

Lilly to Present New Data on Olumiant® (baricitinib) in Rheumatoid Arthritis and Taltz® (ixekizumab) in Psoriatic Arthritis at the Annual European Congress of Rheumatology (EULAR 2017)

June 13, 2017

INDIANAPOLIS, June 13, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) and Incyte Corporation (NASDAQ: INCY) announced today that new data on safety and long-term efficacy from the Olumiant® (baricitinib) clinical trials will be presented in 21 abstracts, including one oral presentation, at the Annual European Congress of Rheumatology (EULAR 2017) in Madrid, June 14-17, 2017.

Lilly will also present six abstracts evaluating Taltz® (ixekizumab) for the treatment of psoriatic arthritis (PsA), including two oral presentations highlighting data from two Phase 3 studies (SPIRIT-P1 and SPIRIT-P2).

Additionally, Lilly will present two abstracts from its ongoing research to advance the understanding of rheumatologic diseases. One abstract is focused on the relationship between the degree of skin involvement and joint activity in patients with PsA based on information from the Corona® registry, and the other abstract is on the symptomology, disease status and remission rate of non-radiographic axial spondyloarthritis and ankylosing spondylitis patients in Europe.

"Rheumatoid arthritis, psoriatic arthritis and psoriasis are chronic, debilitating diseases that significantly impact the physical wellbeing of millions of people worldwide, many of whom are not currently achieving their treatment goals with existing therapies," said J. Anthony Ware, M.D., senior vice president, product development, Lilly Bio-Medicines. "We are excited to present new data for Olumiant and Taltz at EULAR 2017, all of which highlight our commitment to the ongoing research and development of innovative therapies for people living with these immune-mediated diseases."

Studies, as well as dates and times of the data sessions, are highlighted below.

Olumiant Data

Thursday, June 15, 11:45 - 13:30 CEST - POSTER PRESENTATIONS

- Differences in Patient-Reported Outcomes (PROs) Between Baricitinib (BARI) and Comparators among Patients with Rheumatoid Arthritis (RA) Who Achieved Low Disease Activity (LDA) or Remission (Presenting author: Bruno Fautrel) Abstract: THU0081
- Concomitant Use of Conventional Synthetic DMARDs and Response to Baricitinib (Presenting author: Arthur Kavanaugh) Abstract: THU0078
- Structural Damage Progression in Patients Treated with Methotrexate, Baricitinib Monotherapy or Baricitinib + Methotrexate Based on Their Level of Clinical Response: RA-BEGIN Study Sub-analysis (Presenting author: Désirée van der Heijde) Abstract: THU0088
- Effects of Smoking on Baricitinib Efficacy in Patients with Rheumatoid Arthritis: Pooled Analysis from Two Phase 3 Clinical Trials (Presenting author: Jeffrey R. Curtis) Abstract: THU0114

Friday, June 16, 10:15 - 10:45 CEST - ORAL PRESENTATION

- Serious Infection and Associated Risk Factors in Patients with Moderate-to-Severe Rheumatoid Arthritis Treated with Baricitinib (Presenting author: Kevin Winthrop) Abstract: OP0248 / Presentation Location: South Auditorium

Friday, June 16, 11:45 - 13:30 CEST - POSTER PRESENTATIONS

- Pain Reduction is Associated with Improved Work Productivity in Patients with Rheumatoid Arthritis (Presenting author: Kaleb Michaud) Abstract: FRI0099
- A High Level of Clinical Response Based on Composite Indices is Associated with Improved Health-Related Quality of Life: Analyses from a Phase 3 Clinical Trial in Patients with Rheumatoid Arthritis (Presenting author: Maxime Dougados) Abstract: FRI0116
- Effect of Starting Dose of Baricitinib in Achieving Sustained Low Disease Activity (Presenting author: Jeffrey R. Curtis) Abstract: FRI0089
- Low Rates of Radiographic Progression of Structural Joint Damage over 2 Years of Baricitinib Treatment in Patients with Rheumatoid Arthritis (RA) (Presenting author: Désirée van der Heijde) Abstract: FRI0087
- Effects of Baricitinib on Haemoglobin and Related Laboratory Parameters in Rheumatoid Arthritis Patients (Presenting author: Jonathan Kay) Abstract: FRI0092
- Temporary Interruptions of Study Drug During the Baricitinib Phase 3 Rheumatoid Arthritis Program (Presenting author: Paul Emery) Abstract: FRI0124
- Efficacy and Safety Data Based on Historical or Pre-existing Conditions at Baseline for Patients with Active Rheumatoid Arthritis Who Were Treated with Baricitinib (Presenting author: Bernard Combe) Abstract: FRI0086

