, Italy.

Newman Yeilding, M.D., Head of Immunology Development, Janssen Research & Development, LLC. said, "Our commitment to immunology and the continued research and development of innovative solutions for the treatment of complex immune and inflammatory diseases has never been stronger. We are pleased to present data from our immunology portfolio at the EULAR congress."

Janssen Immunology Portfolio Highlights At EULAR 2015 Include:[1]

STELARA (ustekinumab):

- Serum biomarkers associated with disease activity and response to ustekinumab in patients with ankylosing spondylitis in the TOPAS study (THU0194)
  - Poster presentation, Thursday 11 June at 12:00
  - Lead author: B. Dasgupta

- A Phase 2 study evaluating the efficacy and safety of subcutaneously administered ustekinumab and guselkumab in patients with active rheumatoid arthritis despite treatment with methotrexate (OP0031)
  - Oral presentation, Thursday 11 June at 10:55
  - Lead author: J. Smolen

- Efficacy and safety of ustekinumab in psoriatic arthritis patients with spondylitis and peripheral joint involvement: Results from a Phase 3, multicenter, double-blind, placebo-controlled study† (OP0174)
  - Oral presentation, Friday 12 June at 11:35
  - Lead author: A. Kavanaugh

- Long-term improvements in physical function are associated with improvements in dactylitis, enthesitis, tender and swollen joint counts, and psoriasis skin involvement:

Results from a Phase 3 study of ustekinumab in psoriatic arthritis patients† (SAT0563)
    - Poster presentation, Saturday 13 June at 10:15
    - Lead author: A. Kavanaugh

- Integrated safety of ustekinumab in psoriatic arthritis: 2 year follow-up from the psoriatic arthritis clinical development program† (THU0419)
    - Poster presentation, Thursday 11 June at 12:00
    - Lead author: A. Kavanaugh

- Serious infection events in the Psoriasis Longitudinal Assessment and Registry study: Current status of observations† (SAT0560)
    - Poster and poster tour presentation, Saturday 13 June at 11:00
    - Lead Author: R. Kalb

- Malignancies in the Psoriasis Longitudinal Assessment and Registry (PSOLAR) study: Current status of observations† (SAT0559)
    - Poster and poster tour presentation, Saturday 13 June at 10:50
    - Lead author: D. Fiorentino

- Persistence of biologic therapy in psoriatic disease: Results from the Psoriasis Longitudinal Assessment and Registry (PSOLAR)†(SAT0561)
    - Poster and poster tour presentation, Saturday 13 June at 11:10
    - Lead author: A. Menter

SIMPONI (golimumab):**

- Clinical meaningfulness of radiographic joint damage on physical function, employability and work productivity in patients with rheumatoid arthritis: Results from the intravenous golimumab study GO-FURTHER (AB0412)
    - Publication only
    - Lead author: C. Han

- Comparison of interferon-γ release assay versus tuberculin skin test in the golimumab PURSUIT UC program and the golimumab SC rheumatology (RA, PsA, and AS) program (AB0413)
    - Publication only
    - Lead author: EC Hsia

- Treatment target status at 6 months and long-term outcomes at 5 years: Analysis of methotrexate-naïve patients with rheumatoid arthritis in the SC GO-BEFORE trial (SAT0162)
    - Poster presentation, Saturday 13 June at 10:15
    - Lead author: P. Emery

- A comparison of EQ5D index from the UK, US, and Japan preference weights model, and mapping algorithm from clinical outcomes in patients with rheumatoid arthritis: Results from SIMPONI ARIA study (THU0091)
    - Poster presentation, Thursday 11 June at 12:00
    - Lead author: C. Han

- Serum biomarkers associated with changes in ASDAS and MRI following treatment of ankylosing spondylitis with golimumab† (THU0223)
    - Poster presentation, Thursday 11 June at 12:00

    - Lead author: R.D. Inman

- Long-term safety of intravenous golimumab and comparison with subcutaneous golimumab in rheumatoid arthritis: Results through 2 years† (FRI0132)
    - Poster presentation, Friday 12 June at 12:00
    - Lead author: R. Westhovens

**The intravenous formulation of golimumab is not approved in Europe. It is approved in the US under the name of SIMPONI® ARIA®.

