Lilly to Showcase New Data at the 27th European Academy of Dermatology and Venereology (EADV) Congress, Furthering Innovation for Patients with Complex Dermatological Conditions

September 10, 2018

- Fifteen abstracts supporting Taltz®, Olumiant® and mirikizumab reveal new findings for the treatment of psoriasis and atopic dermatitis -

INDIANAPOLIS, Sept. 10, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that it will present new data for Taltz® (ixekizumab), Olumiant® (baricitinib) and mirikizumab at the 27th annual European Academy of Dermatology and Venereology (EADV) Congress taking place Sep. 12-16, 2018, in Paris, France. The broad range of research revealed through these abstracts demonstrates the company's strategic approach to advancing treatment for serious dermatological conditions through new medicines, patient-focused research and clinical tools.

The data include seven abstracts for Taltz, with one oral presentation of the results of a head-to-head study comparing Taltz and ustekinumab in the treatment of nail lesions of patients with moderate-to-severe plaque psoriasis. Lilly will also present real-world studies of clinical, quality of life and healthcare resource utilization outcomes in psoriasis patients and patient-reported studies of the benefit of complete skin clearance.

Lilly also will present an oral abstract of an efficacy and safety analysis from baricitinib's Phase 2 trial for the treatment of atopic dermatitis (Lilly and Incyte Corporation are partners in the clinical development of baricitinib). Additionally, Lilly will present an oral abstract of a study investigating the clinical utility of the Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™) for the assessment of disease severity, which was conducted in collaboration with atopic dermatitis experts, academic institutions and other pharmaceutical companies.

Abstracts to be presented around mirikizumab include three positive analyses from its Phase 2 trial for the treatment of moderate-to-severe plaque psoriasis, including patient-reported outcomes data and long-term 52-week safety and efficacy data. This also includes an oral presentation of mirikizumab's safety and efficacy data for the treatment of scalp psoriasis.

"By exploring creative clinical approaches and patient-centric pathways, Lilly is bringing forth innovation to more thoroughly address the key aspects of treating these complex conditions," said Lotus Mallbris, M.D., Ph.D., vice president, Immunology Development, Lilly Bio-Medicines. "We are confident that our scientific expertise in the field of dermatology will play a meaningful role in progressing the treatment paradigm for more patients in the future."

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

Taltz Data

Oral Presentations

Thursday, Sept. 13

- Abstract FC04.05: 15:40–15:50 CEST, Room 241
  - Comparison of ixekizumab and ustekinumab efficacy in the treatment of nail lesions of patients with moderate-to-severe plaque psoriasis: 52-week data from the IXORA-S trial
  - Presenter: Yves Dutronc, M.D., Eli Lilly and Company, Indianapolis, Indiana, United States

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- Abstract #P1024: Ixekizumab Provides Greater Economic Value Versus Other Biologic Therapies Over the First 16 Weeks of Psoriasis Therapy in the U.S.
- Abstract #P1824: Ixekizumab Provides Greater Cumulative Benefits Than Other Biologic Treatments Over the First 4 Months of Treatment
- Abstract #P1825: An Update on the Long-Term Safety Experience of Ixekizumab: Results from the Psoriasis Clinical Development Program with More than 3 Years of Follow-up from 12 Clinical Trials and More Than 15000 Patient-Years of Exposure to Ixekizumab
- Abstract #P1826: Consistency of Ixekizumab's Efficacy in Subgroups of Patients with Plaque Psoriasis Based on Country-Specific Treatment Requirements in Clinical Practice Across Europe
- Abstract #P1827: No Reactivation of Tuberculosis in Psoriasis Patients with Latent Tuberculosis Infection While on Ixekizumab Treatment: A Report from 11 Clinical Studies
- Abstract #P1829: 12-Week Efficacy and Safety Results of Asian Patients with Moderate-to-Severe Plaque Psoriasis Treated with Ixekizumab: Post Hoc Analysis of the Asian Subpopulation from the IXORA-P Study

Baricitinib Data

Oral Presentations

Thursday, Sept. 13

- Abstract #FC03.02: 13:25–13:35 CEST, Room 241
  - Rapid and Concurrent Improvements in Signs and Symptoms of Atopic Dermatitis with Baricitinib in a Phase 2 Study
  - Presenter: Eric Simpson M.D., M.C.R., Oregon Health and Science University, Portland, Oregon, United States

