Lilly Reinforces its Commitment to Rheumatology through Data Showcased at the ACR/ARP Annual Meeting

November 8, 2019

Thirty-one abstracts supporting Taltz® and Olumiant® highlight the latest innovative data in axial spondyloarthritis, psoriatic arthritis, systemic lupus erythematosus and rheumatoid arthritis

INDIANAPOLIS, Nov. 8, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that it will present new data from Taltz® (ixekizumab) and Olumiant® (baricitinib) at the American College of Rheumatology (ACR)/Association of Rheumatology Professionals (ARP) annual meeting taking place Nov. 8-13, 2019 in Atlanta. The presentations will highlight the latest therapeutic data available in chronic rheumatologic conditions including radiographic axial spondyloarthritis, also known as ankylosing spondylitis (AS); psoriatic arthritis (PsA) and rheumatoid arthritis (RA), along with the latest investigative data for non-radiographic axial spondyloarthritis (nr-axSpA) and systemic lupus erythematosus (SLE).

"Elevating the standard of care for people living with immune-mediated rheumatic diseases is a core part of our mission at Lilly," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "The breadth of data we're presenting at this ACR meeting underscores our unwavering commitment to provide cutting edge innovations for the millions of people living with these conditions."

At this year's meeting, Lilly will present data from clinical studies of Taltz as a treatment for PsA, AS and as a potential treatment for nr-axSpA. Highlights of the data include late-breaking 52-week results from the SPIRIT-H2H study comparing Taltz vs. Humira® (adalimumab) in patients with active PsA. Full results from the Phase 3 COAST-X trial in nr-axSpA will also be presented.

In addition, data being presented on Olumiant reinforce the medicine's promise as a treatment option for adult patients with moderately to severely active RA who have had an inadequate response to one or more TNF antagonist therapies. An integrated, seven-year safety analysis on Olumiant will be presented as well as data on Olumiant's effect on pain associated with RA.

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

Taltz Data

Oral Presentations (All times EST)

Sunday, November 10, 2:30-4:00 PM

- Patient-Reported Outcomes from a Randomised, Open-Label, Parallel-Group Study Evaluating Ixekizumab versus Adalimumab in Patients with PsA Who Are Biologic DMARD Naive: 24-Week Results (Presenting Author: Filip Van den Bosch) Abstract: 836

Monday, November 11, 2:30-2:45 PM

- Continuing versus Withdrawing Ixekizumab in Patients with Psoriatic Arthritis Who Achieved Sustained Minimal Disease Activity: Results from the SPIRIT-P3 Study (Presenting Author: Laura Coates) Abstract: 1818

Tuesday, November 12, 11:30-11:45 AM (Plenary)

- Ixekizumab in Non-Radiographic Axial Spondyloarthritis: Primary Results from a Phase 3 Trial (Presenting Author: Atul Deodhar) Abstract: 2729

Tuesday, November 12, 4:00-6:00 PM

- A Head-to-Head Comparison of Ixekizumab and Adalimumab in Biologic-Naive Patients with Active Psoriatic Arthritis: Efficacy and Safety Outcomes from a Randomized, Open-Label, Blinded Assessor Study Through 52 Weeks (Presenting Author: Josef Smolen) Abstract: L20

Poster Presentations

Sunday, November 10, 9:00-11:00 AM

- Ixekizumab Significantly Improves Patient-Reported Overall Health as Measured by SF-36 in Patients with Active Ankylosing Spondylitis/Radiographic Axial Spondyloarthritis: 52-Week Results of Two Phase 3 Trials (Presenting Author: James Cheng-Chung Wei) Abstract: 434
- Comparing Symptoms, Treatments Patterns, and Quality of Life of Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis Patients: Findings from a US Survey (Presenting Author: Theresa Hunter) Abstract: 557

