New Findings From The Psoriasis Longitudinal Assessment And Registry (PSOLAR)

October 9, 2014
New Findings From The Psoriasis Longitudinal Assessment And Registry (PSOLAR)

Amsterdam, The Netherlands, October 9, 2014 - Janssen-Cilag International NV reported new findings at the annual meeting of the European Academy of Dermatology and Venereology (EADV) showing significantly better persistency and lower rates of discontinuation with STELARA® (ustekinumab) therapy compared with anti-tumor necrosis factor (TNF)-alpha treatments among patients participating in Psoriasis Longitudinal Assessment and Registry (PSOLAR), a post-marketing registry following patients with moderate to severe plaque psoriasis. The analysis reports on patients starting treatment, longevity of treatment and discontinuation rates of biologic therapies, including STELARA, infliximab, etanercept and adalimumab.

"Finding a safe therapy that patients can continue long-term for a lifelong disease like psoriasis is important, especially when considering the potential consequences from stopping or switching treatment," said Alan Menter, M.D., Chief, Division of Dermatology, Baylor University Medical Center, and lead investigator. "This particular analysis of the PSOLAR registry showed higher treatment longevity and lower rates of discontinuation with ustekinumab compared with anti-TNF-alpha agents."

PSOLAR is a longitudinal, observational study evaluating safety and clinical outcomes for patients with psoriasis who are treated with or are candidates for treatment with STELARA, infliximab, adalimumab, etanercept and other conventional systemic agents. In this analysis, duration of treatment was defined by the length in days between the first dose of treatment and discontinuation of treatment, switch to a different treatment, registry withdrawal or the most recent data collection (August 23, 2013), whichever occurred first. Persistence was assessed by Kaplan-Meier (KM) analysis for time to therapy stop/switch, and Cox proportional hazard regression (HR) analysis was used to compare time to stop/switch of STELARA with time to stop/switch of infliximab, adalimumab and etanercept. Separate analyses were performed for first-line use (biologic-naïve patients; i.e., first biologic started, with start occurring on registry), second-line use (second biologic started, with start occurring on registry) and third-line use (third biologic started, with start occurring on registry) to reduce confounding associated with prior exposures.

More patients overall were treated with STELARA (n=1,833) than with adalimumab (n=1,303), etanercept (n=537) or infliximab (n=327). Among first-line use, significantly better persistence was observed for STELARA compared with other biologics (adalimumab vs. STELARA: HR 4.99; confidence interval (CI): 3.39-7.35; P < 0.0001; etanercept vs. STELARA: HR 5.59; CI: 3.77-8.29; P < 0.0001; infliximab vs. STELARA: HR 3.04; CI: 1.66-5.57; P = 0.0003). Similar results were observed among the second- and third-line patient groups, with STELARA showing better treatment longevity and fewer discontinuations than other biologics. Reasons for stop/switch were similar across all four biologics. The analyses have not yet been adjusted for differences among treatment groups such as socioeconomic factors, setting of administration (self-administration vs. in doctor's office) and geographic region.

Additional PSOLAR data presentations, including multiple safety analyses of the various treatment groups, are being presented at the EADV meeting.

About PSOLAR
The prospective, disease-based PSOLAR observational registry is a large, international study assessing patients with psoriasis who are receiving or are candidates for treatment with systemic therapies. The registry is a major component of the post-marketing safety monitoring commitment to regulatory agencies for STELARA and infliximab and is fully enrolled with 12,095 patients and a median duration of follow-up of 2.5 years. Patients are to be followed for eight years. Key demographics, disease characteristics and medication history were collected at enrollment. Adverse events and efficacy data are collected longitudinally. A PSOLAR global Steering Committee manages epidemiological research on psoriasis and its therapies.[1]

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.[2-6] 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.[7] The disease symptoms can range from mild, to moderate, to severe and disabling. It is estimated that nearly 3 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.[2]

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 PUVA (psoralen plus UVA). 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.

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, which is currently approved for the treatment of moderate to severe plaque psoriasis in 79 countries.

Important Safety Information (EU)[8]
STELARA 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.

STELARA is a selective immunosuppressant. Immunosuppressive agents have the potential to increase the risk of malignancy. Malignancies have been observed in patients receiving STELARA 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 aged 65 and older who received STELARA were observed compared to 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[8]
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.ema.europa.eu.

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

###

References

1. Papp KA, et. al. PSOLAR: Design, utility, and preliminary results of a prospective, international, disease-based, registry of patients with psoriasis who are receiving, or are candidates for, conventional systemic treatments or biologic agents. *J Drugs Dermatol*. 2012;11(10):1210-7.
2. About Psoriasis: Statistics. National Psoriasis Foundation website. http://www.psoriasis.org/research/science-of-psoriasis/statistics. Accessed October 7, 2014.
3. Augustin M, Herberger K, Hintzen S, Heigel H, Franzke N, Schäfer I. Prevalence of skin lesions and need for treatment in a cohort of 90880 workers. *Br J Dermatol*. 2011;165(4):865-873.
4. Ortonne JP, Prinz JC. Alefacept: a novel and selective biologic agent for the treatment of chronic plaque psoriasis. *Eur J Dermatol*. 2004;14(1):41-45.
5. Parisi R, Symmons DP, Griffiths CE, Ashcroft DM. Global epidemiology of psoriasis: a systematic review of incidence and prevalence. *J Invest Dermatol*. 2013;133(2):377-385.
6. How many people live in the EU? European Union website. http://europa.eu/abc/keyfigures/sizeandpopulation/index_en.htm. Accessed September 10, 2014.
7. About Psoriasis. National Psoriasis Foundation website. http://psoriasis.org/about-psoriasis. Accessed October 7, 2014.
8. Ustekinumab European Summary of Product Characteristics.

Media Contact:
Laura Dobell
Office: +44 (0)1494 658 151
Mobile: +44 (0)7825 920 827

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

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