Sirukumab:

- Improvement in measures of depressed mood and anhedonia, and fatigue, in a randomized, placebo-controlled, Phase 2 study of sirukumab, a human anti-interleukin-6 antibody, in patients with rheumatoid arthritis (SAT0182)
    - Poster presentation, Saturday 13 June at 10:15
    - Lead author: B. Hsu

- Neutralization of IL-6 by sirukumab inhibits inflammation and cellular stress in a human vascular surrogate system of atherosclerosis (FRI0069)
    - Poster and poster tour presentation, Friday 12 June at 13:25
    - Lead author: B. Hsu

- Preclinical characterization of sirukumab, a human monoclonal antibody that targets human interleukin -6 signaling† (THU0042)
    - Poster and poster tour presentation, Thursday 11 June at 12:05
    - Lead author: D. Gardner

Janssen-sponsored Symposia

- IL-6: a central cytokine in rheumatoid arthritis, Thursday 11 June 2015 at 17:45–19:15 in Hall 10, Room C, Fiera Roma, Rome, Italy

- The spectrum of spondyloarthropathies: molecules to medicine, Friday 12 June 2015 at 08:30–10:00 in Hall 2, Fiera Roma, Rome, Italy

† *Encore presentation*

About Ankylosing Spondylitis

Ankylosing spondylitis is a chronic, immune-mediated disease that causes enthesitis, or inflammation where ligaments and muscles attach to bones, most commonly those within the spine. It is the primary disease in a group of arthritis-related diseases known as spondylitis, spondyloarthropathy or spondyloarthritis.[2,3] It is estimated that 0.1 to 1.4 percent of the world's population are living with ankylosing spondylitis.[4] The disease affects men more often than women and typically manifests in early adulthood.[5] In contrast to mechanical low back pain, low back pain and stiffness with ankylosing spondylitis worsen after a period of rest or upon waking up in the morning and improve after exercise, a hot bath or a shower.[2]

About Rheumatoid Arthritis

Rheumatoid arthritis is a chronic inflammatory disorder that occurs when the immune system attacks the lining of the membranes that surround joints, also known as the synovium. Unlike the wear-and-tear damage associated with other types of arthritis, rheumatoid arthritis causes painful swelling and destroys the cartilage and bone, eventually resulting in permanent joint deformity. Rheumatoid arthritis can be difficult to diagnose in its initial stages because the early signs and symptoms mimic those of many other diseases. Currently, there is no single blood test or physical finding to confirm the diagnosis.[6] It is estimated that 0.3 to 1 percent of the world's population are living with rheumatoid arthritis. The disease is most common in women and is more prevalent in developed countries. It tends to strike during the most productive years of adulthood, between the ages of 20 and 40.[7]

About Psoriatic Arthritis

Psoriatic arthritis is a chronic immune-mediated inflammatory disease characterised by both joint and surrounding tissue inflammation, and the skin lesions associated with psoriasis, which affects as many as 37 million people worldwide[8] and approximately 4.2 million people across Europe.[8,9,10,11,12,13] While estimates of the prevalence of psoriatic arthritis among people living with psoriasis vary, up to 30 percent may develop inflammatory arthritis.[13] Although the exact cause of psoriatic arthritis is unknown, it is believed to be an immune-mediated inflammatory disease with a genetic link.[14] Environmental factors may play a role in the development of the disease.[15] Early signs of psoriatic arthritis can include enthesitis and dactylitis. Other arthritic symptoms of psoriatic arthritis include swelling, pain, stiffness of the joints and surrounding tissue, and reduced range of motion.[14,16]

About Psoriasis

Psoriasis, a chronic, immune-mediated disease that results from the overproduction of skin cells, affects 125 million people worldwide, including nearly 14 million Europeans.[9-13] Plaque psoriasis often results in patches of thick, red or inflamed skin covered with silvery scales known as plaques. These plaques can crack and bleed, and may occur anywhere on the body.[17] The disease symptoms can range from mild, to moderate, to severe and disabling. It is estimated that nearly three percent of the world's population is living with psoriasis and nearly one-quarter of those people have cases that are considered moderate to severe.[12]

About STELARA (ustekinumab)[18]

STELARA, a human interleukin (IL)-12 and IL-23 antagonist, is approved for the treatment of moderate to severe plaque psoriasis in adults who failed to respond to, or who have a contraindication to, or are intolerant to other systemic therapies including ciclosporin, methotrexate (MTX) or psoralen plus Ultraviolet A (PUVA). STELARA is also approved alone or in combination with MTX, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying antirheumatic drug (DMARD) therapy has been inadequate.

STELARA is not recommended for use in children and adolescents below the age of 18.

The Janssen Pharmaceutical Companies maintain exclusive worldwide marketing rights to STELARA, which is currently approved for the treatment of moderate to severe plaque psoriasis in 84 countries and for psoriatic arthritis in 55 countries.

