Lilly to Showcase Scientific Innovation within Dermatology Portfolio at 24th World Congress of Dermatology

June 5, 2019

- Eighteen abstracts will reveal new insights for the management of moderate-to-severe plaque psoriasis and psoriatic arthritis, as well as the potential treatment of moderate-to-severe atopic dermatitis and alopecia areata -

INDIANAPOLIS, June 5, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) will present data for Taltz® (ixekizumab), Olumiant® (baricitinib) and mirikizumab at the 24th World Congress of Dermatology (WCD) taking place June 10-15, 2019 in Milan, Italy.

The data include 11 abstracts reflecting clinical studies of Taltz for the treatment of moderate-to-severe plaque psoriasis and real-world investigations of treatment patterns in psoriasis and psoriatic arthritis patient populations. This includes new long-term safety and efficacy data for Taltz in patients with psoriasis treated for up to five years, as well as results detailing the medicine's onset of action and long-term response rates.

Lilly will also share the 16-week placebo-controlled results from BREEZE-AD1 and BREEZE-AD2, two Phase 3 studies evaluating the efficacy and safety of baricitinib for the treatment of adult patients with moderate-to-severe atopic dermatitis. Earlier this year, Lilly revealed that both of these studies met their primary endpoints. BREEZE-AD1 and BREEZE-AD2 are among the seven total studies comprising the Phase 3 program that is intended to support global registrations.

Additionally, Lilly will share short- and long-term health outcomes data, as well as long-term data on efficacy in patients with scalp psoriasis, from the Phase 2 clinical program of its investigational medicine mirkizumab for the treatment of moderate-to-severe plaque psoriasis.

"Lilly is excited to share our data at WCD, an event that provides a global platform for discussions about how new innovations in dermatology can help the patients we serve," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "We are proud of the significant progress we've made in our dermatology portfolio since the last WCD four years ago, with Taltz not only approved for the treatment of moderate-to-severe plaque psoriasis but psoriatic arthritis, and also has data on genital psoriasis included in the label. We also have ongoing investigational clinical programs for baricitinib in atopic dermatitis and alopecia areata and mirikizumab in psoriasis."

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

Taltz Data

Posters

- Abstract 1451:
  - Rapid Skin Clearance Leads to Better Quality of Life Outcomes: A Post Hoc Analysis of a Japanese Study on Patients with Moderate-to-Severe Psoriasis (UNCOVER-J)
  - Presenter: Masaru Honma
- Abstract 2696:
  - Relapse Rate After 12 Weeks of Continued Treatment with Ixekizumab and Assessing the Long-Term Response Rate When Switched to Ixekizumab Following Relapse
  - Presenter: Yu-Huei Huan

- Abstract 2776:
    - Long-Term Efficacy of Ixekizumab and Absolute PASI Response in Patients with Moderate-to-Severe Psoriasis: 4 Years of Follow-up from UNCOVER-3
    - Presenter: Gaia Gallo
- Abstract 2791:
    - Ixekizumab Results in Persistent Improvements in Quality of Life in Patients with Moderate-to-Severe Genital Psoriasis Over One Year of Treatment: Results of a Randomized, Placebo Controlled Clinical Trial (IXORA-Q)
    - Presenter: Lyn Guenther
- Abstract 2903:
    - Independent Impacts of Early Improvements in Itch and Psoriasis Area and Severity Index on Quality of Life in Psoriasis Patients
    - Presenter: Gil Yosipovitch
- Abstract 3076:
    - Ixekizumab Treatment Results in More Rapid and Sustained Resolution of Patients' Itch, Skin Pain and Improvement in Quality of Life in Patients With Moderate-to-Severe Psoriasis Compared to Ustekinumab: Results From the IXORA-S, a Phase 3 Trial
    - Presenter: Kristian Reich
- Abstract 3141:
    - Efficacy of Continuous Ixekizumab Treatment Over 60 Weeks in Systemic-Naïve Patients and After Switching From Methotrexate
    - Presenter: Marc Alexander Radtke
- Abstract 548:
    - Ixekizumab Demonstrates High Sustained Efficacy and a Favourable Safety Profile in Patients with Moderate-to-Severe Psoriasis Through 5 Years of Treatment
    - Presenter: Craig Leonardi

Baricitinib Data

Oral Presentations (All times CEST)

Saturday, June 15

- Abstract 6536: 10:45-10:55, Room Yellow 3
    - Efficacy and Safety of Baricitinib in Moderate to Severe Atopic Dermatitis: Results of Two Phase 3 Monotherapy Randomized, Double-Blind, Placebo-Controlled 16-week Trials (BREEZE-AD1 and BREEZE-AD2)
    - Presenter: Eric Simpson

Posters

- Abstract 2268:
    - Inhibitory Effects of Baricitinib on a Human Skin Model of Atopic Dermatitis
    - Presenter: Brian Nickoloff

Mirikizumab Data

Oral Presentations (All times CEST)

Wednesday, June 12

- Abstract 2892: 15:50-16:00, Room Brown 3
    - Improvement in Psoriasis Scalp Severity Index (PSSI) during Maintenance Treatment with Mirikizumab
    - Presenter: Phoebe Rich

Posters

- Abstract 2887:
    - Patient-Reported Improvements in Health-Related Quality of Life by Improvements in Clinician-Rated Psoriasis Severity: A Phase 2 Study Analysis in Patients With Psoriasis Treated With Mirikizumab
    - Presenter: Melinda Gooderham
- Abstract 3211:
    - Impact of Mirikizumab Maintenance Dosing on Patients Who Had <PASI 90 Response at Week 16: A Phase 2 Study Analysis Using the SF-36
    - Presenter: Jerry Bagel

Additional Data

Oral Presentations (All times CEST)

Tuesday, June 11

- Abstract 4477: 15:00-15:10, Room Red 1
  - Development and Content Validation of a Clinically Meaningful Patient-Reported Outcome (PRO) for Scalp Hair Assessment
  - Presenter: Brett King

Posters

- Abstract 1838:
  - Development of Clinical Phenotypes of Atopic Dermatitis: Preliminary Results from a Literature Review
  - Presenter: Louise Newton
- Abstract 2970:
  - Access to Information on Psoriasis Treatment and Disease: Which Different Sources Do Patients Use? Results From an International Survey
  - Presenter: Tiago Torres
- Abstract 3635:
  - Pattern of Drug Use in Patients with Psoriatic Arthritis in a Real-World Setting in Italy
  - Presenter: Valentina Perrone
- Abstract 3636:
  - Patterns of Use of Systemic Therapies in Psoriasis Patients in a Real-World Setting in Italy
  - Presenter: Valentina Perrone

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 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 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 our 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 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; Olumiant (baricitinib) as a treatment for moderate-to-severe rheumatoid arthritis and as a potential treatment for moderate-to-severe atopic dermatitis and severe or very severe alopecia areata; and

mirikizumab as a potential treatment for moderate-to-severe plaque psoriasis; 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 mirikizumab will receive regulatory approvals; that Olumiant will receive additional regulatory approvals; or that Taltz, Olumiant, or mirikizumab will be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertake no duty to update forward-looking statements to reflect events after the date of this release.

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