Lilly Highlights the Evolution of Its Dermatology Portfolio at Annual American Academy of Dermatology Meeting (AAD)

June 12, 2020

Data from Taltz®, baricitinib, mirikizumab and lebrikizumab underscore Lilly's commitment to discover and develop medicines for patients living with dermatological conditions

INDIANAPOLIS, June 12, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that it will present new data from Taltz® (ixekizumab), Olumiant® (baricitinib), mirikizumab and lebrikizumab at the virtual American Academy of Dermatology (AAD) meeting. The data being highlighted at this year's virtual conference include the latest therapeutic data available in dermatological conditions such as psoriasis and atopic dermatitis (AD). Lilly will present 24 e-Posters, including 14 for Taltz, five for baricitinib, three for mirikizumab and two for lebrikizumab.

"At Lilly, we discover and develop new medicines because we want to help people get better and feel better," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "We're pleased to share new data from our dermatology pipeline at the virtual AAD meeting because we believe our medicines have the potential to help people living with dermatological conditions."

Lilly announced earlier this year that it would be expanding its dermatology portfolio through the acquisition of Dermira, a biopharmaceutical company dedicated to developing new medicines for chronic skin conditions. This acquisition reinforces Lilly's commitment to dermatology and creating new medicines for those living with skin-related diseases. Through the virtual conference, Lilly will be sharing long term data from Taltz clinical trials on itch, skin pain and health related quality of life for patients with moderate to severe plaque psoriasis who have been on the medicine for up to five-years of continuous treatment. Additional new study results will be disclosed exploring, through drug survival, the effectiveness of Taltz in the real-world setting; health economic data associated with Taltz cumulative clinical benefit will also be presented.

Data being presented on baricitinib support the medicine's potential to be a treatment option for adult patients with moderate to severe AD. Highlights of the data being presented at this year's AAD meeting include additional results from BREEZE-AD1 and BREEZE-AD2, Lilly's Phase 3 trials that are part of the baricitinib development program to support global submissions for baricitinib as a treatment for AD.

Lilly will also highlight Phase 2 safety and efficacy data from its investigational medicine mirikizumab in patients with moderate to severe plaque psoriasis. In addition, Lilly will be highlighting data surrounding the investigational therapy lebrikizumab and results from its Phase 2b studies, which is currently being measured in adult patients with moderate to severe AD.

For more information about this year's virtual AAD meeting, please visit https://www.aad.org/member/meetings-education/aadvmx.

Taltz Data

e-Posters

- Indirect comparisons in psoriasis: implications for clinical practice (Presenting Authors: Kristian Reich, Alexander Nast, Richard Warren, Matthias Augustin, Christopher Schuster, Daniel Saure and Carle Paul) Abstract: 15431
- Speed of Improvement in Genital Psoriasis, Genital Itch, Sexual Impact, and Health-Related Quality of Life in Patients with Moderate-to-Severe Genital Psoriasis Treated with Ixekizumab (Presenting Authors: Joseph F. Merola, Lyn Guenther, Peter Foley, Russel Burge, Kyoungah See, Missy McKean-Matthews, Gaia Gallo and Caitriona Ryan) Abstract: 14157
- Patient-reported outcomes in a head-to-head, randomized, double-blinded clinical trial of ixekizumab and guselkumab in patients with moderate-to-severe plaque psoriasis (Presenting Authors: Andrew Blauvelt, Catherine Maari, Alice Gottlieb, Hany Elmaraghy, So Young Park, Renata Gontijo Lima, Russel Burge, Gaia Gallo, Lisa Renda and Jerry Bagel) Abstract: 14152
- Sustained Improvements in Itch, Skin Pain, and Health-Related Quality of Life through 5 years of Treatment with Ixekizumab in Patients with Moderate-to-Severe Plaque Psoriasis (Presenting Authors: Melinda Gooderham, Boni Elewski, Mathias Augustin, Lars Iversen, Hideshi Torii, Russel Burge, Baojin Zhu, Gaia Gallo, Joe Eastman and Peter Foley) Abstract: 14159
- Efficacy Of Ixekizumab Versus Adalimumab In Patients with Psoriatic Arthritis and Nail Involvement: Week-24 Post-Hoc Analysis of A Multicenter, Randomized, Open-Label Study (Presenting Authors: Saxon Smith, Lars Erik Kristensen, Christopher Schuster, Christophe Sapin, Soyi Liu Leage, Elisabeth Riedl, Kristian Reich and Phoebe Rich) Abstract: 13771
- Psoriasis Patients Treated With Ixekizumab Were Maintained Longer On Monotherapy Compared To Other Biologics In Real-World Clinical Practice Settings: Results From IBM Marketscan® Databases (Presenting Authors: Mark Lebwohl, Andrew Blauvelt, Baojin Zhu, Russel Burge, Mwangi James Murage and Craig Leonardi) Abstract: 15984
- Ixekizumab is Superior to Placebo for the Treatment of Nail, Scalp, and Palmoplantar Psoriasis in Pediatric Patients with

