



Lilly to Unveil New Data for the Treatments of Complex Dermatological Conditions at the 28th Annual European Academy of Dermatology and Venereology (EADV) Congress

October 8, 2019

Research from Taltz®, Olumiant® and mirikizumab highlight the impact Lilly's medicines may have for patients around the world

INDIANAPOLIS, Oct. 8, 2019 /PRNewswire/ -- Eli Lilly and Company (NYSE: LLY) announced today that it will present new data for Taltz® (ixekizumab), Olumiant® (baricitinib) and mirikizumab at the 28th annual European Academy of Dermatology and Venereology (EADV) Congress taking place Oct. 9-13 in Madrid, Spain. The research being highlighted at this year's meeting reinforces Lilly's commitment to developing treatments for individuals living with dermatological conditions such as psoriasis, psoriatic arthritis, atopic dermatitis and alopecia areata.

"Lilly is proud to showcase data from our dermatology portfolio at EADV this year. Our scientific expertise in dermatology has helped increase the number of available treatment options for patients around the world living with skin-related diseases," said Lotus Mallbris, M.D., Ph.D., vice president of immunology development at Lilly. "We aspire to raise expectations as to how these diseases are treated so people can live their lives without compromise."

Lilly will present findings from a Phase 3 trial of Taltz for pediatric patients with moderate to severe psoriasis as a late-breaking oral presentation at this year's meeting. The company also will be sharing results from a patient survey evaluating treatment expectations and burden of disease for patients living with psoriasis.

For baricitinib, Lilly will present a late-breaking presentation of the BREEZE-AD7 clinical trial. BREEZE-AD7 is an investigational study measuring the efficacy and safety of baricitinib in combination with topical corticosteroids for the treatment of moderate to severe atopic dermatitis (AD) in adults. Lilly and Incyte Corporation (NASDAQ: INCY) are partners in the clinical development of baricitinib. Further, Lilly will present data findings from a real-world study assessing how elements of an individual's quality of life (both functional and emotional) may be impacted by AD.

Posters to be shared around Lilly's investigational compound, mirikizumab, include research from a study measuring patient outcomes and health-related elements of quality of life for individuals with moderate to severe psoriasis.

Studies, along with the times and locations for the data sessions, are highlighted below.

Taltz Data

Oral Presentations

Thursday, October 10

- 09:50 – 10:00 CEST: The Value of Indirect Comparison and Network Meta-Analysis Methodologies in Psoriasis for Treatment Decisions in Clinical Practice (Presenting author: Matthias Augustin) Abstract: FC01.09
- 13:25 – 13:35 CEST: 24-Week Results from a Multicentre, Randomised Study Evaluating Ixekizumab Versus Adalimumab in Psoriatic Arthritis Patients with Psoriasis of ≥10% or <10% Body Surface Area Involvement at Baseline (Presenting author: Saxon Smith) Abstract: FC03.02
- 14:35 – 14:45 CEST: Ixekizumab and Pregnancy Outcomes in Patients with Psoriasis or Psoriatic Arthritis (Presenting author: Alexander Egeberg) Abstract: FC03.09

Saturday, October 12

- 08:45 – 09:00 CEST: Efficacy and Safety of Ixekizumab in a Phase 3, Randomized, Double-Blind, Placebo-Controlled Study in Pediatric Patients with Moderate-to-Severe Plaque Psoriasis (Presenting author: Kim Papp) Abstract: D3T01.1B

Poster Presentations

- Efficacy of Ixekizumab Versus Adalimumab in Psoriatic Arthritis Patients with Moderate-to-Severe Psoriasis: 24-Week Results from a Multicentre, Randomised Study (Presenting author: Kristian Reich) Abstract: P1765
- Persistence of Improvement in Sexual Impact Associated with Moderate-to-Severe Genital Psoriasis for up to 52 Weeks of Treatment with Ixekizumab (Presenting author: Caitriona Ryan) Abstract: P1654
- Duration of Response – Application of Adjusted Kaplan-Meier Curves Comparing Ixekizumab and Ustekinumab (Presenting author: Marc Radtke) Abstract: P1776
- Sustained High Efficacy and a Favorable Safety Profile in Hard-To-Treat Areas in Patients with Moderate-to-Severe Psoriasis: Five Year Results from a Phase 3 Trial (Presenting author: Kim Papp) Abstract: P1658
- Rapid Improvement in Clinical Outcomes and Complete Clearance with Ixekizumab versus Etanercept or Ustekinumab: An Analysis of Severe Psoriasis Patients as Stratified by Body Surface Area (Presenting author: Howard L Sofen) Abstract: P1659
- Ixekizumab Achieves Rapid and High Clearance in Psoriasis Patients With or Without Prior Exposure to Biologics (Presenting author: Andreas Pinter) Abstract: P1660
- Treatment Expectations and Burden of Under-Treatment in Moderate to Severe Psoriasis Patients: Results of a US Web-Based Patient Survey (Presenting author: Joseph Gorelick) Abstract: P1620
- Japanese Psoriasis Patients and Their Physicians Do Not Share the Same Treatment Satisfaction Levels (Presenting author: Ann Chuo Tang) Abstract: P1847

