Lilly to Present New Data for Olumiant® (baricitinib) and Taltz® (ixekizumab) at the European Academy of Dermatology and Venereology (EADV) Annual Congress

September 11, 2017

Lilly will showcase 18 abstracts, including data for Olumiant in atopic dermatitis and Taltz in psoriatic diseases

INDIANAPOLIS, Sept. 11, 2017 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that data across its immunology portfolio will be presented at the annual European Academy of Dermatology and Venereology Congress (EADV), including Phase 2 safety and efficacy data evaluating Olumiant® (baricitinib) for the treatment of moderate-to-severe atopic dermatitis (Lilly and Incyte Corporation are partners on the development of Olumiant). EADV will take place Sept. 13-17, 2017, in Geneva, Switzerland.

Lilly will also present data for Taltz® (ixekizumab) from 11 abstracts, including six oral presentations in psoriasis. Highlighted abstracts include one late-breaker presentation showcasing Phase 3 data evaluating Taltz for the treatment of moderate-to-severe genital psoriasis, as well as long-term results from a five-year, open-label study in moderate-to-severe plaque psoriasis. Analyses from the IXORA-S study comparing Taltz to Stelara®* (ustekinumab) and integrated safety and efficacy results from the SPIRIT-P1 and SPIRIT-P2 studies evaluating Taltz for the treatment of active psoriatic arthritis will also be presented.

Two e-posters from the Closer Together Survey, a survey where 1,457 people with moderate-to-severe psoriasis from nine countries across Europe and Canada shared how psoriasis impacts their quality of life and their overall satisfaction with treatment, will also be presented. An additional four abstracts will detail results from a selection of studies evaluating the impact of immune-mediated diseases.

“As a leading forum for dermatologists from around the world, we are pleased to share a variety of data from across our immunology portfolio at EADV,” said Dr. Lotus Mallbris, vice president, immunology platform team leader, Lilly Bio-Medicines. “We look forward to presenting the new clinical and health outcomes results for Olumiant and Taltz, which reinforce our commitment to advancing research to address the unmet needs of people living with dermatologic diseases.”

Highlighted presentations and posters include:

**Olumiant Data**

**Oral Presentation**

**Thursday, Sept. 14**

- Abstract FC04.01: 15:00–15:10 CEST, Room F  
  - Baricitinib in Patients with Moderate-to-Severe Atopic Dermatitis: A Phase 2 Parallel, Double-Blinded, Randomized Placebo-Controlled Multiple Dose Study
  - Presenter: Emma Guttman-Yassky, M.D., Ph.D., Icahn School of Medicine, Mount Sinai Medical Center, New York, New York, United States

**Taltz Data**

**Oral Presentations**

**Thursday, Sept. 14**

- Abstract FC02.06: 10:35–10:45 CEST, Room F  
  - Efficacy of Ixekizumab in Patients Previously Treated with IL-17 Inhibitors
  - Presenter: Kim Papp, M.D., Ph.D., Probiity Medical Research, Waterloo, Ontario, Canada

- Abstract OP01.01: 10:50–11:00 CEST, Room Q  
  - Efficacy, Health-Related Outcomes, and Safety of Ixekizumab for up to Five Years of Open-Label Treatment in a Phase 2 Study in Chronic Plaque Psoriasis
  - Presenter: Andrew Blauvelt, M.D., M.B.A., Oregon Medical Research Center, Portland, Oregon, United States

- Abstract FC04.04: 15:30–15:40 CEST, Room F  
  - Further Analysis of Initial Non-Responders to Ixekizumab Regarding Patient Characteristics and Long-Term Outcomes
  - Presenter: Lajos Kemény, M.D., D.Sc., University of Szeged, Szeged, Hungary
Abstract P03.01: 10:50–11:00 CEST, Room Q
- Comparison of Ixekizumab and Ustekinumab Efficacy in the Treatment of Nail Lesions of Patients with Moderate-to-Severe Plaque Psoriasis: 24-Week Data from the IXORA-S Trial
  - Presenter: Yves Dutronc, M.D., Eli Lilly and Company, Indianapolis, Indiana, United States

