



Lilly to Unveil New Data at the Annual European Congress of Rheumatology, Furthering Commitment to Scientific Discovery in Immunology

June 11, 2018

Highlights include new Phase 2 data for baricitinib in systemic lupus erythematosus

INDIANAPOLIS, June 11, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today it will present new data from its immunology portfolio, including cornerstone treatments OLUMIANT® (baricitinib) and Taltz® (ixekizumab), at the Annual European Congress of Rheumatology (EULAR 2018) in Amsterdam from June 13-16, 2018. Highlights for baricitinib include results from a global Phase 2 study evaluating the safety and efficacy of two doses of baricitinib for the treatment of systemic lupus erythematosus (SLE), which will be featured in a podium presentation on Wednesday, June 13 from 4:15-5:45 PM CET and highlighted as part of a EULAR press conference on Thursday, June 14, 2018 from 9-10 AM CET. Highlights for Taltz at EULAR include three-year safety and efficacy data from SPIRIT-P1, a Phase 3 study evaluating Taltz for the treatment of psoriatic arthritis in patients naïve to biologic treatment.

"The data being presented at EULAR demonstrate Lilly's commitment to developing treatment advancements to help patients with severe auto-immune diseases," said Lotus Mallbris, M.D., global head of immunology product development, Lilly Bio-Medicines. "We are excited to be sharing data evaluating baricitinib as a potential treatment for systemic lupus erythematosus, underscoring the potential of our immunology portfolio."

OLUMIANT is featured in 10 additional abstracts discussing efficacy and safety results in the treatment of rheumatoid arthritis (Lilly and Incyte Corporation (NASDAQ: INCY) are partners in the development of baricitinib). Eight abstracts evaluating the efficacy and safety of Taltz for the treatment of active psoriatic arthritis will also be presented. Ten additional abstracts will detail results from a selection of studies evaluating the impact of immune-mediated diseases on patients, including rheumatoid arthritis, psoriatic arthritis and SLE.

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

Baricitinib Data

Wednesday, June 13, 16:15 – 17:45 CET – PODIUM PRESENTATION

- Baricitinib in Systemic Lupus Erythematosus (SLE): Results from a Phase 2, Randomized, Double-Blind, Placebo-Controlled Study (Presenting author: Daniel Wallace) Abstract: OP0019

Thursday, June 14, 11:45 – 13:30 CET – POSTER PRESENTATIONS

- Converting Patient-Reported Outcome Measures of Fatigue and Pain to PROMIS Scores: Data from Phase 3 Baricitinib Rheumatoid Arthritis Trials (Presenting author: Bing Bingham) Abstract: THU0106
- Autoantibody Profiling for Response to Baricitinib in Patients with Rheumatoid Arthritis and No or Limited Exposure to Methotrexate (Presenting author: Lorena Gamboa) Abstract: THU0109

Friday, June 15, 11:45 – 13:30 CET – POSTER PRESENTATIONS

- Hepatic Safety in Patients with Rheumatic Arthritis Who Received Isoniazid for Latent Tuberculosis: Post-Hoc Analysis from Phase 3 Baricitinib Studies (Presenting author: Tsu-Yi Hsieh) Abstract: FRI0098
- Converting Patient-Reported Physical Function Outcomes Scores to PROMIS Metric Scores in Phase 3 Trials of Baricitinib in Rheumatoid Arthritis (Presenting author: Bing Bingham) Abstract: FRI0013
- Hepatitis B Virus Reactivation in Patients with Rheumatoid Arthritis Treated with Baricitinib: Post-Hoc Analysis from Clinical Trials (Presenting author: Masayoshi Harigai) Abstract: FRI0077

Saturday, June 16, 10:30 – 12 CET – POSTER PRESENTATIONS

- Efficacy and Safety of Baricitinib in MTX-IR Patients with Rheumatoid Arthritis: 52-Week Results from a Phase 3 Study (Presenting author: Zhichang Li) Abstract: SAT0218
- Efficacy of Baricitinib in Patients with Rheumatoid Arthritis Who Failed 2 or More DMARDs (Presenting author: Mark Genovese) Abstract: SAT0237
- Comparative Effectiveness in Pain and HAQ-DI Improvement for Baricitinib Versus Adalimumab, Tocilizumab and Tofacitinib Monotherapies in csDMARD-Naïve Rheumatoid Arthritis Patients: A Matching-Adjusted Indirect Comparison (Presenting author: Bruno Fautrel) Abstract: SAT0225

