



Lilly to Present New Data for Olumiant® (baricitinib) and Taltz® (ixekizumab) at the European Academy of Dermatology and Venereology (EADV) Annual Congress

September 11, 2017

Lilly will showcase 18 abstracts, including data for Olumiant in atopic dermatitis and Taltz in psoriatic diseases

INDIANAPOLIS, Sept. 11, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that data across its immunology portfolio will be presented at the annual European Academy of Dermatology and Venereology Congress (EADV), including Phase 2 safety and efficacy data evaluating Olumiant® (baricitinib) for the treatment of moderate-to-severe atopic dermatitis (Lilly and Incyte Corporation are partners on the development of Olumiant). EADV will take place Sept. 13-17, 2017, in Geneva, Switzerland.

Lilly will also present data for Taltz® (ixekizumab) from 11 abstracts, including six oral presentations in psoriasis. Highlighted abstracts include one late-breaker presentation showcasing Phase 3 data evaluating Taltz for the treatment of moderate-to-severe genital psoriasis, as well as long-term results from a five-year, open-label study in moderate-to-severe plaque psoriasis. Analyses from the IXORA-S study comparing Taltz to Stelara®* (ustekinumab) and integrated safety and efficacy results from the SPIRIT-P1 and SPIRIT-P2 studies evaluating Taltz for the treatment of active psoriatic arthritis will also be presented.

Two e-posters from the Closer Together Survey, a survey where 1,457 people with moderate-to-severe psoriasis from nine countries across Europe and Canada shared how psoriasis impacts their quality of life and their overall satisfaction with treatment, will also be presented. An additional four abstracts will detail results from a selection of studies evaluating the impact of immune-mediated diseases.

"As a leading forum for dermatologists from around the world, we are pleased to share a variety of data from across our immunology portfolio at EADV," said Dr. Lotus Mallbris, vice president, immunology platform team leader, Lilly Bio-Medicines. "We look forward to presenting the new clinical and health outcomes results for Olumiant and Taltz, which reinforce our commitment to advancing research to address the unmet needs of people living with dermatologic diseases."

Highlighted presentations and posters include:

Olumiant Data

Oral Presentation

Thursday, Sept. 14

- Abstract FC04.01: 15:00–15:10 CEST, Room F
 - Baricitinib in Patients with Moderate-to-Severe Atopic Dermatitis: A Phase 2 Parallel, Double-Blinded, Randomized Placebo-Controlled Multiple Dose Study
 - Presenter: Emma Guttman-Yassky, M.D., Ph.D., Icahn School of Medicine, Mount Sinai Medical Center, New York, New York, United States

Taltz Data

Oral Presentations

Thursday, Sept. 14

- Abstract FC02.06: 10:35–10:45 CEST, Room F
 - Efficacy of Ixekizumab in Patients Previously Treated with IL-17 Inhibitors
 - Presenter: Kim Papp, M.D., Ph.D., Probit Medical Research, Waterloo, Ontario, Canada
- Abstract OP01.01: 10:50–11:00 CEST, Room Q
 - Efficacy, Health-Related Outcomes, and Safety of Ixekizumab for up to Five Years of Open-Label Treatment in a Phase 2 Study in Chronic Plaque Psoriasis
 - Presenter: Andrew Blauvelt, M.D., M.B.A., Oregon Medical Research Center, Portland, Oregon, United States
- Abstract FC04.04: 15:30–15:40 CEST, Room F
 - Further Analysis of Initial Non-Responders to Ixekizumab Regarding Patient Characteristics and Long-Term Outcomes
 - Presenter: Lajos Kemény, M.D., D.Sc., University of Szeged, Szeged, Hungary

Friday, Sept. 15

- Abstract P03.01: 10:50–11:00 CEST, Room Q
 - Comparison of Ixekizumab and Ustekinumab Efficacy in the Treatment of Nail Lesions of Patients with Moderate-

to-Severe Plaque Psoriasis: 24-Week Data from the IXORA-S Trial

- Presenter: Yves Dutronc, M.D., Eli Lilly and Company, Indianapolis, Indiana, United States
- Abstract OP04.03: 13:35–13:45 CEST, Room Q
 - Efficacy and Safety of Continuous Every Two-Week Dosing of Ixekizumab over 52 Weeks in Patients with Moderate-to-Severe Plaque Psoriasis
 - Presenter: Melinda Gooderham, M.D., SKiN Centre for Dermatology, Peterborough, Ontario, Canada