Monday, November 11, 9:00-11:00 AM

- Safety Profile of Ixekizumab Treatment in Patients with Moderate-to-Severe Plaque Psoriasis and Psoriatic Arthritis: Integrated Analysis of 18 Clinical Trials (Presenting Author: Mark Genovese) Abstract: 1503
- Inflammatory Bowel Disease and Anterior Uveitis in Patients Treated with Ixekizumab for Radiographic Axial Spondyloarthritis: Results from Two Phase 3 Studies Through 52 Weeks (Presenting Author: Sergio Schwartzman) Abstract: 1522
- Infections in Patients with Active Radiographic Axial Spondyloarthritis Treated with Ixekizumab in 2 Phase 3 Clinical Trials (Presenting Author: Marina Magrey) Abstract: 1515
- Ixekizumab Improves Fatigue, Pain, and Sleep up to 52 Weeks in Patients with Radiographic Axial Spondyloarthritis (Presenting Author: Atul Deodhar) Abstract: 1510
- Improvement in the Signs and Symptoms of Psoriatic Arthritis with Ixekizumab Compared to Adalimumab in Patient Subgroups Defined by Baseline Disease Characteristics (Presenting Author: Joseph Merola) Abstract: 1493
- Withdrawal of Ixekizumab Results in Loss of Efficacy in Multiple Clinical Domains in Patients with Psoriatic Arthritis Who Had Achieved Minimal Disease Activity: Results from the SPIRIT-P3 Study (Presenting Author: Laura Coats) Abstract: 1532
- Ixekizumab Significantly Improves Self-Reported Overall Health as Measured by Short-Form-36 in Patients with Active Non-Radiographic Axial Spondyloarthritis: 16- and 52-Week Results of a Phase 3 Randomized Trial (COAST-X) (Presenting Author: Jessica Walsh) Abstract: 1545
- Ixekizumab Improves Self-Reported Overall Functioning and Health as Measured by the Assessment of Spondyloarthritis International Society Health Index in Patients with Active Radiographic Axial Spondyloarthritis: 52-Week Results of Two Phase 3 Randomized Trials (Presenting Author: Uta Kiltz) Abstract: 1547
- Ixekizumab Demonstrates Consistent Improvement up to Week 108 in Psoriatic Arthritis Across Individual ACR Components for Patients Naive to Biologic DMARDs or with Previous Inadequate Response to TNF Inhibitors (Presenting Author: Anthony Turkiewicz) Abstract: 1550
- Ixekizumab Demonstrates Improvement Comparable to Adalimumab Across ACR Components in Biologic-Naive Patients with Psoriatic Arthritis (Presenting Author: Elaine Husni) Abstract: 1488
- Ixekizumab is Effective in the Treatment of Radiographic Axial Spondyloarthritis Regardless of the Level of C-Reactive Protein or Magnetic Resonance Imaging Scores (Presenting Author: Walter Maksymowych) Abstract: 1521
- Resolution of Enthesitis and Dactylitis is Maintained over Two Years of Ixekizumab Treatment in Patients with Psoriatic Arthritis (Presenting Author: Arthur Kavanaugh) Abstract: 1528
- Comparing Symptoms, Treatments Patterns, and Quality of Life of Non-Radiographic Axial Spondyloarthritis and Ankylosing Spondylitis Patients: Findings from a US Survey (Presenting Author: Theresa Hunter) Abstract: 557
- Ixekizumab: 52-Week Efficacy and Safety in Radiographic Axial Spondyloarthritis Patients with Prior Inadequate Response/Intolerance to Tumor Necrosis Factor Inhibitors (Presenting Author: Maxime Dougados) Abstract: 1501
- Primary 1-Year Data of Ixekizumab in Biologic Disease-Modifying Anti-Rheumatic Drug-Naive Patients with Radiographic Axial Spondyloarthritis Including Data in Patients Rerandomized from Adalimumab to Ixekizumab (Presenting Author: Cheng-Chung Wei) Abstract: 1549

