# Lilly to Present New Data and Commitment to Patient-Centered Solutions at the Annual European Congress of Rheumatology

June 6, 2019

**- Thirty abstracts will reflect investigations into the treatment of a broad range of rheumatic diseases -**

INDIANAPOLIS, June 6, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will present data for Taltz® (ixekizumab) and Olumiant® (baricitinib) at the Annual European Congress of Rheumatology (EULAR 2019) in Madrid from June 12-15, 2019.

The data include clinical studies of Taltz in the treatment of patients with psoriatic arthritis, and as a potential treatment for ankylosing spondylitis and non-radiographic axial spondyloarthritis, for which it is currently under investigation.

Of note, Lilly will share in a late-breaking oral presentation the detailed results from the SPIRIT-H2H study, which directly investigated and compared the efficacy and safety of Taltz and Humira® (adalimumab) in biologic disease-modifying antirheumatic drug (bDMARD)-naïve patients with active psoriatic arthritis. These results can help healthcare providers form evidence-based treatment decisions with regard to current biologic standard of care for the treatment of psoriatic arthritis.

Lilly will also share an updated integrated safety analysis of Olumiant in rheumatoid arthritis (RA) patients treated up to seven years, as well as updated analyses from an investigational Phase 2 trial in the treatment of systemic lupus erythematosus. Additionally, Lilly will present results from RA Matters, an international survey of RA patients that evaluates what patients value in terms of their treatment goals. The RA Matters survey will underscore how important it is for patients to have a range of treatment options to fit their unique experiences.

"As we continue to build our product portfolio and explore how Taltz and Olumiant can offer value for patients living with a range of rheumatic diseases, we aspire to collaborate with the medical community on future innovation for patients," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "We are pleased with the variety of data we are presenting at EULAR and the potential contributions these medicines may make in the treatment of rheumatologic diseases."

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

**Taltz Data**

Thursday, June 13, 10:15 – 11:15 CEST – ORAL PRESENTATION

- Ixekizumab Improves Signs and Symptoms of Psoriatic Arthritis in Patients Who Have Had Inadequate Response to 1 or 2 Tumor Necrosis Factor Inhibitors (Presenting author: L Bruce Kirkham) Abstract: OP0110

Friday, June 14, 10:15 – 11:15 CEST – ORAL PRESENTATION

- Work Productivity and Activity Impairment Among Patients with Active Ankylosing Spondylitis/Radiographic Axial Spondyloarthritis and Treated with Ixekizumab for 16 Weeks: Results from COAST-V and COAST-W (Presenting author: Annelies Boonen) Abstract: OP0238

Friday, June 14, 11:45– 13:30 CEST – POSTER PRESENTATIONS

- Ixekizumab Makes Remission and Low Disease Activity Possible in Patients With Psoriatic Arthritis: Two-Year Results in TNF Inadequate Responders or Biologic-Naïve Patients (Presenting author: Laura C. Coates) Abstract: FRI0426
- Long-Term Safety of Ixekizumab in Patients with Radiographic Axial Spondyloarthritis/Ankylosing Spondylitis: An Integrated Analysis of COAST-V and COAST-W (Presenting author: Helena Marzo-Ortega) Abstract: FRI0400
- Ixekizumab Is Effective in the Treatment of Radiographic Axial Spondyloarthritis Regardless of the Level of C-Reactive Protein or Magnetic Resonance Imaging Scores: 16-Week Data from COAST-V and COAST-W (Presenting author: Walter P. Maksymowych) Abstract: FRI0398
- Ixekizumab Significantly Reduced Pain, Inflammation, and Fatigue in Patients with Radiographic Axial Spondylarthritis (r-axSpA)/Ankylosing Spondylitis (AS) (Presenting author: James Cheng-Chung Wei) Abstract: FRI0421
- Ixekizumab Significantly Improves Self-Reported Overall Health in Patients with Active Ankylosing Spondylitis/Radiographic Axial Spondyloarthritis: SF-36 Results of Two Phase 3 Trials (Presenting author: Jessica A. Walsh) Abstract: FRI0420
- Ixekizumab Improves the Signs and Symptoms of Psoriatic Arthritis Regardless of Sex, Duration of Disease, or Body Mass Index in Two Randomized, Phase 3 Clinical Trials (Presenting author: Lihi Eder) Abstract: FRI0430