Saturday, Sept. 16

- Abstract D3T01.1F: 9:15-9:30 CEST, Room 1
 - Efficacy and Safety of Ixekizumab in a Randomized, Double-Blinded, Placebo-Controlled Phase 3b Clinical Trial in Patients with Moderate-to-Severe Genital Psoriasis
 - Presenter: Caitriona Ryan, M.D., Consultant Dermatologist, St. Vincent's Hospital, Dublin, Ireland

e-Posters

- Abstract P0389: Integrated Efficacy and Safety Results from SPIRIT-P1 and SPIRIT-P2, Two Phase 3 Trials of Ixekizumab for the Treatment of Psoriatic Arthritis
- Abstract P1311: Safety and Tolerability of Ixekizumab: Integrated Analysis of Safety in Patients with Moderate-to-Severe Psoriasis from 11 Clinical Trials with more than 12,000 Patient-Years of Exposure to Ixekizumab
- Abstract P1765: Essential Information for Estimating Total Psoriasis Area and Severity Index (PASI): A Model Developed from a Post-hoc Analysis of Phase 3 Trials with Ixekizumab and its Potential Application in Tele dermatology
- Abstract P1928: Comparison of Ixekizumab and Ustekinumab in the Treatment of Scalp Psoriasis in Patients with Moderate-to-Severe Psoriasis: 24-Week Data from the IXORA-S Trial
- Abstract P1938: A 24-Week, Randomized, Open-Label Comparison of Ixekizumab Versus Fumaric Acid Esters and Methotrexate in Patients with Moderate-to-Severe Plaque Psoriasis Naïve to Systemic Therapy

Additional Data

Oral Presentations

Thursday, Sept. 14

- Abstract FC02.03: 10:05–10:15 CEST, Room F
 - Patient Perspectives on Symptoms of Genital vs. Non-Genital Psoriasis: A Qualitative Study
 - Presenter: Kim Meeuwis, M.D., Radboud University Medical Center, Nijmegen, Netherlands
- Abstract FC02.09: 11:05–11:15 CEST, Room F
 - How Do Current Treatments for Psoriasis Differ in Terms of Reaching Low Levels of Absolute Psoriasis Area and Severity Index (PASI)? Results of a Network Meta-Analysis
 - Presenter: Ulrich Mrowietz, M.D., University Medical Center Schleswig-Holstein, Kiel, Germany

e-Posters

- Abstract P1024: Association between Duration of Psoriatic Skin Disease and Subsequent Onset of Psoriatic Arthritis
- Abstract P1799: Content Validity Assessment of the Psoriasis Symptom Scale for Use in Patients with Moderate-to-Severe Psoriasis
- Abstract P1998: The Impact of Life Factors on Patients Living with Psoriasis: An International, Quantitative Survey
- Abstract P1999: Impact of Treatment Goals on Patient Satisfaction with Treatment of Moderate-to-Severe Psoriasis: Results from an International Quantitative Survey

INDICATIONS AND USAGE FOR OLUMIANT

Therapeutic Indications

Baricitinib was approved in February 2017 for the treatment of adults with moderate-to-severe-active rheumatoid arthritis in the European Union and is marketed as Olumiant

IMPORTANT SAFETY INFORMATION FOR OLUMIANT BASED ON THE EU APPROVED SUMMARY OF PRODUCT CHARACTERISTICS

CONTRAINDICATIONS

Hypersensitivity to the active substance or to any of the excipients.
Pregnancy.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE

Infections

Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo. In treatment naïve patients, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. The risks and benefits of treatment with Olumiant should be carefully considered prior to initiating therapy in patients with active, chronic or recurrent infections. If an infection

develops, the patient should be monitored carefully and Olumiant therapy should be temporarily interrupted if the patient is not responding to standard therapy. Olumiant treatment should not be resumed until the infection resolves.

Tuberculosis

Patients should be screened for tuberculosis (TB) before starting Olumiant therapy. Olumiant should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of Olumiant in patients with previously untreated latent TB.

Haematological Abnormalities

Absolute Neutrophil Count (ANC) < 1×10^9 cells/L, Absolute Lymphocyte Count (ALC) < 0.5×10^9 cells/L and haemoglobin < 8 g/dL were reported in less than 1% of patients in clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC < 1×10^9 cells/L, ALC < 0.5×10^9 cells/L or haemoglobin < 8 g/dL observed during routine patient management.

The risk of lymphocytosis is increased in elderly patients with rheumatoid arthritis. Rare cases of lymphoproliferative disorders have been reported.

Viral Reactivation

Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies. Herpes zoster was reported more commonly in patients ≥ 65 years of age who had previously been treated with both biologic and conventional DMARDs. If a patient develops herpes zoster, Olumiant treatment should be temporarily interrupted until the episode resolves.

Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with Olumiant. Patients with evidence of active hepatitis B or C infection were excluded from clinical trials. Patients, who were positive for hepatitis C antibody but negative for hepatitis C virus RNA, were allowed to participate. Patients with hepatitis B surface antibody and hepatitis B core antibody, without hepatitis B surface antigen, were also allowed to participate; such patients should be monitored for expression of hepatitis B virus (HBV) DNA. If HBV DNA is detected, a liver specialist should be consulted to determine if treatment interruption is warranted.

Vaccination

No data are available on the response to vaccination with live or inactivated vaccines in patients receiving baricitinib. Use with live, attenuated vaccines during, or immediately prior to, Olumiant therapy is not recommended. International treatment guidelines on vaccination in rheumatoid arthritis patients should be followed when varicella zoster vaccination is considered prior to treatment with Olumiant.

Lipids

Dose dependent increases in blood lipid parameters were reported in patients treated with baricitinib compared to placebo. Elevations in LDL cholesterol decreased to pre-treatment levels in response to statin therapy. Lipid parameters should be assessed approximately 12 weeks following initiation of Olumiant therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined.

Hepatic transaminase elevations

Increases in alanine transaminase (ALT) and aspartate transaminase (AST) to ≥ 5 and $\geq 10 \times$ upper limit of normal (ULN) were reported in less than 1% of patients in clinical trials. In treatment-naïve patients, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy. If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, Olumiant should be temporarily interrupted until this diagnosis is excluded.

Malignancy

The risk of malignancies including lymphoma is increased in patients with rheumatoid arthritis. Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. The clinical data are insufficient to assess the potential incidence of malignancies following exposure to baricitinib. Long-term safety evaluations are ongoing.

Venous Thromboembolism

Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. Olumiant should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilisation. If clinical features of DVT/PE occur, Olumiant treatment should be temporarily interrupted and patients should be evaluated promptly, followed by appropriate treatment.

Laboratory Monitoring

Please refer to the SmPC for laboratory measures and monitoring guidance.

Immunosuppressive Medicinal Products

Combination with biologic DMARDs or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. Data concerning use of baricitinib with potent immunosuppressive medicinal products (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations.

ADVERSE REACTIONS

Undesirable Effects: Summary of Safety Profile

The most commonly reported adverse drug reactions (ADRs) occurring in $\geq 2\%$ of patients treated with Olumiant monotherapy or in combination with conventional synthetic DMARDs were increased LDL cholesterol (33.6%), upper respiratory tract infections (14.7%) and nausea (2.8%). Infections reported with Olumiant treatment included Herpes zoster.

Please see [Summary of Product Characteristics](#) for additional information.

INDICATIONS AND USAGE FOR TALTZ

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 FOR TALTZ

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. Anaphylaxis, including cases leading to hospitalization, has been reported in post-marketing use with TALTZ. 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.

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About Atopic Dermatitis

Atopic dermatitis (AD), a serious form of eczema, is a chronic, relapsing skin disease characterized by intense itching, dry skin and inflammation that can be present on any part of the body.¹ AD is a heterogeneous disease both clinically and biologically, but may be characterized by chronic baseline symptoms of itch, redness and skin damage that are often punctuated with episodic, sometimes unpredictable, flares or exacerbations.^{2,3} AD affects approximately 1-3 percent of adults worldwide.⁴

Moderate-to-severe AD is characterized by intense itching, resulting in visibly damaged skin, sleep loss and a significant impact on patients' quality of life. AD patients often experience anxiety, depression and reduced self-esteem.⁵ Like other chronic inflammatory diseases, AD is immune-mediated and involves a complex interplay of immune cells and inflammatory cytokines.⁶

About Rheumatoid Arthritis

Rheumatoid arthritis (RA) is an autoimmune disease characterized by inflammation and progressive destruction of joints. More than 23 million people worldwide suffer from RA.⁷ Approximately three times as many women as men have the disease.⁸ Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs (NSAIDs), oral conventional disease-modifying antirheumatic drugs (cDMARDs) – such as methotrexate, the current standard of care, and injectable and intravenous biological disease-modifying antirheumatic drugs (bDMARDs) that target selected mediators implicated in the pathogenesis of RA.⁹ Despite current treatment options, many patients do not reach their therapeutic goals or are not able to achieve sustained remission.¹⁰ There remains an important need to provide additional treatment options to improve overall patient care.

About Olumiant®

Olumiant® (baricitinib) is a once-daily oral JAK inhibitor currently in clinical studies for inflammatory and autoimmune diseases. There are four known JAK enzymes: JAK1, JAK2, JAK3 and TYK2. JAK-dependent cytokines have been implicated in the pathogenesis of a number of inflammatory and autoimmune diseases, suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions, including rheumatoid arthritis.