- Dose Reduction of Baricitinib in Patients with Rheumatoid Arthritis Achieving Sustained Disease Control: Results of a Prospective Study (Presenting author: Tsutomu Takeuchi) Abstract: SAT0253

PUBLISHED ONLY – NO PRESENTATION

- Impact of Controlling Disease Activity on Regaining Normal Physical Function, and Achieving No or Limited Pain in Patients with Rheumatoid Arthritis Treated with Baricitinib (Lead author: Kurt de Vlam) Abstract: AB0258

Taltz Data

Thursday, June 14, 11:45– 13:30 CET – POSTER PRESENTATIONS

- Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis: Three Year Results from a Phase 3 Study (SPIRIT-P1) (Presenting author: Vinod Chandran) Abstract: THU0333
- Ixekizumab Makes Very Low Disease Activity and Remission with Psoriatic Arthritis Disease Activity Score Possible in Active Psoriatic Arthritis Patients for Up to One Year: SPIRIT-P1 and SPIRIT-P2 Trials (Presenting author: Laura Coates) Abstract: THU3014
- Ixekizumab Improves Nail and Skin Lesions Through 52 Weeks in Patients with Active Psoriatic Arthritis and Inadequate Response to Tumor Necrosis Factor Inhibitors (Presenting author: Adeline Ruyssen-Witrand) Abstract: THU0313

Saturday, June 16 10:30 – 12 CET – POSTER PRESENTATIONS

- Safety of Ixekizumab in Patients with Psoriatic Arthritis: Results from a Pooled Analysis of Three Clinical Trials (Presenting author: Philippe Goupille) Abstract: SAT0348
- Ixekizumab Treatment Resolves Enthesitis and Dactylitis in Patients with Active Psoriatic Arthritis: Results from the SPIRIT Trials (Presenting author: Dafna Gladman) Abstract: SAT0321
- Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis and Previous Inadequate Response to TNF inhibitors: 52-week Results from a Phase 3 Study (Presenting author: Mark Genovese) Abstract: SAT0341

PUBLISHED ONLY – NO PRESENTATION

- Ixekizumab Improves Fatigue in Patients with Psoriatic Arthritis (Lead author: Ana-Maria Orbai) Abstract: AB0906
- Efficacy and Safety of Ixekizumab When Used Alone or in Combination with Conventional Disease-Modifying Anti-Rheumatic Drugs (DMARDs) in TNF-Experienced Patients with Psoriatic Arthritis (Lead author: Peter Nash) Abstract: AB0944

Additional Data

Thursday, June 14, 11:45 – 13:30 CET – POSTER PRESENTATIONS

- Real World (RW) Experience with an Anti-IL-17A Inhibitor in Biologic Naïve and Biologic Experienced Psoriatic Arthritis (PsA) Patients (Presenting author: Rachel Moon) Abstract: THU0327
- Effects of Biologic DMARDs on Physical Function in Patients with Active Psoriatic Arthritis: Results of Network Meta-Analyses (Presenting author: Adeline Ruyssen-Witrand) Abstract: THU0290
- Factors Associated with High-Dose Corticosteroid Use in SLE Patients Post Initiation of SLE Therapy (Presenting author: Robert Hoffman) Abstract: THU0374

Friday, June 15, 11:45 – 13:30 CET – POSTER PRESENTATIONS

- The Role of Pain in Rheumatoid Arthritis (RA) Patients' Assessments of Their Health (Presenting author: Patricia Katz) Abstract: FRI0080
- The Impact of Disease Activity and Pain Level on Productivity in Rheumatoid Arthritis (RA) Patients (Presenting author: James Galloway) Abstract: FRI0526

