



## **New Data Showcasing Lilly's Growing Commitment in Rheumatology to be Featured at the ACR/ARHP Annual Meeting**

October 15, 2018

**- Forty-one abstracts supporting Taltz® and Olumiant® reveal new data including findings in ankylosing spondylitis (radiographic axial spondyloarthritis), psoriatic arthritis, systemic lupus erythematosus and rheumatoid arthritis -**

INDIANAPOLIS, Oct. 15, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that it will present new data for Taltz® (ixekizumab) and Olumiant® (baricitinib) at the American College of Rheumatology (ACR)/Association of Rheumatology Health Professionals (ARHP) annual meeting taking place Oct. 19-24, 2018, in Chicago.

Lilly will present 21 abstracts featuring new data for Taltz, including a late-breaking abstract and four oral presentations. Highlights include complete results from two Phase 3 studies, COAST-V and COAST-W, in adult patients with Ankylosing Spondylitis (AS), also known as radiographic axial spondyloarthritis (rad-axSpA). Based on the positive results from the COAST-V and COAST-W studies, the company plans to submit for U.S. regulatory approval in AS/axSpA later this year.

In addition, Lilly will highlight new data for Olumiant in 20 abstracts, including seven oral presentations on rheumatoid arthritis (RA) and systemic lupus erythematosus (SLE) (Lilly and Incyte Corporation are partners in the clinical development of baricitinib). Notable presentations include an updated integrated safety analysis of Olumiant in the treatment of adults with moderately-to-severely active RA. The FDA approved the 2-mg dose of Olumiant for the treatment of adults with moderately-to-severely active RA who have had an inadequate response to one or more tumor necrosis factor (TNF) inhibitor therapies in June 2018.

"The advancements in treating rheumatic diseases over the past two decades have made a positive impact on patients' lives, but there continues to be a need for new treatment options," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "The data disclosed at the ACR/ARHP annual meeting is part of our robust ongoing late-phase clinical research in rheumatology with 25 ongoing clinical trials in eight different rheumatological disorders. At Lilly, our goal is to redefine our approach to research and science to elevate expectations even further and achieve better outcomes for patients who are living with these debilitating diseases."

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

### **Taltz Data**

#### **Oral Presentations (All times CST)**

##### **Sunday, October 21**

- Abstract 910: 2:30 - 2:45 PM, Room W471b
  - In Diagnostic Prevalence and Treatment Patterns of Male and Female Ankylosing Spondylitis Patients in the United States, 2006-2016
  - Presenter: Jessica Walsh

##### **Monday, October 22**

- Abstract 1864: 2:30 - 2:45 PM, Room W375a
  - Ixekizumab Significantly Improves the Signs and Symptoms of Active Ankylosing Spondylitis/Radiographic Axial Spondyloarthritis: 16 Week Results of a Phase 3 Randomized, Active and Placebo-Controlled Trial
  - Presenter: Désirée van der Heijde
- Abstract 1865: 2:45 - 3:00 PM, Room W375a
  - Ixekizumab Significantly Improves Self-Reported Overall Functioning and Health in Patients with Active AS/Radiographic Axial Spondyloarthritis Naive to Biologic DMARD Therapy: 16 Week Results of a Phase 3 Randomized, Active and Placebo-Controlled Trial
  - Presenter: Uta Kiltz
- Abstract 1866: 3:00 - 3:15 PM, Room W375a
  - Incidence of Inflammatory Bowel Disease Among Patients Treated with Ixekizumab: an Update on Adjudicated Data From an Integrated Database of Patients With Psoriasis and Psoriatic Arthritis
  - Presenter: Mark C. Genovese

### **Posters**

#### Sunday, October 21

- Abstract 662: 9:00 - 11:00 AM
  - Radiographic Progression of Structural Joint Damage in Patients with Active Psoriatic Arthritis Treated with Ixekizumab for Up to 3 Years
  - Presenter: Désirée van der Heijde
- Abstract 663: 9:00 - 11:00 AM
  - Relative Contributions of Improvements in the Psoriasis Area and Severity Index (PASI) and Disease Activity Index for Psoriatic Arthritis (DAPSA) to Improvements in Quality of Life and Function in Patients with Psoriatic Arthritis
  - Presenter: Alexis Ogdie
- Abstract 684: 9:00 - 11:00 AM
  - Efficacy of Ixekizumab in Different Phenotypes of Patients with Active Psoriatic Arthritis (PsA): Results from the Spirit Trials
  - Presenter: Frank Behrens

#### Monday, October 22

- Abstract 1600: 9:00 - 11:00 AM
  - Psychometric Properties of the Assessment of Spondyloarthritis International Society Health Index in Patients with Active AS/Radiographic Axial Spondyloarthritis in a Phase 3 Clinical Study
  - Presenter: Uta Kiltz
- Abstract 1610: 9:00 - 11:00 AM
  - Incremental Benefits to Quality of Life Associated with Achieving Higher Levels of American College of Rheumatology Response and Skin Clearance in Patients with Psoriatic Arthritis
  - Presenter: Josef S. Smolen
- Abstract 1659: 9:00 - 11:00 AM
  - Sustained Improvements in Physical Function, Quality of Life, and Work Productivity after Ixekizumab Therapy in Patients with Active Psoriatic Arthritis: 3-Year Results
  - Presenter: Roy Fleischmann