Moderate-to-Severe Plaque Psoriasis (Presenting Authors: Amy Paller, Gabriel Alejandro Magariños, Andreas Pinter, Jennifer Cather, Mark Lebwohl, Stuart Keller, Claudia Rodriguez Capriles, Gaia Gallo, Emily Heredia, Lingnan Li and Kim Papp) Abstract: 14161

- Treatment Goals of Patients with Psoriasis as assessed by the Patient Benefit Index: Results of a National Psoriasis Foundation Survey (Presenting Authors: April Armstrong, Emily Edson-Hereda, Baojin Zhu, David Shrom, Russel Burge, Stacie Bell, Jeffery Crowley and Stacy Smith) Abstract: 13877
- Cost Per Cumulative Clinical Benefit of Biologic Therapies for Patients with Plaque Psoriasis (Presenting Authors: Richard B. Warren, Russel Burge, Baojin Zhu, William Malatestinic, Alan Brnabic, David Shrom, Jiaying Guo and Andrew Blauvelt) Abstract: 14162
- Long-term Treatment Effects of Ixekizumab among Psoriasis Patients Who Achieved Early High Level Treatment Outcomes in a Real-World Setting: Results from a Single US Dermatology Referral Practice (Presenting Authors: Craig Leonardi, Rei Tao, Solmaz Setayeshgar, Sisi Wang, Suzanne McMullen, Russel Burge, Baojin Zhu and William N Malatestinic) Abstract: 14216
- Achieving a PASI 50 at 2 weeks was associated with better long term clinical outcomes and low discontinuation: a subgroup analysis of a phase 3 trial of ixekizumab and etanercept in moderate to severe psoriasis (Presenting Authors: Rosmarin, Gorelick, Smith, Shrom, Burge, See, Mckean, Ridenour and Lin) Abstract: 13876
- Ixekizumab demonstrated longer medication persistence than other biologics in the treatment of psoriasis patients: Results from IBM MarketScan® database (Presenting Authors: Andrew Blauvelt, Craig Leonardi, Baojin Zhu, Joe Eastman, William Malatestinic, Jiaying Guo, Russel Burge, David Shrom, Mwangi Murage and Mark Lebwohl) Abstract: 16007
- Treatment Satisfaction in Patients with Moderate-to-Severe Psoriasis by Drug Class and Dose Frequency: Results from a United States Web-Based Survey (Presenting Authors: April Armstrong, David Shrom, Russel Burge, Baojin Zhu and Joseph Gorelick) Abstract: 14160
- Pharmacokinetics, Safety and Efficacy of Ixekizumab in Chinese Patients with Plaque Psoriasis: results from a Phase 1, Single- and Multiple-Dose Study (Presenting Authors: Jie Zheng, Min Zheng, Xiang Chen, Kimberley Jackson, Fan Yang and Feng Wang) Abstract: 14066