Saturday, June 15 10:30 – 12 CEST – POSTER PRESENTATIONS

- Ixekizumab, With or Without Concomitant Methotrexate, Improves the Signs and Symptoms of PsA for Up to 52 weeks of Treatment (Presenting author: Bernard Combe) Abstract: SAT0374

- Improvement in the Signs and Symptoms of Psoriatic Arthritis with Ixekizumab Compared to Placebo in Patient Subgroups Defined by Baseline Disease Characteristics (Presenting author: Alexis Ogdie) Abstract: SAT0396

Saturday, June 15, 8:00 – 9:00 CEST – ORAL PRESENTATION

- Multicentre, Randomised, Open-Label, Assessor-Blinded, Parallel-Group Head-to-Head Comparison of the Efficacy and Safety of Ixekizumab Versus Adalimumab in Patients with Psoriatic Arthritis Naive to Biologic Disease-Modifying Anti-Rheumatic Drugs: 24-Week Results (Presenting author: Philip J. Mease) Abstract: LB0005

PUBLISHED ONLY – NO PRESENTATION

- Ixekizumab Improves Signs and Symptoms and Spinal Inflammation of Ankylosing Spondylitis/Radiographic Axial Spondyloarthritis Through One Year of Treatment in Biologic Disease Modifying Anti-Rheumatic Drug-Naïve Patients (Lead author: James Cheng-Chung Wei)
- Ixekizumab Significantly Improves Self-Reported Overall Health as Measured by SF-36 in Patients with Active Ankylosing Spondylitis/Radiographic Axial Spondyloarthritis Naive to Biological Therapy: 52 Week Results of a Phase 3 Trial (Lead author: James Cheng-Chung Wei)
- Psychometric Properties of the ASAS Health Index in Patients with Active AS/Radiographic Axial SpA Who Have Prior Inadequate Response/Intolerance to TNF Inhibitors in a Phase 3 Trial (Lead author: Uta Kiltz)

**Baricitinib Data**

Wednesday, June 12, 17:05 – 17:15 CEST – ORAL PRESENTATION

- JAK-Inhibitors Tofacitinib and Baricitinib Improve Pathological Bone Loss In Vivo (Presenting author: Axel Hueber) Abstract: OP0076

Thursday, June 13, 11:45 – 13:30 CEST – POSTER PRESENTATIONS

- Pharmacokinetics, Safety and Tolerability of Single- and Multiple-Dose Once-Daily Baricitinib in Chinese Healthy Volunteers – a Randomized Placebo-Controlled Study (Presenting author: Feng Wang) Abstract: THU0199
- Baricitinib-Associated Changes in Global Gene Expression During a 24-Week Phase 2 Clinical SLE Trial Describe a Mechanism of Action Through Inhibition of JAK/STAT and IFN Responsive Gene Expression (Presenting author: Thomas Dörner) Abstract: THU0212
- Safety Profile of Baricitinib for the Treatment of Rheumatoid Arthritis Up to 7 Years: An Updated Integrated Safety Analysis (Presenting author: Mark C. Genovese) Abstract: THU0078
- Patient Disease Trajectories in Baricitinib-Treated Patients with Rheumatoid Arthritis and Inadequate Response to Methotrexate (Presenting author: Peter C. Taylor) Abstract: THU0102
- Baricitinib: Early Versus Delayed Start of Baricitinib in Patients with Rheumatoid Arthritis in a Phase 3 Trial of Patients Naive to Methotrexate Treatment (Presenting author: Roy Fleischmann) Abstract: THU0075