#### Tuesday, October 23

- Abstract 2626: 9:00 - 11:00 AM
  - Normalization of CRP Levels and Clinical Response to Ixekizumab in Patients with Psoriatic Arthritis: Results from the SPIRIT Studies
  - Presenter: Bernard Combe
- Abstract 2555: 9:00 - 11:00 AM
  - Ixekizumab Treatment Results in Rapid and Sustained Improvements in the Disease Activity Index for Psoriatic Arthritis (DAPSA) in Patients Naïve to Biologic DMARDs or with Previous Inadequate Response to TNF Inhibitors
  - Presenter: Prashanth Sunkureddi
- Abstract 2559: 9:00 - 11:00 AM
  - Efficacy and Safety of Ixekizumab in Patients with Active Psoriatic Arthritis and Previous Inadequate Response to TNF Inhibitors: Two-Year Follow-up from a Phase 3 Study
  - Presenter: Ana-Maria Orbai
- Abstract 2561: 9:00 - 11:00 AM
  - Rapid and Sustained Improvements in Patient-Reported Signs and Symptoms with Ixekizumab in Biologic-Naïve and TNF-Inadequate Responder Patients with Psoriatic Arthritis
  - Presenter: Ana-Maria Orbai
- Abstract 2576: 9:00 - 11:00 AM
  - Anti-Drug Antibodies, Efficacy, and Impact of Concomitant Methotrexate in Ixekizumab-Treated Patients with Psoriatic Arthritis
  - Presenter: Christopher Ritchlin
- Abstract 2577: 9:00 - 11:00 AM
  - Long-Term Effect of Ixekizumab on Patient-Reported Outcomes in PsA Patients with Inadequate Response to TNF Inhibitors: 2-Year Follow-up from a Phase 3 Study
  - Presenter: Anthony Turkiewicz
- Abstract 2578: 9:00 - 11:00 AM
  - Exposure Response Relationship Between Ixekizumab Concentrations and American College of Rheumatology Criteria (ACR) at Week 24 and Psoriasis Area and Severity Index (PASI) at Week 12 in Psoriatic Arthritis (PsA) Patients
  - Presenter: Leijun Hu

- Abstract 2579: 9:00 - 11:00 AM
  - Ixekizumab Treatment Significantly Improves Enthesitis and Dactylitis in Patients with Active Psoriatic Arthritis: Results from the SPIRIT Trials
  - Presenter: Dafna D. Gladman
- Abstract 2580: 9:00 - 11:00 AM
  - Predicting Persistence, Discontinuation, and Switching Patterns of Newly Initiated TNF Inhibitor Therapy in Ankylosing Spondylitis Patients: A Gender Comparison
  - Presenter: Theresa Hunter
- Abstract 2581: 9:00 - 11:00 AM
  - Comparing Treatment Patterns of Non-Radiographic Axial Spondyloarthritis Patients in the United States and Europe
  - Presenter: Theresa Hunter
- Abstract L12: 9:00 - 11:00 AM
  - Efficacy and Safety of Ixekizumab in the Treatment of Radiographic Axial Spondyloarthritis: 16 Week Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled Trial in Patients with Prior Inadequate Response or Intolerance to 1 or 2 Tumor Necrosis Factor Inhibitors
  - Presenter: Atul Deodhar

## **Baricitinib Data**

### **Oral Presentations**

#### **Sunday, October 21**

- Abstract 886: 2:30 - 2:45 PM, Room S100a
  - Efficacy and Safety of Switching from Adalimumab to Baricitinib: Long-Term Data from Phase 3 Extension Study in Patients with Rheumatoid Arthritis
  - Presenter: Michael Weinblatt
- Abstract 962: 5:30 - 5:45 PM, Room W375a
  - Safety Profile of Baricitinib for the Treatment of Rheumatoid Arthritis up to 6 Years: An Updated Integrated Safety Analysis
  - Presenter: Mark Genovese
- Abstract 970: 4:30 - 4:45 PM, Room S100bc
  - Baricitinib in Patients with Systemic Lupus Erythematosus (SLE): Results from a Phase 2, Randomized, Double-Blind, Placebo-Controlled Study
  - Presenter: Daniel Wallace

#### **Monday, October 22**

- Abstract 1894: 4:45 - 5:00 PM, Room W183a
  - Baricitinib-Associated Changes in Type I IFN Gene Signature during a 24-Week Phase 2 Clinical SLE Trial
  - Presenter: Thomas Dörner
- Abstract 1918: 4:45 - 5:00 PM, Room W194a
  - Defining Pain that does Not Interfere with Activities among Rheumatoid Arthritis (RA) Patients
  - Presenter: Yvonne Lee