Baricitinib Data

e-Posters

- Patients' Characteristics and Treatment Strategies in Pediatric Patients Diagnosed with Atopic Dermatitis Versus Eczema – A Real-World Retrospective Cohort Study (Presenting Authors: Natalie N. Boytsov, Orin M. Goldblum, Magdaliz Gorritz, William N. Malatestinic, Xiang Zhang, Xin Wang and Rolin L. Wade) Abstract: 15342
- Impact of Baricitinib On Patient-Reported Skin Symptoms, Itch, And Quality of Life in Adult Patients with Moderate-To-Severe Atopic Dermatitis and An Inadequate Response to Topical Therapies from Phase 3 Trials, BREEZE-AD1 and BREEZE-AD2 (Presenting Authors: Peter Lio, Audrey Nosbaum, Tracy Cardelo, Amy DeLozier, Margaret Gamalo, Susan Ball and Thomas Bieber) Abstract: 15054
- Baricitinib, An Oral, Reversible Janus Kinase -1 And -2 Inhibitor, For Atopic Dermatitis: Head and Neck Response Across 2 Phase 3 Studies (Presenting Authors: Eric Simpson, Emma Guttman-Yassky, Robert Bissonnette, Na Lu, Yun-Fei Chen, Fabio Nunes, Maria Jose Rueda and Carle Paul) Abstract: 15059
- Safety of Baricitinib in Patients with Atopic Dermatitis: Results of Pooled Data from Two Phase 3 Monotherapy Randomized, Double-Blind, Placebo-Controlled 16-week Trials (BREEZE-AD1 and BREEZE-AD2) (Presenting Authors: Kristian Reich, Jean Philippe Lacour, Antonio Constanzo, Dennis R Brinker, Maria Jose Rueda, Fabio Nunes, Maher Issa, Amy Paller and Jonathan I. Silverberg) Abstract: 15057
- The Effect of Baricitinib On Daily and Workplace Activity from Phase 3 Trials, BREEZE-AD1 and BREEZE-AD2, In Adult Patients with Moderate-To-Severe Atopic Dermatitis (Presenting Authors: Lawrence Eichenfield, Jonathan Silverberg, Jose Manuel Carrascosa, Diana Rubel, Steven Watts, Marta Casillas, Amy M. DeLozier, Evangeline Pierce and Matthias Augustin) Abstract: 15058

Mirikizumab Data

e-Posters

- Efficacy and Safety of Mirikizumab in Patients with Moderate-to-Severe Plaque Psoriasis: 104-Week Results from a Randomized Phase 2 Study (Authors: Robert Bissonnette, Catherine Maari, Alan Menter, Chika Ohata, Kim Papp, Jay Tuttle, Paul Klekotka, Karen Liu, Dipak Patel and Kristian Reich) Abstract: 15328
- Impact of Mirikizumab Maintenance Dosing at Week 104 on Health-related Quality of Life in Patients Who Had <PASI 90 Response at Week 16: A Phase 2 Study Analysis (Authors: Jerry Bagel, Kristian Reich, Phoebe Rich, Robert Bisonnette, Chika Ohata, Kim Papp, Dipak Patel, Baojin Zhu, Emily Edson-Heredia and Melinda Gooderham) Abstract: 14410
- Consistent Scalp Psoriasis Clearance with Mirikizumab Maintenance Treatment at 104 Weeks in Patients Who Had <PASI 90 Response at Week 16: A Phase 2 Study Analysis (Authors: Phoebe Rich, Kristian Reich, Robert Bissonnette, Chika Ohata, Craig Leonardi, Paul Klekotka, Karen Liu, Dipak Patel and Kim Papp) Abstract: 15350