Friday, June 14, 10:15 – 11:45 CEST – ORAL PRESENTATION

- Cost-Effectiveness of a JAK1/JAK2-Inhibitor Vs. a Biologic Disease-Modifying Antirheumatic Drug in a Treat-to-Target Strategy for Rheumatoid Arthritis (Presenting author: Celine van de Laar) Abstract: OP0313

Friday, June 14, 11:45 – 13:30 CEST – POSTER PRESENTATIONS

- Incidence Rate and Characterization of Herpes Zoster in Patients with Moderate-to-Severe Rheumatoid Arthritis: An Update from Baricitinib Clinical Studies (Presenting author: Tsutomu Takeuchi) Abstract: FRI0164

Saturday, June 15, 10:30 – 12 CEST – POSTER PRESENTATIONS

- Baricitinib Improves Joint Mobility After Injury in a Rodent Forced-Ambulation Model (Presenting author: Kelly Knopp) Abstract: SAT0051
- Association Between Baseline Haemoglobin Levels and Radiographic Joint Damage Progression in Patients with Rheumatoid Arthritis Treated with Baricitinib or Standard of Care (Presenting author: Burkhard Moeller) Abstract: SAT0102

PUBLISHED ONLY – NO PRESENTATION

- Benefits of Pain Relief on Fatigue, Function, and Quality of Life When Joint Inflammation is Controlled in Patients with RA (Lead author: Mart van de Laar)

**Additional Data**

Thursday, June 13, 11:50 – 13:30 CEST – GUIDED POSTER PRESENTATION

- The Physical and Emotional Burden of Rheumatoid Arthritis: Data from RA Matters, a Web-Based Survey of Patients and Physicians in Europe and Canada (Presenting author: Rieke Alten) Abstract: PARE0009

Friday, June 14, 11:45– 13:30 CEST – POSTER PRESENTATIONS

- Literature Review of Patient Perspectives on the Management and Treatment of Psoriatic Arthritis (Presenting author: Annelies Boonen) Abstract: FRI0425

Saturday, June 15 10:30 – 12 CEST – POSTER PRESENTATIONS

- Gender Differences in Clinical Characteristics, Quality of Life and Treatment Patterns in Axial Spondyloarthritis Patients: Findings from a Global Survey (Presenting author: Theresa Hunter) Abstract: SAT0332
- Baseline Characteristics and Treatments Among Patients with Rheumatoid Arthritis: The Credit Study in China, 2016-2018 (Presenting author: Nan Jiang) Abstract: SAT0618

PUBLISHED ONLY – NO PRESENTATION

- Relative Impact of Joint and Skin Symptoms on Quality of Life and Work Productivity in Psoriatic Arthritis (PsA) Patients (Lead author: William Tillett)

**INDICATIONS AND USAGE FOR TALTZ (ixekizumab) injection**
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 ≤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.**

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**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.

Closely 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 antimycobacterial 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/$mm^3$) compared to placebo. Avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/$mm^3$. Evaluate at baseline and thereafter according to routine patient management.

***Lymphopenia*** – Absolute lymphocyte count (ALC) <500 cells/$mm^3$ 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/mm$^3$. 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.**
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**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.

**About OLUMIANT®**
OLUMIANT is a once-daily, oral JAK inhibitor approved in the U.S. 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, and approved outside of the U.S. for patients with moderately-to-severely active rheumatoid arthritis who have had an inadequate response to one or more DMARDs. 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. 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. OLUMIANT is approved in more than 60 countries.

**About Lilly in Rheumatology**
Lilly in Rheumatology aims to create a brighter future for people with debilitating rheumatologic diseases through innovative discoveries and patient-centered solutions.

**About Eli Lilly and Company**
Lilly is a global healthcare leader that unites caring with discovery to create medicines that 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. 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 active psoriatic arthritis, and as a potential treatment for ankylosing spondylitis and non-radiographic axial spondyloarthritis; and Olumiant (baricitinib) as a treatment for moderate-to-severe rheumatoid arthritis and as a potential treatment for systemic lupus erythematosus, and reflects Lilly'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 Olumiant 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 undertake no duty to update forward-looking statements to reflect events after the date of this release.

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