September 27, 2016

Lilly to Present Latest Data for Taltz® (ixekizumab) in Psoriasis at the European Academy of Dermatology and Venereology (EADV) Annual Congress

17 abstracts, including eight oral abstracts with one late-breaker presentation, will feature new sub-analyses for Taltz in moderate-to-severe plaque psoriasis

INDIANAPOLIS, Sept. 27, 2016 /CNW/ -- Eli Lilly and Company (NYSE: LLY) will highlight clinical and patient-related health outcomes data evaluating Taltz® (ixekizumab) for the treatment of adult patients with moderate-to-severe plaque psoriasis at the annual European Academy of Dermatology and Venereology Congress (EADV), which will take place Sept. 28-Oct. 2, 2016, in Vienna, Austria.

A total of 17 abstracts, including eight oral abstracts with one late-breaker presentation, will feature sub-analyses from pivotal Phase 3 data of Taltz for the treatment of moderate-to-severe plaque psoriasis across a number of areas.

"EADV represents a tremendous opportunity for dermatologists to exchange information that helps better address unmet needs for patients," said Dr. Lotus Mallbris, Lilly's global brand development leader for Taltz. "Lilly is excited to support the evolution of new treatments in dermatology as we share new data for Taltz in the treatment of moderate-to-severe plaque psoriasis."

Studies, as well as the times and locations of each session, are highlighted below. All times are listed in Central European Time (CET).

Oral Presentations

Thursday, September 29

- Abstract FC03.05: 13:55 - 14:05
  - Safety and Tolerability of Ixekizumab: Integrated Analysis of Safety in Patients with Moderate-to-Severe Psoriasis with More Than 7800 Patient-Years of Exposure to Ixekizumab from 7 Clinical Trials
  - Presenter: Alexandra Kimball, Massachusetts General Hospital, Boston, MA, United States
  - Location: Hall N
- Abstract FC03.06: 14:05 - 14:15
  - Indirect Comparison of Ixekizumab and Secukinumab Using Matched-Adjusted Indirect Comparisons
  - Presenter: Alexander Schacht, Eli Lilly & Company, Indianapolis, IN, United States
  - Location: Hall N
- Abstract FC03.08: 14:25 - 14:35
  - Efficacy and Safety of Ixekizumab in Patients with Moderate-to-Severe Plaque Psoriasis Plus Significant Palmoplantar Involvement: 60-Week Outcomes from UNCOVER-3
  - Presenter: Alan Menter, Baylor University Medical Center, Dallas, TX, United States
  - Location: Hall N
- Abstract FC03.09: 14:35 - 14:45
  - Ixekizumab Treatment Enables Rapid Improvements in Health-Related Quality of Life and Itch: Results from UNCOVER-2 and UNCOVER-3
  - Presenter: Andrew Blauvelt, Oregon Medical Research Center, Portland, OR, United States
  - Location: Hall N
- Abstract FC04.01: 15:00 - 15:10
  - Sustained Response with Ixekizumab Treatment of Scalp Psoriasis in Patients with Moderate-to-Severe Psoriasis: Results from a Phase 3 Trial (UNCOVER-3)
  - Presenter: Kristian Reich, Dermatologikum Hamburg, Hamburg, Germany
  - Location: Hall N
- Abstract FC04.03: 15:20 - 15:30
  - Efficacy and Safety of Ixekizumab Treatment Stratified by Body Weight in Patients with Psoriasis
  - Presenter: Luis Puig, Hospital de la Santa Creu I Sant Pau, Dermatology, Barcelona, Spain
  - Location: Hall N

Saturday, October 1

- Late-Breaking Abstract D3T01.1K: 16:10 - 16:20
  - Efficacy and Safety of Ixekizumab Compared to Ustekinumab in Patients with Moderate-to-Severe Plaque Psoriasis: A Randomized Head-to-Head Trial
  - Presenter: Kristian Reich, Dermtologikum Hamburg, Hamburg, Germany
  - Location: Hall A
- Abstract FC08.08: 16:10 - 16:20
  - Ixekizumab Treatment is Associated with Early Clearance of Facial Psoriasis and Subsequent Overall Plaque Clearance
  - Presenter: Lyn Guenther, University of Western Ontario, London, ON, Canada
  - Location: Hall N