Lebrikizumab Data

e-Posters

- Lebrikizumab, a High-Affinity IL-13 Inhibitor, Demonstrates Rapid and Clinically Meaningful Improvements in Quality of Life Measures in a Phase 2b Trial of Moderate-to-Severe Atopic Dermatitis Patients (Authors: E. Guttman-Yassky, A. Blauvelt, L. Eichenfield, A. Paller, A. Armstrong, J. Drew, R. Gopalan, E. Simpson)
- Lebrikizumab, a High Affinity IL-13 Inhibitor, Improves Clinical Manifestations in Moderate-to-Severe AD: Time Course of Response from a Randomized, Double-Blinded, Placebo-Controlled, Dose-Ranging, Phase 2b Study (Authors: E. Guttman-Yassky, A. Blauvelt, L. Eichenfield, A. Paller, A. Armstrong, J. Drew, R. Gopalan, E. Simpson)

INDICATIONS AND USAGE FOR TALTZ
Taltz is approved for the treatment of adult patients with active non-radiographic axial spondyloarthritis with objective signs of inflammation, active psoriatic arthritis, or active ankylosing spondylitis, and for the treatment of patients 6 years of age and older 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 adult 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 adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis. 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
Patients treated with Taltz may be at an increased risk of inflammatory bowel disease. In clinical trials, Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz group than the placebo group. During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease and if IBD occurs, discontinue Taltz and initiate appropriate medical management.

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 adult patients with psoriatic arthritis, ankylosing spondylitis, non-radiographic axial spondyloarthritis, and pediatric patients with plaque psoriasis were consistent with the safety profile in adult patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis and conjunctivitis, influenza, and urticaria in pediatric psoriasis.

Please see full Prescribing Information and Medication Guide for Taltz. 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.

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.[2] 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. Olumiant is developed by Lilly under license from Incyte Corporation.

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 Lebrikizumab
Lebrikizumab is a novel, injectable, humanized monoclonal antibody designed to bind IL-13 with very high affinity, specifically preventing the formation of the IL-13Rα1/IL-4Rα heterodimer complex and subsequent signaling, thereby inhibiting the biological effects of IL-13 in a targeted and efficient fashion. IL-13 is believed to be a central pathogenic mediator that drives multiple aspects of the pathophysiology of atopic dermatitis by promoting type 2 inflammation and mediating its effects on tissue, resulting in skin barrier dysfunction, itch, skin thickening and infection.

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] 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 and experience negative impact on their quality of life.[4]

About Atopic Dermatitis
Atopic dermatitis (AD), a serious form of atopic 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.[6] 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.[7,8] AD affects approximately 1-3% of adults worldwide.[9]

Moderate to severe AD is characterized by intense itching, resulting in visibly damaged skin.[10] Like other chronic inflammatory diseases, AD is immune-mediated and involves a complex interplay of immune cells and inflammatory cytokines.[11]

About Lilly in Dermatology
By following the science through uncharted territory, we continue Lilly's legacy of delivering innovative medicines that address unmet needs and have significant impacts on people's lives around the world. Skin-related diseases are more than skin deep. We understand the devastating impact this can have on people's lives. At Lilly, we are relentlessly pursuing a robust dermatology pipeline to provide innovative, patient-centered solutions so patients with skin-related diseases can aspire to live life without limitations.

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), OLUMIANT (baricitinib), mirikizumab and lebrikizumab, and reflects Lilly's and Incyte's current beliefs. However, 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 mirikizumab or lebrikizumab will receive regulatory approvals, that Taltz or OLUMIANT will receive additional regulatory approvals, or that any will be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's and Incyte's most recent respective 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, 2020.

[2] Olumiant Prescribing Information, 2019.

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

[4] Psoriasis media kit. National Psoriasis Foundation website. https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed June, 2020.

[5] Skin conditions by the numbers. American Academy of Dermatology website. https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers. Accessed June, 2020.

[6] 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.

[7] 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.

[8] 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.

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

[10] Yosipovitch G, Papoiu AD. What causes itch in atopic dermatitis? Current Allergy and Asthma Reports. 2008;8:306-311.

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

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SOURCE Eli Lilly and Company