In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases. Baricitinib was submitted for regulatory review seeking marketing approval for the treatment of rheumatoid arthritis in the U.S., the European Union and Japan in 2016. Baricitinib was approved in the EU in February 2017 and in Japan in July 2017. In April 2017, the U.S. Food and Drug Administration issued a Complete Response Letter on the New Drug Application for baricitinib. Baricitinib remains under review in other markets. It is also being studied for the treatment of atopic dermatitis and systemic lupus erythematosus. The Phase 3 program for psoriatic arthritis is expected to begin in 2018.

About Moderate-to-Severe Plaque Psoriasis

Psoriasis is a chronic, immune disease that affects the skin.¹¹ 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.^{11,12} Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart

disease.¹¹ The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.¹¹

About Active Psoriatic Arthritis

Psoriatic arthritis (PsA) is a chronic, progressive form of inflammatory arthritis that can cause swelling, stiffness and pain in and around the joints, nail changes and impaired physical function.¹³ It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.¹⁴ Typically, psoriatic arthritis affects peripheral joints in the arms and legs (elbows, wrists, hands and feet), but can also affect joints in the axial skeleton (spine, hips and shoulders).¹⁵ If left untreated, PsA can cause permanent joint damage.¹⁴ Additionally, up to 30 percent of people with psoriasis also develop PsA.¹⁴

About Taltz®

Taltz® (ixekizumab) is a 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.

Lilly has filed a supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for Taltz for the treatment of active PsA. Lilly also submitted Taltz to the European Medicines Agency (EMA) for the treatment of adult patients with active PsA. Taltz is approved for adult patients with active PsA in Japan. Submissions to other regulatory agencies around the world are expected later this year. Taltz is also in Phase 3 trials for the treatment of radiographic and non-radiographic axial spondyloarthritis.

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 www.lilly.com/newsroom/social-channels.

About Incyte

Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's web site at www.incyte.com.

Follow @Incyte on Twitter at <https://twitter.com/Incyte>.

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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. This press release also contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about baricitinib as a potential treatment for patients with rheumatoid arthritis, and reflects Lilly's and Incyte's current belief. 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 future study results will be consistent with the results to date, that Taltz or baricitinib will receive additional regulatory approvals, or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte'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 and Incyte undertake no duty to update forward-looking statements to reflect events after the date of this release.

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² Thijs JL, Strickland I, Bruijnzeel-Koomen C, et. al. Moving toward endotypes in atopic dermatitis: identification of patient clusters based on serum biomarker analysis. *The Journal of Allergy and Clinical Immunology*. 2017.

³ Langan SM, Thomas KS, Williams HC. What is meant by "flare" in atopic dermatitis? A systematic review and proposal. *Arch Dermatol*. 2006;142:1190-1196.

⁴ Nutten S. Atopic dermatitis: global epidemiology and risk factors. *Annals of Nutrition and Metabolism*. 2015;66(suppl 1): 8-16.

⁵ Yosipovitch G, Papoiu AD. What causes itch in atopic dermatitis? *Current Allergy and Asthma Reports*. 2008;8:306-311.

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⁷ WHO Global Burden of Disease Report, (table 7, page 32) 2004, http://www.who.int/healthinfo/global_burden_disease/GBD_report_2004update_full.pdf. Accessed August 30, 2017.

⁸ Arthritis Foundation, What is Rheumatoid Arthritis?, <http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/what-is-rheumatoid-arthritis.php>. Accessed September 8, 2017.

⁹ Arthritis Foundation, Rheumatoid Arthritis Treatment, <http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/treatment.php>. Accessed September 8, 2017.

¹⁰ McWilliams DF, Kiely PDW, Young A, Walsh DA. Baseline factors predicting change from the initial DMARD treatment during the first 2 years of rheumatoid arthritis: experience in the ERAN inception cohort. *BMC Musculoskeletal Disorders*. 2013;14:1-7.

¹¹ Psoriasis media kit. National Psoriasis Foundation website. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed September 8, 2017.

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¹³ About psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/about-psoriatic-arthritis>. Accessed September 8, 2017.

¹⁴ What is psoriatic arthritis? Arthritis Foundation website. <http://www.arthritis.org/about-arthritis/types/psoriatic-arthritis/what-is-psoriatic-arthritis.php>. Accessed September 8, 2017.

¹⁵ Classification of psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/psoriatic-arthritis/classification-of-psoriatic-arthritis>. Accessed September 8, 2017.

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