News Release

Media Contacts:
Laura Dobell
Office: +44 (0) 1494 658 151
Mobile: +44 (0) 7825 920 827
ldobell@its.jnj.com

Brian Kenney
Office: +1 215-628-7010
Mobile: +1 215-620-0111
bkenney1@its.jnj.com

Investor Contacts:
Louise Mehrotra
Johnson & Johnson
Office: +1 732-524-6491

Stan Panasewicz
Johnson & Johnson
Office: +1 732-524-2524

STELARA® RECEIVES EUROPEAN COMMISSION APPROVAL FOR TREATMENT OF ACTIVE PSORIATIC ARTHRITIS

Approval marks a new biologic treatment with alternative mechanism for complex inflammatory disease

Beerse, Belgium, September 23, 2013 – Janssen-Cilag International NV ("Janssen") announced today that the European Commission has approved the use of STELARA (ustekinumab), alone or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

The decision from the European Commission follows a positive opinion recommending the use of STELARA from the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in July 2013. STELARA is the first in a new class of biologics now available for patients living with active psoriatic arthritis, a chronic autoimmune disease characterised by joint swelling and tenderness, periarticular tissue inflammation (enthesitis, inflammation of the site where ligaments or tendons insert into the bones, and dactylitis, inflammation of an entire digit, e.g., finger or toe, often called "sausage digit"), as well as psoriasis. The disease affects approximately 4.2 million people across Europe,[1-5] and there is currently no cure.

"The European Commission approval of STELARA for the treatment of active psoriatic arthritis brings an important new therapeutic option to patients and marks the first treatment approved for this devastating and complex disease since the introduction of anti-tumor necrosis factor (TNF)-alpha agents," said Jerome A. Boscia, M.D., Vice President, Head of Immunology Development, Janssen Research & Development, LLC. "Data from the Phase 3 clinical program, one of the largest conducted for a biologic to date in psoriatic arthritis, showed STELARA effective in improving symptoms and signs of active psoriatic arthritis in anti-TNF-alpha naïve and experienced patients. We believe STELARA will play a critically important role in the treatment of this chronic disease moving forward."

The European Commission provided approval based on a review of data from two pivotal Phase 3 multicenter, randomised, double-blind, placebo-controlled trials of ustekinumab, a fully human anti-interleukin (IL)-12/23p40 monoclonal antibody, administered subcutaneously, in patients with active psoriatic arthritis (PSUMMIT I and PSUMMIT II). The trials evaluated the efficacy and safety of subcutaneously administered STELARA 45 mg or 90 mg at weeks 0, 4 and then every 12 weeks. The trials included patients diagnosed with active psoriatic arthritis who had at least five tender and five swollen joints and C-reactive protein (CRP) levels of at least 0.3 mg/dL despite previous treatment with conventional therapies. PSUMMIT II also included patients who had previously experienced treatment with TNF inhibitors. The primary endpoints for both studies were the proportion of patients demonstrating at least a 20 percent improvement in arthritis signs and symptoms (American College of Rheumatology [ACR] 20) at week 24. Secondary endpoints at week 24 were: improvements in Health Assessment Questionnaire Disability Index (HAQ-DI) scores, a 50 or 70 percent improvement in arthritis signs and symptoms (ACR 50 or ACR 70) and at least a 75 percent improvement in psoriatic skin lesions as measured by the Psoriasis Area Severity Index (PASI 75) in patients with at least three percent body surface area involvement with psoriasis at baseline. The studies also captured improvements in enthesitis and dactylitis scores for patients with enthesitis and/or dactylitis at baseline.

The safety results of STELARA observed in the PSUMMIT studies were consistent with the known safety profile of STELARA in the labelled moderate to severe plaque psoriasis indication with up to 5 years of safety experience in clinical trials. For more information regarding the safety profile for STELARA, please see "Important Safety Information" below.

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[4] and approximately 4.2 million people across Europe.[1-5] While estimates of the prevalence of psoriatic arthritis among people living with psoriasis vary, up to 30 percent may develop inflammatory arthritis.[5] Although the exact cause of psoriatic arthritis is unknown, it is believed to be an immune-mediated inflammatory disease with a genetic link.[6] Environmental factors may play a role in the development of the disease.[7] 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.[6,8]

About STELARA® (ustekinumab)

STELARA, a human interleukin (IL)-12 and IL-23 antagonist, is currently approved in 74 countries for the treatment of moderate to severe plaque psoriasis. IL-12 and IL-23 are naturally occurring proteins that are believed to play a role in immune-mediated inflammatory diseases, including psoriasis and psoriatic arthritis.

In the European Union, STELARA 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 and PUVA (psoralen plus UVA).[9] STELARA is also approved alone, or in combination with methotrexate, for the treatment of active psoriatic arthritis in adult patients when the response to previous non-biological disease-modifying anti-rheumatic drug (DMARD) therapy has been inadequate.

STELARA is not recommended for use in children and adolescents below age 18 as studies in the paediatric population have not yet been completed.

Janssen Biotech, Inc. discovered STELARA and has exclusive marketing rights to the product in the United States. The Janssen Pharmaceutical Companies maintain exclusive worldwide marketing rights to STELARA.

Important Safety Information[9]

Ustekinumab is a selective immunosuppressant and may have the potential to increase the risk of infections and reactivate latent infections. Serious infections have been observed in patients receiving STELARA in clinical trials. Do not start STELARA during an active infection. If a serious infection develops, monitor patients carefully and stop STELARA until the infection resolves. Patients should be evaluated for tuberculosis (TB) infection prior to initiating treatment with STELARA.

Ustekinumab is a selective immunosuppressant. Immunosuppressive agents have the potential to increase the risk of malignancy. Malignancies have been observed in patients receiving ustekinumab in clinical trials. Caution should be exercised when considering the use of STELARA in patients with a history of malignancy or when considering continuing treatment in patients who develop a malignancy.

Serious allergic reactions have been reported in the post-marketing setting, in some cases several days after treatment. Anaphylaxis and angioedema have occurred. If an anaphylactic or other serious allergic reaction occurs, administration of STELARA should be discontinued immediately and appropriate treatment instituted.

It is recommended that live viral or live bacterial vaccines (such as Bacillus of Calmette and Guérin [BCG]) should not be given concurrently with STELARA.

No overall differences in efficacy or safety in patients age 65 and older who received STELARA were observed compared to younger patients, however the number of patients aged 65 and older is not sufficient to determine whether they respond differently from younger patients. Because there is a higher incidence of infections in the elderly population in general, caution should be used in treating the elderly.

Special Warnings and Precautions for Use[9]

Concomitant immunosuppressive therapy: Caution should be exercised when considering concomitant use of other immunosuppressants and ustekinumab or when transitioning from other immunosuppressive biologics.

For complete EU prescribing information, please visit www.emea.europa.eu.

About Janssen-Cilag International NV and Janssen Research & Development, LLC

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-Cilag International NV and Janssen Research & Development, LLC are two of the Janssen Pharmaceutical Companies of Johnson & Johnson. Please visit www.janssen-emea.com for more information.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV*, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; challenges to patents; changes in behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. 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 30, 2012. 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. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.)*

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