Press Release
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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), sirukumab and guselkumab.

The Janssen Pharmaceutical Companies* presented 11 abstracts in ankylosing spondylitis, rheumatoid arthritis, psoriatic arthritis and psoriasis, 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)
  o Poster presentation, Thursday 11 June at 12:00
  o Lead author: B. Dasgupta

- 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)
  o Oral presentation, Friday 12 June at 11:35
  o Lead author: A. Kavanaugh

Sirukumab:
- Neutralization of IL-6 by sirukumab inhibits inflammation and cellular stress in a human vascular surrogate system of atherosclerosis (FRI0069)
  o Poster and poster tour presentation, Friday 12 June at 13:25
  o Lead author: B. Hsu
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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. It is estimated that 0.1 to 1.4 percent of the world’s population are living with ankylosing spondylitis. The disease affects men more often than women and typically manifests in early adulthood.

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.

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. 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.

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 and approximately 4.2 million people across Europe. While estimates of the prevalence of psoriatic arthritis among people living with psoriasis vary, up to 30 percent may develop inflammatory arthritis. Although the exact cause of psoriatic arthritis is unknown, it is believed to be an immune-mediated inflammatory disease with a genetic link. Environmental factors may play a role
in the development of the disease. Early signs of psoriatic arthritis can include enthesitis and dactyliitis. Other arthritic symptoms of psoriatic arthritis include swelling, pain, stiffness of the joints and surrounding tissue, and reduced range of motion.

**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. 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. 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.

**About STELARA (ustekinumab)**
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**
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 immunsuppressive therapy:** Exercise caution, including when changing immunsuppressive biologic agents. In psoriasis studies, the safety and efficacy of STELARA in combination with other immunsuppressants, 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 erythodermic 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.


**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. 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.

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**
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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References