Abstract OP04.03: 13:35–13:45 CEST, Room Q
- Efficacy and Safety of Continuous Every Two-Week Dosing of Ixekizumab over 52 Weeks in Patients with Moderate-to-Severe Plaque Psoriasis
  - Presenter: Melinda Gooderham, M.D., SKiN Centre for Dermatology, Peterborough, Ontario, Canada

Saturday, Sept. 16

Abstract D3T01.1F: 9:15-9:30 CEST, Room 1
- Efficacy and Safety of Ixekizumab in a Randomized, Double-Blinded, Placebo-Controlled Phase 3b Clinical Trial in Patients with Moderate-to-Severe Genital Psoriasis
  - Presenter: Caitriona Ryan, M.D., Consultant Dermatologist, St. Vincent's Hospital, Dublin, Ireland

e-Posters

Abstract P0389: Integrated Efficacy and Safety Results from SPIRIT-P1 and SPIRIT-P2, Two Phase 3 Trials of Ixekizumab for the Treatment of Psoriatic Arthritis

Abstract P1311: Safety and Tolerability of Ixekizumab: Integrated Analysis of Safety in Patients with Moderate-to-Severe Psoriasis from 11 Clinical Trials with more than 12,000 Patient-Years of Exposure to Ixekizumab

Abstract P1765: Essential Information for Estimating Total Psoriasis Area and Severity Index (PASI): A Model Developed from a Post-hoc Analysis of Phase 3 Trials with Ixekizumab and its Potential Application in Teledermatology

Abstract P1928: Comparison of Ixekizumab and Ustekinumab in the Treatment of Scalp Psoriasis in Patients with Moderate-to-Severe Psoriasis: 24-Week Data from the IXORA-S Trial

Abstract P1938: A 24-Week, Randomized, Open-Label Comparison of Ixekizumab Versus Fumaric Acid Esters and Methotrexate in Patients with Moderate-to-Severe Plaque Psoriasis Naïve to Systemic Therapy

Additional Data

Oral Presentations

Thursday, Sept. 14

Abstract FC02.03: 10:05–10:15 CEST, Room F
- Patient Perspectives on Symptoms of Genital vs. Non-Genital Psoriasis: A Qualitative Study
  - Presenter: Kim Meeuwis, M.D., Radboud University Medical Center, Nijmegen, Netherlands

Abstract FC02.09: 11:05–11:15 CEST, Room F
- How Do Current Treatments for Psoriasis Differ in Terms of Reaching Low Levels of Absolute Psoriasis Area and Severity Index (PASI)? Results of a Network Meta-Analysis
  - Presenter: Ulrich Mrowietz, M.D., University Medical Center Schleswig-Holstein, Kiel, Germany

e-Posters

Abstract P1024: Association between Duration of Psoriatic Skin Disease and Subsequent Onset of Psoriatic Arthritis

Abstract P1799: Content Validity Assessment of the Psoriasis Symptom Scale for Use in Patients with Moderate-to-Severe Psoriasis


Abstract P1999: Impact of Treatment Goals on Patient Satisfaction with Treatment of Moderate-to-Severe Psoriasis: Results from an International Quantitative Survey

INDICATIONS AND USAGE FOR OLUMIANT

Therapeutic Indications
Baricitinib was approved in February 2017 for the treatment of adults with moderate-to-severe-active rheumatoid arthritis in the European Union and is marketed as Olumiant

IMPORTANT SAFETY INFORMATION FOR OLUMIANT BASED ON THE EU APPROVED SUMMARY OF PRODUCT CHARACTERISTICS

CONTRAINDICATIONS
- Hypersensitivity to the active substance or to any of the excipients.
- Pregnancy.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE
Infections
Baricitinib is associated with an increased rate of infections such as upper respiratory tract infections compared to placebo. In treatment naïve patients, combination with methotrexate resulted in increased frequency of infections compared to baricitinib monotherapy. The risks and benefits of treatment with Olumiant should be carefully considered prior to initiating therapy in patients with active, chronic or recurrent infections. If an infection develops, the patient should be monitored carefully and Olumiant therapy should be temporarily interrupted if the patient is not responding to standard therapy. Olumiant treatment should not be resumed until the infection resolves.