Important Safety Information[18]

SPECIAL WARNINGS & PRECAUTIONS: ***Infections:*** Potential to increase risk of infections and reactivate latent infections. Exercise caution in patients with a chronic infection or history of recurrent infection, particularly TB. Patients should be evaluated for tuberculosis and treated for latent TB prior to initiation of STELARA. Also, consider anti-tuberculosis therapy prior to initiation of STELARA in patients with past history of latent or active tuberculosis. Patients should seek medical advice if signs or symptoms suggestive of an infection occur. If a serious infection develops, they should be closely monitored and STELARA should not be administered until infection resolves. ***Malignancies****:* Potential to increase the risk of malignancy. No studies have been conducted in patients with a history of malignancy or in those who continue to receive STELARA after being diagnosed with a malignancy. Exercise caution when considering STELARA in these patients. Monitoring for the appearance of non-melanoma skin cancer recommended, in particular for patients greater than 60 years of age, or with a medical history of prolonged immunosuppressant therapy or a history of PUVA treatment. ***Hypersensitivity reactions:*** Serious hypersensitivity reactions (anaphylaxis and angioedema) reported, in some cases several days after treatment. If these occur, institute appropriate therapy and discontinue use of STELARA. ***Vaccinations:*** Patients receiving STELARA should not receive concurrent live viral or live bacterial vaccines such as BCG. Before live viral or live bacterial vaccination, treatment with STELARA should be withheld for at least 15 weeks after the last dose and can be resumed at least 2 weeks after vaccination. Patients receiving STELARA may receive concurrent inactivated or non live vaccinations. ***Concomitant immunosuppressive therapy:*** Exercise caution, including when changing immunosuppressive biologic agents. In psoriasis studies, the safety and efficacy of STELARA in combination with other immunosuppressants, including biologics, or phototherapy have not been evaluated. In psoriatic arthritis studies, concomitant MTX use did not appear to influence the safety or efficacy of STELARA. ***Immunotherapy:*** Not known whether STELARA affects allergy immunotherapy. ***Serious skin conditions:*** In patients with psoriasis, exfoliative dermatitis has been reported following STELARA treatment. Patients with plaque psoriasis may develop erythrodermic psoriasis, with symptoms that may be clinically indistinguishable from exfoliative dermatitis, as part of the natural course of their disease. If these symptoms occur, appropriate therapy should be instituted. STELARA should be discontinued if a drug reaction is suspected. ***Latex sensitivity*****:** Needle cover contains natural rubber (latex), may cause allergic reactions. ***Elderly Patients > 65years:*** Use caution when treating elderly patients.

For complete European Union (EU) prescribing information, please visit:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000958/human_med_001065.jsp&mid=WC0b01ac058001d124

About SIMPONI (golimumab)[19]

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 for the treatment of moderate-to-severe, active rheumatoid arthritis in combination with methotrexate (MTX), for the treatment of active and progressive psoriatic arthritis alone or in combination with MTX and for the treatment of severe and active ankylosing spondylitis. SIMPONI is also approved in 59 countries for the treatment of moderately to severely active ulcerative colitis.

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. Janssen Biologics BV is the marketing authorization holder in the EU.

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[19]

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 rheumatoid arthritis, 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:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000992/human_med_001053.jsp&mid=WC0b01ac058001d124

About Sirukumab

Sirukumab is an investigational human monoclonal IgG1 kappa antibody in Phase 3 development for the treatment of moderately to severely active rheumatoid arthritis.[20] It is not approved as a treatment for rheumatoid arthritis or any other indication anywhere in the world. Sirukumab targets the cytokine interleukin IL-6, a naturally occurring protein that is believed to play a role in autoimmune conditions like rheumatoid arthritis.[21]

Janssen Research & Development, LLC was developing sirukumab for rheumatoid arthritis and in December 2011, Janssen Biologics (Ireland) and GSK entered into a co-development and co-commercialisation license agreement with respect to sirukumab to continue such development.

About Guselkumab[22]

Guselkumab is an investigational human monoclonal antibody that targets interleukin IL-23 and is currently in Phase 3 study for the treatment of moderate to severe plaque psoriasis. It is not approved as a treatment for plaque psoriasis or any other indication anywhere in the world. Guselkumab is being studied to determine whether blockade of IL-23 alone can achieve high levels of complete skin clearance.

About Janssen

At Janssen, we are dedicated to addressing and solving some of the most important unmet medical needs of our time in immunology, oncology, 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.

*The Janssen Pharmaceutical Companies operate through different legal entities in various countries. Therefore, the legal entity acting as the sponsor or the marketing authorisation holder may vary. Janssen Research & Development, LLC, Janssen Biotech, Inc.; Janssen Biologics, BV; Janssen-Cilag International NV are all Janssen affiliates. Please visit www.janssen-emea.com for more information. Follow us on www.twitter.com/JanssenEMEA.

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