Saturday, June 16, 10:30 – 12 CET – POSTER PRESENTATIONS

- Risk of Venous Thromboembolism in Rheumatoid Arthritis Patients Treated with Biologic and Non-Biologic DMARDs (Presenting author: Judith Maro) Abstract: SAT0140
- Rapid and Sustained Improvements in Both Skin and Musculoskeletal Symptoms Correlates with Improved Quality of Life in Patients with Active Psoriatic Arthritis (Presenting author: Arthur Kavanaugh) Abstract: SAT0316

PUBLISHED ONLY – NO PRESENTATION

- Burden of Skin and Joint Symptoms of Psoriatic Disease: Results of a Multi-National Patient Survey (Lead author: Joseph Merola) Abstract: AB0929
- Reduction in Fatigue and Pain Are Associated with Improved Work Productivity in Patients with RA (Lead author: Janet

Pope) Abstract: AB0240

- Towards Reforming the Taxonomy of Human Disease: The Preciseads Cross Sectional Study (Lead author: Laurence Laigle) Abstract: AB1372

Indication and Usage for OLUMIANT (baricitinib) tablets (in the United States) for RA patients

OLUMIANT® (baricitinib) 2 mg is indicated for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to one or more tumor necrosis factor (TNF) antagonist therapies. Limitation of Use: Use of OLUMIANT in combination with other JAK inhibitors, biologic disease-modifying antirheumatic drugs (DMARDs), or with potent immunosuppressants such as azathioprine and cyclosporine is not recommended.

IMPORTANT SAFETY INFORMATION FOR OLUMIANT (baricitinib) tablets

WARNING: SERIOUS INFECTIONS, MALIGNANCY, AND THROMBOSIS

SERIOUS INFECTIONS: Patients treated with OLUMIANT are at risk for developing serious infections that may lead to hospitalization or death. Most patients who developed these infections were taking concomitant immunosuppressants such as methotrexate or corticosteroids. If a serious infection develops, interrupt OLUMIANT until the infection is controlled. Reported infections include:

- **Active tuberculosis (TB), which may present with pulmonary or extrapulmonary disease. Test patients for latent TB before initiating OLUMIANT and during therapy. Treatment for latent infection should be considered prior to OLUMIANT use.**
- **Invasive fungal infections, including candidiasis and pneumocystosis. Patients with invasive fungal infections may present with disseminated, rather than localized, disease.**
- **Bacterial, viral, and other infections due to opportunistic pathogens.**

Carefully consider the risks and benefits of OLUMIANT prior to initiating therapy in patients with chronic or recurrent infection.

Closely monitor patients for the development of signs and symptoms of infection during and after treatment with OLUMIANT, including the possible development of TB in patients who tested negative for latent TB infection prior to initiating therapy.

MALIGNANCIES: Lymphoma and other malignancies have been observed in patients treated with OLUMIANT.

THROMBOSIS: Thrombosis, including deep venous thrombosis (DVT) and pulmonary embolism (PE), has been observed at an increased incidence in patients treated with OLUMIANT compared to placebo. In addition, there were cases of arterial thrombosis. Many of these adverse events were serious and some resulted in death. Patients with symptoms of thrombosis should be promptly evaluated.

WARNINGS AND PRECAUTIONS

SERIOUS INFECTIONS: The most common serious infections reported with OLUMIANT included pneumonia, herpes zoster, and urinary tract infection. Among opportunistic infections, tuberculosis, multidermatomal herpes zoster, esophageal candidiasis, pneumocystosis, acute histoplasmosis, cryptococcosis, cytomegalovirus, and BK virus were reported with OLUMIANT. Some patients have presented with disseminated rather than local disease, and were often taking concomitant immunosuppressants such as methotrexate or corticosteroids. Avoid OLUMIANT in patients with an active, serious infection, including localized infections. Consider the risks and benefits of treatment prior to initiating OLUMIANT in patients:

- with chronic or recurrent infection
- who have been exposed to TB
- with a history of a serious or an opportunistic infection
- who have resided or traveled in areas of endemic tuberculosis or endemic mycoses; or
- with underlying conditions that may predispose them to infection.

Monitor patients for infections during and after OLUMIANT treatment. Interrupt OLUMIANT if a patient develops a serious infection, an opportunistic infection, or sepsis. Do not resume OLUMIANT until the infection is controlled.