- Analysis of Neutrophils, Lymphocytes, and Platelets in Pooled Phase 2 and Phase 3 Studies of Baricitinib for Rheumatoid Arthritis (Presenting author: Joel M. Kremer) Abstract: FRI0090
- Durability and Maintenance of Efficacy Following Prolonged Treatment with Baricitinib (Presenting author: Josef S. Smolen) Abstract: FRI0096

Saturday, June 17, 10:15 - 12:00 CEST - POSTER PRESENTATIONS

- Dose Reduction of Baricitinib in Patients with Rheumatoid Arthritis (RA) Achieving Sustained Disease Control: Results of a Prospective Study (Presenting author: Tsutomu Takeuchi) Abstract: SAT0072
- Effects of Baricitinib on Patients who Stop Methotrexate Monotherapy and Switch to Baricitinib Monotherapy (Presenting author: Roy Fleischmann) Abstract: SAT0058
- Baricitinib Versus Adalimumab* in Patients with Active Rheumatoid Arthritis (RA): Analysis of Patients Achieving a Moderate EULAR Response at Week 4 (Presenting author: Tore K. Kvien) Abstract: SAT0070
- A RAPID3-like Index Documents Superior Efficacy of Baricitinib to Adalimumab and Placebo, Similar to DAS28 and CDAI in the RA-BEAM Clinical Trial in Patients with Rheumatoid Arthritis (Presenting author: Ted Pincus) Abstract: SAT0069
- Baricitinib Showed Rapid and Greater Reduction in Pain Compared to Adalimumab or Placebo in Patients with Rheumatoid Arthritis (Presenting author: Peter Taylor) Abstract: SAT0055

PUBLISHED ONLY - NO PRESENTATION

- Effect of Baseline Disease Activity on Achieving Sustained Low Disease Activity in Baricitinib Phase 3 Studies (Lead author: Jeffrey R. Curtis) Abstract: AB0235
- Characterization of Changes in Lymphocyte Subsets in Baricitinib-Treated Patients with Early, DMARD Naïve, Rheumatoid Arthritis in a Phase 3 Study (Lead author: Tsutomu Takeuchi) Abstract: AB0281

Taltz Data

Thursday, June 15, 16:35 CEST - ORAL PRESENTATION

- A Phase 3 Study of the Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis and Inadequate Response to Tumor Necrosis Factor Inhibitor(s) (Presenting author: Peter Nash) Abstract: OP0201

Friday, June 16, 11:10 CEST - ORAL PRESENTATION

- Radiographic Progression of Structural Joint Damage in Patients with Active Psoriatic Arthritis Treated with Ixekizumab Over 52 weeks (Presenting author: Désirée van der Heijde) Abstract: OP0221

Friday, June 16, 11:45 - 13:30 CEST - POSTER PRESENTATION

- Ixekizumab Reduces Disease Activity in Active Psoriatic Arthritis Patients Who Had Previous Inadequate Response to Tumor Necrosis Factor-Inhibitors (Presenting author: Laura Coates) Abstract: FRI0502

Saturday, June 17, 10:15 - 12:00 CEST - POSTER PRESENTATION

- Ixekizumab Improves Patient-Reported Outcomes in Patients with Active Psoriatic Arthritis and Previous Inadequate Response to Tumor Necrosis Factor-Inhibitors (Presenting author: Arthur Kavanaugh) Abstract: SAT0446

Saturday, June 17, 11:00 CEST - GUIDED POSTER TOUR

- Ixekizumab Improves Nail and Skin Lesions in Patients with Active Psoriatic Arthritis and Prior TNF Inadequate Response (Presenting author: Lars Kristensen) Abstract: SAT0437

