Lilly to Showcase New Data for Taltz® (ixekizumab) and Other Products Across Immunology Pipeline at AAD Annual Meeting

February 14, 2018

- 14 abstracts include data for Taltz in genital psoriasis, baricitinib in atopic dermatitis and mirikizumab in plaque psoriasis -

INDIANAPOLIS, Feb. 14, 2018 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced that it will present new data for Taltz® (ixekizumab), baricitinib and mirikizumab at the American Academy of Dermatology (AAD) annual meeting taking place Feb. 16-20, 2018, in San Diego, Calif.

The data include eight abstracts for Taltz, featuring two oral presentations highlighting patient-reported outcomes from a Phase 3 clinical trial evaluating Taltz for the treatment of moderate-to-severe genital psoriasis, as well as findings from the Corrona Psoriasis Registry on Taltz patient clinical characteristics and treatment history. Two abstracts evaluating the efficacy and safety of Taltz for the treatment of active psoriatic arthritis will also be presented.

Additionally, Lilly will present Phase 2 efficacy, safety and patient-reported outcomes data for mirikizumab in moderate-to-severe plaque psoriasis. Lilly will also present a late-breaker abstract on patient-reported outcomes data from a Phase 2 study evaluating baricitinib for the treatment of moderate-to-severe atopic dermatitis (Lilly and Incyte Corporation are partners in the development of baricitinib). One abstract from the Closer Together Survey, a survey where nearly 2,000 people with moderate-to-severe psoriasis from 17 countries cross Europe and Canada shared how psoriasis impacts their quality of life and their overall satisfaction with treatment, will also be presented. An additional three abstracts will detail results from studies investigating immune-mediated diseases.

"The data being presented at AAD demonstrates our commitment to developing treatment advancements to help patients with severe diseases such as psoriasis and atopic dermatitis find relief," said Lotus Mallbris, M.D., vice president, immunology platform team leader, Lilly Bio-Medicines. "We are pleased to share data underscoring the potential of our immunology portfolio."

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

Taltz Data

Oral Presentations

Saturday, Feb. 17

- Abstract #6061: 11:25–11:30 a.m. PST, ePoster Presentation Center 2
  - Ixekizumab Patient Clinical Characteristics and Treatment History in Routine Clinical Practice: Findings from the Corrona Psoriasis Registry
  - Presenter: Jashin J. Wu, M.D., Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA

Monday, Feb. 19

- Abstract #5935: 10:41–10:49 a.m. PST, Room 1A
  - Ixekizumab Provides Greater Improvement Versus Placebo on the Impact of Genital Psoriasis on Sexual Activity for Patients with Moderate-to-Severe Genital Psoriasis in a Randomized, Double-Blind Phase 3b Clinical Trial
  - Presenter: Jennifer Clay Cather, M.D., Modern Research Associates, Dallas, TX

Posters

- Abstract #6037: Ixekizumab Provides Rapid and Greater Improvement of the Symptoms of Genital Psoriasis Compared to Placebo in a Randomized, Double-Blind, Phase 3b Clinical Trial
  - Lead author: Gil Yosipovitch, M.D., University of Miami, Miami, FL
- Abstract #6041: Ixekizumab Improves Nail and Skin Lesions through 52 Weeks in Patients with Active Psoriatic Arthritis and Inadequate Response to Tumor Necrosis Factor Inhibitors
  - Lead author: Joseph F. Merola, M.D., Harvard Medical School and Brigham and Women's Hospital, Boston, MA
- Abstract #6062: Ixekizumab Patient Demographics and Self-Reported Burden in Routine Clinical Practice: Findings from the Corrona Psoriasis Registry
  - Lead author: Jashin J. Wu, M.D., Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA
- Abstract #6581: Long-Term Efficacy and Safety of Ixekizumab for the Treatment of Moderate-to-Severe Plaque Psoriasis Sustained for 3 Years: Results of a Randomized, Controlled Phase 3 Study (UNCOVER-3)
  - Lead author: Craig Leonardi, M.D., St. Louis University School of Medicine, St. Louis, MO

- Abstract #6587: Ixekizumab Reduces Disease Activity up to 52 Weeks in Active Psoriatic Arthritis Patients with Inadequate Response to Tumor Necrosis Factor Inhibitors: An Assessment Using Minimal Disease Activity Scores
    - Lead author: Joseph F. Merola, M.D., Harvard Medical School and Brigham and Women's Hospital, Boston, MA
- Abstract #7534: Ixekizumab Provides Greater Cumulative Benefits Versus Ustekinumab over 24 Weeks for Patients with Moderate-to-Severe Psoriasis in a Randomized, Double-Blind Phase 3b Clinical Trial
    - Lead author: Andrew Blauvelt, M.D., M.B.A., Oregon Medical Research Center, Portland, OR