Tuberculosis
Patients should be screened for tuberculosis (TB) before starting Olumiant therapy. Olumiant should not be given to patients with active TB. Anti-TB therapy should be considered prior to initiation of Olumiant in patients with previously untreated latent TB.

Haematological Abnormalities
Absolute Neutrophil Count (ANC) < 1 x 10^9 cells/L, Absolute Lymphocyte Count (ALC) < 0.5 x 10^9 cells/L or haemoglobin < 8 g/dL were reported in less than 1% of patients in clinical trials. Treatment should not be initiated, or should be temporarily interrupted, in patients with an ANC < 1 x 10^9 cells/L, ALC < 0.5 x 10^9 cells/L or haemoglobin < 8 g/dL observed during routine patient management.

The risk of lymphocytosis is increased in elderly patients with rheumatoid arthritis. Rare cases of lymphoproliferative disorders have been reported.

Viral Reactivation
Viral reactivation, including cases of herpes virus reactivation (e.g., herpes zoster, herpes simplex), were reported in clinical studies. Herpes zoster was reported more commonly in patients ≥ 65 years of age who had previously been treated with both biologic and conventional DMARDs. If a patient develops herpes zoster, Olumiant treatment should be temporarily interrupted until the episode resolves.

Screening for viral hepatitis should be performed in accordance with clinical guidelines before starting therapy with Olumiant. Patients with evidence of active hepatitis B or C infection were excluded from clinical trials. Patients, who were positive for hepatitis C antibody but negative for hepatitis C virus RNA, were allowed to participate. Patients with hepatitis B surface antibody and hepatitis B core antibody, without hepatitis B surface antigen, were also allowed to participate; such patients should be monitored for expression of hepatitis B virus (HBV) DNA. If HBV DNA is detected, a liver specialist should be consulted to determine if treatment interruption is warranted.

Vaccination
No data are available on the response to vaccination with live or inactivated vaccines in patients receiving baricitinib. Use with live, attenuated vaccines during, or immediately prior to, Olumiant therapy is not recommended. International treatment guidelines on vaccination in rheumatoid arthritis patients should be followed when varicella zoster vaccination is considered prior to treatment with Olumiant.

Lipids
Dose dependent increases in blood lipid parameters were reported in patients treated with baricitinib compared to placebo. Elevations in LDL cholesterol decreased in pre-treatment levels in response to statin therapy. Lipid parameters should be assessed approximately 12 weeks following initiation of Olumiant therapy and thereafter patients should be managed according to international clinical guidelines for hyperlipidaemia. The effect of these lipid parameter elevations on cardiovascular morbidity and mortality has not been determined.

Hepatic transaminase elevations
Increases in alanine transaminase (ALT) and aspartate transaminase (AST) to ≥ 5 and ≥ 10 x upper limit of normal (ULN) were reported in less than 1% of patients in clinical trials. In treatment-naïve patients, combination with methotrexate resulted in increased frequency of hepatic transaminase elevations compared with baricitinib monotherapy. If increases in ALT or AST are observed during routine patient management and drug-induced liver injury is suspected, Olumiant should be temporarily interrupted until this diagnosis is excluded.

Malignancy
The risk of malignancies including lymphoma is increased in patients with rheumatoid arthritis. Immunomodulatory medicinal products may increase the risk of malignancies including lymphoma. The clinical data are insufficient to assess the potential incidence of malignancies following exposure to baricitinib. Long-term safety evaluations are ongoing.