PUBLISHED ONLY - NO PRESENTATION

- Efficacy of Ixekizumab Improving SF-36 Scores in Biologic DMARD-Naïve Patients with Active Psoriatic Arthritis: Results from a Phase 3 Study (SPIRIT-P1) (Lead author: Vibeke Strand) Abstract: AB0793

Additional Data

Friday, June 16, 11:45 - 13:30 CEST - POSTER PRESENTATIONS

- Differences between RA Patients with and without ILD from a United States Tertiary Referral Center (Presenting author:

Saturday, June 17, 10:15 - 12:00 CEST - POSTER PRESENTATION

- Symptomology, Disease Status, and Remission Rates of Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis Patients in Europe (Presenting author: Theresa Hunter) Abstract: SAT0425

Saturday, June 17, 10:50 CEST - GUIDED POSTER TOUR

- Longitudinal Analysis of Response, Costs and Resource Use of Patients with Rheumatoid Arthritis Initiating Biologic Disease-Modifying Antirheumatic Drugs (bDMARDs) in Taiwan Using the National Health Insurance Research Database (Presenting author: Qiang Shi) Abstract: SAT0720-HPR

PUBLISHED ONLY - NO PRESENTATION

- The Relationship Between the Degree of Skin Involvement and Joint Activity in Patients with PSA: Experience from the Corrona[®] Registry (Lead author: Philip Mease) Abstract: AB0783

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

INDICATIONS AND USAGE FOR OLUMIANT

Therapeutic indications

Olumiant is indicated for the treatment of moderate to severe active rheumatoid arthritis in adult patients who have responded inadequately to, or who are intolerant to one or more disease-modifying anti-rheumatic drugs. Olumiant may be used as monotherapy or in combination with methotrexate.

IMPORTANT SAFETY INFORMATION FOR OLUMIANT

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) $< 1 \times 10^9$ cells/L, Absolute Lymphocyte Count (ALC) $< 0.5 \times 10^9$ 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 $< 1 \times 10^9$ cells/L, ALC $< 0.5 \times 10^9$ 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 ≥ 10 x 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.

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](#).

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 anaphylaxis, angioedema and urticaria, have been reported 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 ($\geq 1\%$) 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.

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.ⁱ Approximately three times as many women as men have the disease.ⁱⁱ 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.ⁱⁱⁱ Despite current treatment options, many patients do not reach their therapeutic goals or are not able to achieve sustained remission.^{iv} 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., European Union and Japan in 2016, and was approved in the EU in February 2017.

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.^v It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.^{vi} 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).^{vii} If left untreated, PsA can cause permanent joint damage.^v Additionally, up to 30 percent of people with psoriasis also develop PsA.^v

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. 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 newsroom.lilly.com/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.

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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 baricitinib as a potential treatment for patients with rheumatoid arthritis, and reflects Lilly's and Incyte'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 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 future study results will be consistent with the results to date, that baricitinib or Taltz will receive 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.

ⁱ 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: May, 16, 2017)

ⁱⁱ Arthritis Foundation, What is Rheumatoid Arthritis?, <http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/what-is-rheumatoid-arthritis.php> (Accessed: May, 16, 2017)

ⁱⁱⁱ Arthritis Foundation, Rheumatoid Arthritis Treatment, <http://www.arthritis.org/about-arthritis/types/rheumatoid-arthritis/treatment.php> (Accessed: May, 16, 2017)

^{iv} 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.

^v About psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/about-psoriatic-arthritis>. (Accessed: May 12, 2017)

^{vi} What is psoriatic arthritis? Arthritis Foundation website. <http://www.arthritis.org/about-arthritis/types/psoriatic-arthritis/what-is-psoriatic-arthritis.php>. (Accessed: May 12, 2017)

^{vii} Classification of psoriatic arthritis. National Psoriasis Foundation website. <https://www.psoriasis.org/psoriatic-arthritis/classification-of-psoriatic-arthritis>. (Accessed: May 12, 2017)

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