Mirikizumab Data

Oral Presentations

Saturday, Sept. 15

- Abstract #OP06.01: 13:15–13:25 CEST, Room 311-312
  - Mirikizumab Significantly Improves Scalp Psoriasis in Patients with Moderate-to-Severe Psoriasis
  - Presenter: Robert Bissonnette, M.D., Innovaderm Research, Inc., Montreal, Quebec, Canada

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- Abstract #P1823: Mirikizumab Improves Patient-Reported Signs and Symptoms of Psoriasis
- Abstract #P1932: Response to Mirikizumab at Week 52 Among Patients Who Do Not Achieve a PASI 90 Response at Week 16

Additional Data

Oral Presentations

Thursday, Sept. 13

- Abstract #FC01.09: 9:20–9:30 CEST, Room 241
  - The Validated Investigator Global Assessment for Atopic Dermatitis (vIGA-AD™): A Clinical Outcome Measure for the Severity of Atopic Dermatitis
  - Presenter: Eric Simpson M.D., M.C.R., Oregon Health and Science University, Portland, Oregon, United States

Saturday, Sept. 15

- Abstract #OP05.04: 10:15–10:25 CEST, Room 311-312
  - Novel Immunoassay for Serum IL-19 as a Predictive Biomarker to Improve Management of Psoriasis Patients
  - Presenter: Brian J. Nickoloff M.D., Ph.D., Eli Lilly and Company, Indianapolis, Indiana, United States

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- Abstract #P1863: Assessment of the Benefit of Achieving Complete Versus Almost Complete Skin Clearance of Psoriasis Patients, in the United States: A Patient's Perspective
- Abstract #P1892: Real-World Clinical, Quality of Life and Health Care Resource Utilization Outcomes in Moderate-to-Severe Psoriasis Patients

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 ≤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.

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^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.[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 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.[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 40 countries.

About Mirikizumab

Mirikizumab is a humanized IgG4 monoclonal antibody that binds to the P19 subunit of interleukin 23. Mirikizumab is being studied for the treatment of immune diseases, including psoriasis, ulcerative colitis and Crohn's disease.

About Moderate-to-Severe Plaque Psoriasis

Psoriasis is a chronic, immune disease that affects the skin.[4] It occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells. Psoriasis affects approximately 125 million people worldwide, approximately 20 percent of whom have moderate-to-severe plaque psoriasis.[4,5] Psoriasis can occur on any part of the body, including the genital area.[4] Between 32 percent and 63 percent of patients with plaque psoriasis have or will develop psoriasis in the genital area.[6] The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.[4] Patients with plaque psoriasis often have other serious health conditions, such as diabetes and heart disease.[4]

About Atopic Dermatitis

Atopic dermatitis (AD), a serious form of eczema, is a chronic, relapsing skin disease characterized by intense itching, dry skin and inflammation that can be present on any part of the body.[7] AD is a heterogeneous disease both clinically and biologically, but may be characterized by chronic baseline symptoms of itch, redness and skin damage that are often punctuated with episodic, sometimes unpredictable, flares or exacerbations.[8,9] AD affects approximately 1-3 percent of adults worldwide.[10]

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 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, moderate-to-severe genital psoriasis and active psoriatic arthritis; and mirikizumab as a potential treatment for moderate-to-severe plaque psoriasis, ulcerative colitis and Crohn's disease, and reflects Lilly's current belief. This press release also contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about 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, OLUMIANT or mirikizumab 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.

[1] Taltz Prescribing Information, 2018.

[2] Olumiant [package insert]. Indianapolis, IN: Eli Lilly and Company; 2018.

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[6] Cather JC, Ryan C, Meeuwis, K et al. Patients' Perspectives on the Impact of Genital Psoriasis: A Qualitative Study. Dermatology Therapy. 2017 Dec; 7(4): 447–461.

[7] Zuberbier T, Orlow SJ, Paller AS, et al. Patient perspectives on the management of atopic dermatitis. *The Journal of Allergy and Clinical Immunology*. 2006;118: 226-32.

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[9] Langan SM, Thomas KS, Williams HC. What is meant by "flare" in atopic dermatitis? A systematic review and proposal. *Arch Dermatol*. 2006;142:1190-1196.

[10] Nutten S. Atopic dermatitis: global epidemiology and risk factors. *Annals of Nutrition and Metabolism.* 2015;66(suppl 1): 8-16.

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