Venous Thromboembolism
Events of deep venous thrombosis (DVT) and pulmonary embolism (PE) have been reported in patients receiving baricitinib. Olumiant should be used with caution in patients with risk factors for DVT/PE, such as older age, obesity, a medical history of DVT/PE, or patients undergoing surgery and immobilisation. If clinical features of DVT/PE occur, Olumiant treatment should be temporarily interrupted and patients should be evaluated promptly, followed by appropriate treatment.

Laboratory Monitoring
Please refer to the SmPC for laboratory measures and monitoring guidance.

Immunosuppressive Medicinal Products
Combination with biologic DMARDS or other Janus kinase (JAK) inhibitors is not recommended, as a risk of additive immunosuppression cannot be excluded. Data concerning use of baricitinib with potent immunosuppressive medicinal products (e.g., azathioprine, tacrolimus, ciclosporin) are limited and caution should be exercised when using such combinations.

ADVERSE REACTIONS
Undesirable Effects: Summary of Safety Profile
The most commonly reported adverse drug reactions (ADRs) occurring in ≥ 2% of patients treated with Olumiant monotherapy or in combination with conventional synthetic DMARDs were increased LDL cholesterol (33.6%), upper respiratory tract infections (14.7%) and nausea (2.8%). Infections reported with Olumiant treatment included Herpes zoster.

Please see Summary of Product Characteristics for additional information.

INDICATIONS AND USAGE FOR TALTZ
Taltz® is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.
Baricitinib is a once-daily oral JAK inhibitor currently in clinical studies for inflammatory and autoimmune diseases. 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, suggesting that JAK inhibitors may be useful for the treatment of a broad range of inflammatory conditions, including rheumatoid arthritis.

In December 2009, Lilly and Incyte announced an exclusive worldwide license and collaboration agreement for the development and commercialization of baricitinib and certain follow-on compounds for patients with inflammatory and autoimmune diseases. Baricitinib was submitted for regulatory review seeking marketing approval for the treatment of rheumatoid arthritis in the U.S., the European Union and Japan in 2016. Baricitinib was approved in the EU in February 2017 and in Japan in July 2017. In April 2017, the U.S. Food and Drug Administration issued a Complete Response Letter on the New Drug Application for baricitinib. Baricitinib remains under review in other markets. It is also being studied for the treatment of atopic dermatitis and systemic lupus erythematosus. The Phase 3 program for psoriatic arthritis is expected to begin in 2018.
Psoriasis is a chronic, immune disease that affects the skin. 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. Psoriasis can occur on any part of the body and is associated with other serious health conditions, such as diabetes and heart disease. The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.

### About Active Psoriatic Arthritis
Psoriatic arthritis (PsA) is a chronic, progressive form of inflammatory arthritis that can cause swelling, stiffness and pain in and around the joints, nail changes and impaired physical function. It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons. Typically, psoriatic arthritis affects peripheral joints in the arms and legs (elbows, wrists, hands and feet), but can also affect joints in the axial skeleton (spine, hips and shoulders). If left untreated, PsA can cause permanent joint damage. Additionally, up to 30 percent of people with psoriasis also develop PsA.

### 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.

Lilly has filed a supplemental Biologics License Application (sBLA) with the U.S. Food and Drug Administration (FDA) for Taltz for the treatment of active PsA. Lilly also submitted Taltz to the European Medicines Agency (EMA) for the treatment of adult patients with active PsA. Taltz is approved for adult patients with active PsA in Japan. Submissions to other regulatory agencies around the world are expected later this year. Taltz is also in Phase 3 trials for the treatment of radiographic and non-radiographic axial spondyloarthritis.

### 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).

### About Incyte
Incyte Corporation is a Wilmington, Delaware-based biopharmaceutical company focused on the discovery, development and commercialization of proprietary therapeutics. For additional information on Incyte, please visit the Company's web site at [www.incyte.com](http://www.incyte.com).

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