Tuberculosis – Before initiating OLUMIANT, evaluate and test patients for latent or active infection and treat patients with latent TB with standard antimicrobial therapy. OLUMIANT should not be given to patients with active TB. Consider anti-TB therapy prior to initiating OLUMIANT in patients with a history of latent or active TB in whom an adequate course of treatment cannot be confirmed, and for patients with a negative test for latent TB but who have risk factors for TB infection. Monitor patients for TB during OLUMIANT treatment.

Viral Reactivation – Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster), were reported in clinical studies with OLUMIANT. If a patient develops herpes zoster, interrupt OLUMIANT treatment until the episode resolves.

The impact of OLUMIANT on chronic viral hepatitis reactivation is unknown. Screen for viral hepatitis in accordance with clinical guidelines before initiating OLUMIANT.

MALIGNANCY AND LYMPHOPROLIFERATIVE DISORDERS: Malignancies were observed in OLUMIANT clinical studies. Consider the risks and benefits of OLUMIANT prior to initiating therapy in patients with a known malignancy other than a successfully treated non-melanoma skin cancer (NMSC) or when considering continuing OLUMIANT in patients who develop a malignancy. NMSCs were reported in patients treated with OLUMIANT. Periodic skin examination is recommended for patients who are at increased risk for skin cancer.

THROMBOSIS: Thrombosis, including DVT and PE, has been observed at an increased incidence in OLUMIANT-treated patients compared to placebo. In addition, arterial thrombosis events in the extremities have been reported in clinical studies with OLUMIANT. Many of these adverse events

were serious and some resulted in death. There was no clear relationship between platelet count elevations and thrombotic events. Use OLUMIANT with caution in patients who may be at increased risk of thrombosis. If clinical features of DVT/PE or arterial thrombosis occur, evaluate patients promptly and treat appropriately.

GASTROINTESTINAL PERFORATIONS: Gastrointestinal perforations have been reported in OLUMIANT clinical studies, although the role of JAK inhibition in these events is not known. Use OLUMIANT with caution in patients who may be at increased risk for gastrointestinal perforation (e.g., patients with a history of diverticulitis). Promptly evaluate patients who present with new onset abdominal symptoms for early identification of gastrointestinal perforation.

LABORATORY ABNORMALITIES:

Neutropenia – OLUMIANT treatment was associated with an increased incidence of neutropenia (absolute neutrophil count [ANC] <1000 cells/mm³) compared to placebo. Avoid initiation or interrupt OLUMIANT treatment in patients with an ANC <1000 cells/mm³. Evaluate at baseline and thereafter according to routine patient management.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm³ were reported in OLUMIANT clinical trials. Lymphocyte counts less than the lower limit of normal were associated with infection in patients treated with OLUMIANT, but not placebo. Avoid initiation or interrupt OLUMIANT treatment in patients with an ALC <500 cells/mm³. Evaluate at baseline and thereafter according to routine patient management.

Anemia – Decreases in hemoglobin levels to <8 g/dL were reported in OLUMIANT clinical trials. Avoid initiation or interrupt OLUMIANT treatment in patients with hemoglobin <8 g/dL. Evaluate at baseline and thereafter according to routine patient management.

Liver Enzyme Elevations – OLUMIANT treatment was associated with increased incidence of liver enzyme elevation compared to placebo. Increases to ≥5x and ≥10x upper limit of normal were observed for both ALT and AST in patients in OLUMIANT clinical trials.

Evaluate at baseline and thereafter according to routine patient management. Promptly investigate the cause of liver enzyme elevation to identify potential cases of drug-induced liver injury. If increases in ALT or AST are observed and drug-induced liver injury is suspected, interrupt OLUMIANT until this diagnosis is excluded.

Lipid Elevations – Treatment with OLUMIANT was associated with increases in lipid parameters, including total cholesterol, low-density lipoprotein cholesterol, and high-density lipoprotein cholesterol. Assess lipid parameters approximately 12 weeks following OLUMIANT initiation. Manage patients according to clinical guidelines for the management of hyperlipidemia.