e-Poster Presentations

Wednesday, September 28 - Sunday, October 2
Location/Time: Hall N, 13:25 - 14:45

- Safety and Tolerability of Ixekizumab: Integrated Analysis of Injection-Site Reactions in Patients with Moderate-to-Severe Psoriasis Treated with Ixekizumab Compared with Placebo or Etanercept from Three Phase 3 Trials
- Continued Treatment with Ixekizumab Maintained Long-Term Improvements in Itch: Results from UNCOVER-3
- Relationship of Itch and Psoriasis Area and Severity Index Improvement in Patients with Moderate-to-Severe Psoriasis Treated with Ixekizumab or Etanercept
- Impact of Ixekizumab Treatment Withdrawal on Skin Symptoms in Responder Patients: Results from UNCOVER-1 and UNCOVER-2, Two Randomized Phase 3 Trials
- Sustained Efficacy of Ixekizumab in Patients with Moderate-to-Severe Plaque Psoriasis and Concomitant Psoriatic Arthritis: A Subanalysis of UNCOVER-3
- Efficacy and Safety of Ixekizumab in Patients Previously Treated with Etanercept
- Efficacy and Safety of Ixekizumab in Patients with Plaque Psoriasis Across Different Degrees of Disease Severity (Results from UNCOVER-2 and UNCOVER-3)
- Ixekizumab Allows Patients to Maintain Relationship Improvements over 60 Weeks: Integrated Results from UNCOVER-1 and -2
- Using the Absolute Psoriasis Area and Severity Index for Comparison of the Efficacy of Ixekizumab to Etanercept and Placebo in Patients with Moderate-to-Severe Plaque Psoriasis

Indications and Usage

Taltz® is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

Taltz is contraindicated in patients with a previous serious hypersensitivity reaction, such as anaphylaxis, to ixekizumab or to any of the excipients.

WARNINGS AND PRECAUTIONS

Infections

Taltz may increase the risk of infection. The Taltz group had a higher rate of infections than the placebo group (27% vs. 23%). Serious infections have occurred. Instruct patients to seek medical advice if signs or symptoms of clinically important chronic or acute infection occur. If a serious infection develops, discontinue Taltz until the infection resolves.

Pre-Treatment Evaluation for Tuberculosis

Evaluate patients for tuberculosis (TB) infection prior to initiating treatment with Taltz. Do not administer to patients with active TB infection. Initiate treatment of latent TB prior to administering Taltz. Patients receiving Taltz should be monitored closely for signs and symptoms of active TB during and after treatment.

Hypersensitivity

Serious hypersensitivity reactions, including angioedema and urticaria (each $\leq$ 0.1%), occurred in the Taltz group in clinical trials. If a serious hypersensitivity reaction occurs, discontinue Taltz immediately and initiate appropriate therapy.

Inflammatory Bowel Disease

Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease.

Immunizations
Prior to initiating therapy with Taltz, consider completion of all age-appropriate immunizations according to current immunization guidelines. Live vaccines should not be given with Taltz.

ADVERSE REACTIONS
Most common adverse reactions (≥ 1%) associated with Taltz treatment are injection site reactions, upper respiratory tract infections, nausea, and tinea infections.

Please see accompanying Prescribing Information and Medication Guide. Please see Instructions for Use included with the device.

IX HCP ISI 22MAR2016

About Taltz® (ixekizumab)

Taltz® (ixekizumab) is an IgG4 monoclonal antibody that selectively binds with interleukin 17A (IL-17A) cytokine and inhibits its interaction with the IL-17 receptor. IL-17A is a naturally occurring cytokine that is involved in normal inflammatory and immune responses. Taltz inhibits the release of pro-inflammatory cytokines and chemokines.

About Moderate-to-Severe Plaque Psoriasis

Psoriasis is a chronic, immune disease that affects the skin.[1] It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells. Psoriasis affects approximately 125 million people worldwide, approximately 20 percent of whom have moderate-to-severe plaque psoriasis.[1,2] Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart disease.[1] The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.[1]

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and newsroom.lilly.com/social-channels.

P-LLY
This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about Taltz (ixekizumab) as a treatment for moderate-to-severe plaque psoriasis, and reflects Lilly's current belief. However, as with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that Taltz will receive additional regulatory approvals or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

[1] Psoriasis media kit. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed September 27, 2016.

[2] Psoriasis. American Academy of Dermatology website. https://www.aad.org/media-resources/stats-and-facts/conditions/psoriasis. Accessed September 27, 2016.

Refer to: Jen Dial; dial_jennifer_kay@lilly.com; 317-220-1172 (Lilly BioMedicines)

Logo - http://photos.prnewswire.com/prnh/20031219/LLYLOGO

To view the original version on PR Newswire, visit:http://www.prnewswire.com/news-releases/lilly-to-present-latest-data-for-taltz-ixekizumab-in-psoriasis-at-the-european-academy-of-dermatology-and-venereology-eadv-annual-congress-300334962.html

SOURCE Eli Lilly and Company

News Provided by Acquire Media