#### **Tuesday, October 23**

- Abstract 2815: 2:45 - 3:00 PM, Room S100bc
  - Cardiovascular Safety - Update from up to 6 Years of Treatment with Baricitinib in Rheumatoid Arthritis Clinical
  - Presenter: Michael Weinblatt
- Abstract 2856: 4:30 - 5:00 PM, Room W190a
  - Do Patients with Moderate or High Disease Activity Escalate RA Therapy According to Treat-To-Target Principles? Results from the ACR's RISE Registry
  - Presenter: Huifeng Yun

### **Posters**

#### **Sunday, October 21**

- Abstract 291: 9:00 - 11:00 AM
  - Factors Associated with High-Dose Corticosteroid Use in SLE Patients Post Initiation of SLE Therapy
  - Presenter: Jim Paik
- Abstract 546: 9:00 - 11:00 AM

- Baricitinib: Early vs. Delayed Start in Patients with Rheumatoid Arthritis
  - Presenter: Peter Taylor
- Abstract 574: 9:00 - 11:00 AM
  - Longitudinal Efficacy Analysis of Patients with Active Rheumatoid Arthritis and Inadequate Response to Csdmards: Response Following Rescue from Baricitinib 2mg to 4mg Once-Daily
  - Presenter: Roy Fleischmann
- Abstract 599: 9:00 - 11:00 AM
  - 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 (MAIC)
  - Presenter: Bruno Fautrel
- Abstract 2531: 9:00 - 11:00 AM
  - Assessment of Pain Relief with Baricitinib by Treatment History in Patients with Refractory Rheumatoid Arthritis
  - Presenter: Janet Pope

#### Monday, October 22

- Abstract 1457: 9:00 - 11:00 AM
  - Association between Disease Activity and Radiographic Progression in the Current Treat-to-Target Paradigm of Rheumatoid Arthritis: Real World Data from the Dutch Rheumatoid Arthritis Monitoring (DREAM) Registry
  - Presenter: Peter M ten Klooster
- Abstract 1478: 9:00 - 11:00 AM
  - Factors Associated with Disability in Rheumatoid Arthritis Patients with Persistent Moderate Disease Activity
  - Presenter: Bruce Kirkham
- Abstract 1530: 9:00 - 11:00 AM
  - CRP Changes during Bacterial Infections in Baricitinib-treated Patients with RA
  - Presenter: Oliver Hendricks
- Abstract 1536: 9:00 - 11:00 AM
  - Mean Platelet Volume Changes with Baricitinib Indicate Absence of New Platelet Production in Baricitinib-Treated Patients
  - Presenter: Jon Giles

#### Tuesday, October 23

- Abstract 2035: 9:00 - 11:00 AM
  - Effect of Baricitinib on Joint-Related Biomarkers in Patients with Moderate-to-Severe Rheumatoid Arthritis
  - Presenter: Christian Thudium
- Abstract 2531: 9:00 - 11:00 AM
  - Assessment of Pain Relief with Baricitinib by Treatment History in Patients with Refractory Rheumatoid Arthritis
  - Presenter: Janet Pope
- Abstract 2455: 9:00 - 11:00 AM
  - Risk of Venous Thromboembolism in Rheumatoid Arthritis Patients Treated with Biologic and Non-Biologic DMARDs
  - Presenter: Jon Giles
- Abstract 2456: 9:00 - 11:00 AM
  - Risk of Venous Thromboembolism in Rheumatoid Arthritis Patients in Truven MarketScan Data (Jan 2010–Sept 2015) Treated with Biologic or Conventional DMARDs
  - Presenter: Jon Giles

#### **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  $\leq 0.1\%$ ), 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

### 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/mm<sup>3</sup>) compared to placebo. Avoid initiation or interrupt OLUMIANT treatment in patients with an ANC <1000 cells/mm<sup>3</sup>. Evaluate at baseline and thereafter according to routine patient management.

**Lymphopenia** – Absolute lymphocyte count (ALC) <500 cells/mm<sup>3</sup> 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<sup>3</sup>. 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](#).

#### 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.<sup>1</sup> 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.<sup>1</sup>

#### 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.<sup>2</sup> 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.<sup>3</sup> 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.<sup>2</sup> OLUMIANT is approved in more than 50 countries.

#### About Lilly in Immunology

Lilly is bringing our heritage of championing groundbreaking, novel science to immunology and is driven to change what's possible for people living with autoimmune diseases. There are still significant unmet needs, as well as personal and societal costs, for people living with a variety of autoimmune diseases and our goal is to minimize the burden of disease. Lilly is investing in leading-edge clinical approaches across its immunology portfolio in hopes of transforming the autoimmune disease treatment experience. We've built a deep pipeline and are focused on advancing cutting edge science to find new treatments that offer meaningful improvements to support the people and the communities we serve.

#### 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](http://www.lilly.com) and [www.lilly.com/newsroom/social-channels](http://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 active psoriatic arthritis and as a potential treatment for Ankylosing Spondylitis. This press release also 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 moderate-to-severe rheumatoid arthritis and as a potential treatment for atopic dermatitis and systemic lupus erythematosus, 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 OLUMIANT 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.

<sup>1</sup> Taltz Prescribing Information, 2018.

<sup>2</sup> Olumiant Prescribing Information, 2018.

<sup>3</sup> Walker JG and Smith MD. J Rheumatol. 2005;32;1650-1653.

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