VACCINATIONS: Avoid use of live vaccines with OLUMIANT. Update immunizations in agreement with current immunization guidelines prior to initiating OLUMIANT therapy.

ADVERSE REACTIONS

Adverse reactions (≥1%) include: upper respiratory tract infections (16.3%, 14.7%, 11.7%), nausea (2.7%, 2.8%, 1.6%), herpes simplex (0.8%, 1.8%, 0.7%), and herpes zoster (1.0%, 1.4%, 0.4%) for OLUMIANT 2 mg, baricitinib 4 mg, and placebo, respectively.

USE IN SPECIFIC POPULATIONS

PREGNANCY AND LACTATION: No information is available to support the use of OLUMIANT in pregnancy or lactation. Advise women not to breastfeed during treatment with OLUMIANT.

HEPATIC AND RENAL IMPAIRMENT: OLUMIANT is not recommended in patients with severe hepatic impairment or in patients with moderate or severe renal impairment.

Please click to access full [Prescribing Information](#), including Boxed Warning about Serious infections, Malignancies, and Thrombosis, and [Medication Guide](#).

BA HCP ISI 01JUN2018

INDICATIONS AND USAGE FOR TALTZ

Taltz is approved for the treatment of adults with active psoriatic arthritis. Taltz is also approved to treat 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. In clinical trials of patients with plaque psoriasis, the Taltz group had a higher rate of infections than the placebo group (27% vs 23%). A similar increase in risk of infection was seen in placebo-controlled trials of patients with psoriatic arthritis. 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. Closely monitor patients receiving Taltz 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 in patients with plaque psoriasis. 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. Avoid use of live vaccines in patients treated 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. Overall, the safety profile observed in patients with psoriatic arthritis was consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis.

Please see accompanying [Prescribing Information](#) and [Medication Guide](#). Please see [Instructions for Use](#) included with the device.

IX HCP ISI 01DEC2017

About Systemic Lupus Erythematosus

Systemic lupus erythematosus (SLE) is a chronic, multi-organ autoimmune disease that can cause widespread tissue and organ damage.¹ SLE is characterized by periods of flare and remission and is associated with a variety of symptoms, including extreme fatigue, unexplained fever, joint pain/swelling and butterfly rash.^{1,2} Approximately 90 percent of all cases occur in women at a time when life and family demands are greatest.³

About 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 and impaired physical function.⁴ It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.⁶ Psoriatic arthritis can affect peripheral joints in the arms and legs (elbows, wrists, hands and feet).⁶ If left untreated, PsA can cause permanent joint damage.⁶ Up to 30 percent of people with psoriasis also develop PsA.⁶

About Rheumatoid Arthritis

Rheumatoid arthritis is a systemic autoimmune disease characterized by inflammation and progressive destruction of joints.^{5,6} Approximately three times as many women as men have the disease.⁷ Current treatment of RA includes the use of non-steroidal anti-inflammatory drugs, oral conventional synthetic disease-modifying antirheumatic drugs (csDMARDs) — such as methotrexate, the current standard of care, and injectable, biological disease-modifying antirheumatic drugs (bDMARDs) that target selected mediators implicated in the pathogenesis of RA.⁸ Despite current treatment options, many patients do not reach their therapeutic goals.^{8,9} There remains an important need to provide additional treatment options to improve overall patient care.

About OLUMIANT

OLUMIANT is a once-daily, oral JAK inhibitor for the treatment of adults with moderately-to-severely active rheumatoid arthritis who have had an inadequate response to one or more TNF inhibitor therapies.¹⁰ 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.¹¹ OLUMIANT has greater inhibitory potency at JAK1, JAK2 and TYK2 relative to JAK3; however, the relevance of inhibition of specific JAK enzymes to therapeutic effectiveness is not currently known.¹¹ OLUMIANT is approved in more than 40 countries.

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.¹² 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.¹³

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 OLUMIANT (baricitinib) as a treatment for patients with rheumatoid arthritis and a potential treatment for systemic lupus erythematosus and Taltz (ixekizumab) as a treatment for active psoriatic arthritis. These statements reflect Lilly's current belief. As with any pharmaceutical products, however, 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 ixekizumab will receive additional regulatory approvals or will 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.

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