Tuesday, November 12, 9:00-11:00 AM

- Impact of Enthesitis on Patient Reported Outcomes and Physician Satisfaction with Treatment: Data from a Multinational Patient and Physician Survey (Presenting Author: Ana-Marie Orbai) Abstract: 2455

Olumiant Data

Oral Presentations

Sunday, November 10, 2:30-4:00 PM

- Safety Profile of Baricitinib for the Treatment of Rheumatoid Arthritis up to 7 Years: An Updated Integrated Safety Analysis (Presenting Author: Mark Genovese) Abstract: 847

Monday, November 11, 4:30-6:00 PM

- Baricitinib 4-mg and 2-mg Once Daily Reduced Pain in Both Patients Who Were Opioid Users and Non-users in Active Rheumatoid Arthritis: A Post-hoc Analysis of Phase 3 Trials (Presenting Author: Janet Pope) Abstract: 1880

Poster Presentations

Sunday, November 10, 9:00-11:00 AM

- Understanding Which Patient-Reported Outcomes Are Important to Rheumatology Patients: Findings from ArthritisPower (Presenting Author: W. Benjamin Nowell) Abstract: 435

- Contribution of Pain Relief on Function, Fatigue and Quality of Life when Inflammation is Controlled in Patients with Rheumatoid Arthritis (Presenting Author: Mart van de Laar) Abstract: 417
- Prevalence of Renal Impairment in a US Rheumatoid Arthritis Population (Presenting Author: Jon Giles) Abstract: 181

Monday, November 11, 9:00-11:00 AM

- Baricitinib Provides Better Pain Relief Across All Disease Activity Levels Compared with Placebo and Adalimumab in Rheumatoid Arthritis (Presenting Author: Peter Taylor) Abstract: 1407
- Molecular Profiling Identifies Immunologic Subgroups and Informs Mechanism of Action of Baricitinib in SLE (Presenting Author: Thomas Dörner) Abstract: 1039
- Effect of Baricitinib on Functional Impairment in RA Patients with Moderate Disease Activity and an Inadequate Response to Conventional DMARDs (Presenting Author: Bruce Kirkham) Abstract: 1439
- Patient Disease Trajectories in Baricitinib-2 mg-Treated Patients with Rheumatoid Arthritis and Inadequate Response to Biologic DMARDs (Presenting Author: Mark Genovese) Abstract: 1350

Tuesday, November 12, 9:00-11:00 AM

- Safety of Baricitinib Under Clinical Settings in Patients with Rheumatoid Arthritis, Using Data from All-Case Post-marketing Surveillance and Spontaneous Reports (Presenting Author: Hiroaki Matsuno) Abstract: 2375

INDICATIONS AND USAGE FOR TALTZ
Taltz is approved for the treatment of adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Taltz is also approved for the treatment of adults with active psoriatic arthritis and active ankylosing spondylitis.

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 and ankylosing spondylitis. 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
During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease. Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz 80 mg Q2W group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials in patients with plaque psoriasis and in the Taltz Q4W group in ankylosing spondylitis trials (Crohn's disease 1.0% [2 patients], ulcerative colitis 0.5% [1 patient]) than in the placebo group (Crohn's disease 0.5% [1 patient], ulcerative colitis 0%). In the ankylosing spondylitis trials, serious events occurred in 1 patient in the Taltz group and 1 patient in the placebo group.

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 profiles observed in patients with psoriatic arthritis and ankylosing spondylitis were consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis.

Please see accompanying Prescribing Information **and** Medication Guide. **Please see** Instructions for Use **included with the device.**

IX HCP ISI 23AUG2019

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 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.[1] 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.[1]

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.[2] 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.[3] 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.[2] 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 health care 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 lilly.com and lilly.com/newsroom. 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, active psoriatic arthritis and ankylosing spondylitis, and as a potential treatment for 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.

[1] Taltz Prescribing Information, 2019.

[2] Olumiant Prescribing Information, 2018.

[3] Walker JG and Smith MD. J Rheumatol. 2005;32;1650-1653.

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