Baricitinib Data

Late-Breaker Presentation

Saturday, Feb. 17

- Abstract F061: 1 p.m. – 3 p.m. PST, Ballroom 20A
    - Patient-Reported Outcomes from a Phase 2 Double-Blinded, Randomized, Multi-Center, Placebo-Controlled Study of Baricitinib in Adult Patients with Moderate-to-Severe Atopic Dermatitis
    - Presenter: Emma Guttman-Yassky, M.D., Ph.D., Icahn School of Medicine, Mount Sinai Medical Center, New York, NY

Mirikizumab Data

Poster

- Abstract #6131: Efficacy, Safety and Quality of Life in Patients with Moderate-to-Severe Plaque Psoriasis Treated with Mirikizumab (LY3074828) in a Phase 2 Study
    - Lead author: Phoebe Rich, M.D., Oregon Dermatology & Research Center, Portland, OR

Additional Data

Posters

- Abstract #6109: The Impact of Psoriasis on Quality of Life in Europe and Canada
    - Lead author: Prof. Manuelle Viguier, Centre Hospitalier Universitaire de Reims, Reims, France
- Abstract #6110: Demographics and Disease Burden of Patients on IL-17A Inhibitors as Compared to Other Biologics: Data from the Corrona Psoriasis Registry
    - Lead author: Jashin J. Wu, M.D., Kaiser Permanente Los Angeles Medical Center, Los Angeles, CA
- Abstract #6459: Prevalence of Inflammatory Bowel Disease among Patients Enrolled in the Corrona Psoriasis Registry
    - Lead author: Elsie Grace, Ph.D., Eli Lilly and Company, Indianapolis, IN
- Abstract #7086: Patient Perspective on the Burden of Skin and Joint Symptoms of Psoriatic Arthritis: Results of a Multi-National Patient Survey
    - Lead author: Joseph F. Merola, M.D., Harvard Medical School and Brigham and Women's Hospital, Boston, MA

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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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 Baricitinib
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 and atopic dermatitis.

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. In January 2018 the FDA has accepted the resubmission of baricitinib for rheumatoid arthritis. The resubmission package included new safety and efficacy data. Baricitinib remains under review in other markets. It is also being studied for the treatment of atopic dermatitis and systemic lupus erythematosus.

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.[1] 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.[1,2] Psoriasis can occur on any part of the body, including the genital area.[1] Between 32 percent and 63 percent of patients with plaque psoriasis have or will develop psoriasis in the genital area.[3] The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.[1] Patients with plaque psoriasis often have other serious health conditions, such as diabetes and heart disease.[1]

About 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 and impaired physical function.[4] It occurs when an overactive immune system sends out faulty signals that cause inflammation, leading to swollen and painful joints and tendons.[6] Psoriatic arthritis can affect peripheral joints in the arms and legs (elbows, wrists, hands and feet).[6] If left untreated, PsA can cause permanent joint damage.[6] Up to 30 percent of people with psoriasis also develop PsA.[6]

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.[5] 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.[6,7] AD affects approximately 1-3 percent of adults worldwide.[8]

Moderate-to-severe AD is characterized by intense itching, resulting in visibly damaged skin and sleep loss.[9] Like other chronic inflammatory diseases, AD is immune-mediated and involves a complex interplay of immune cells and inflammatory cytokines.[10]

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.

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.

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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, and as a potential treatment for moderate-to-severe genital psoriasis; and mirikizumab as a potential treatment for moderate-to-severe plaque psoriasis, 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 baricitinib as a potential treatment for moderate-to-severe atopic dermatitis, 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, baricitinib 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] Psoriasis media kit. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed February 14, 2018.

[2] Skin Conditions by the Numbers. American Academy of Dermatology website. https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers. Accessed February 14, 2018.

[3] 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.

[4] Ritchlin C, et. al. Psoriatic Arthritis. *New England Journal of Medicine*. 2017;376:957-70.

[5] 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.

[6] Thijs JL, Strickland I, Bruijnzeel-Koomen C, et. al. Moving toward endotypes in atopic dermatitis: identification of patient clusters based on serum biomarker analysis. *The Journal of Allergy and Clinical Immunology.* 2017.

[7] 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.

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

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[10] Weidinger, S, Novak, N. Atopic dermatitis. *The Lancet* Volume 387. 2016;10023:1109-1122.

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