Baricitinib Data

Oral Presentations

Saturday, October 12

- 10:30 – 10:45 CEST: Efficacy and Safety of Baricitinib in Combination with Topical Corticosteroids in Moderate to Severe Atopic Dermatitis: Results of a Phase 3 Randomized, Double-Blind, Placebo-Controlled 16-week Trial (BREEZE-AD7) (Presenting Author Kristian Reich) Abstract: D3T01.1H
- 13:35 – 13:45 CEST: Onset of Effect on Symptoms Reported in Daily Diaries in Patients with Atopic Dermatitis Treated with Baricitinib: Results from Two Phase 3 Trials (Presenting author: Andreas Wollenberg) Abstract: FC07.03

Poster Presentations

- A Qualitative Interview Study to Understand the Psychosocial Burden of Alopecia Areata (First author: Kathleen Wyrwich)

- Rapid and Concurrent Improvements in Signs and Symptoms of Atopic Dermatitis with Baricitinib in Phase 3 Studies (First author: Eric L. Simpson) Abstract: P0231
- Impact of Atopic Dermatitis Lesion Location on Quality of Life in Adult Patients Results from a Real-World Study (First author: Evangeline J. Pierce) Abstract: P0233

Mirikizumab Data

Poster Presentations

- Consistent PASI90 Response Leads to Improved Health-Related Quality of Life in Patients with Moderate-To-Severe Plaque Psoriasis (Presenting author: Melinda Gooderham) Abstract: P1848

INDICATIONS AND USAGE FOR TALTZ

Taltz is approved for the treatment of adults with adults with moderate to severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Taltz is also approved for the treatment of adults with active psoriatic arthritis and active ankylosing spondylitis.

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 and ankylosing spondylitis. 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 $\leq 0.1\%$), 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

During Taltz treatment, monitor patients for onset or exacerbations of inflammatory bowel disease. Crohn's disease and ulcerative colitis, including exacerbations, occurred at a greater frequency in the Taltz 80 mg Q2W group (Crohn's disease 0.1%, ulcerative colitis 0.2%) than in the placebo group (0%) during clinical trials in patients with plaque psoriasis and in the Taltz Q4W group in ankylosing spondylitis trials (Crohn's disease 1.0% [2 patients], ulcerative colitis 0.5% [1 patient]) than in the placebo group (Crohn's disease 0.5% [1 patient], ulcerative colitis 0%). In the ankylosing spondylitis trials, serious events occurred in 1 patient in the Taltz group and 1 patient in the placebo group.

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 ($\geq 1\%$) associated with Taltz treatment are injection site reactions, upper respiratory tract infections, nausea and tinea infections. Overall, the safety profiles observed in patients with psoriatic arthritis and ankylosing spondylitis were consistent with the safety profile in patients with plaque psoriasis, with the exception of influenza and conjunctivitis in psoriatic arthritis.

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.

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/mm³) compared to placebo. Avoid initiation or interrupt Olumiant treatment in patients with an ANC <1000 cells/mm³. Evaluate at baseline and thereafter according to routine patient management.

Lymphopenia – Absolute lymphocyte count (ALC) <500 cells/mm³ 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/mm³. 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 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.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 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 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 percent 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 BREEZE-AD7

The BREEZE-AD7 clinical trial is a multicenter, randomized, double-blind, placebo-controlled, Phase 3 study that evaluated the efficacy and safety of baricitinib in combination with topical corticosteroids in adult patients with moderate to severe atopic dermatitis. Two doses were evaluated separately such that the primary objective of the study could be met if one or both doses achieved the primary endpoint. The primary endpoint evaluated significant improvement in disease activity as determined by the proportion of patients on baricitinib achieving clear (0) or almost clear skin (1) with a greater than or equal to 2-point improvement as measured by the validated 5-point Investigator's Global Assessment for AD (vIGA) scale at 16 weeks of treatment. BREEZE-AD7 is the third of five Phase 3 studies that make up the BREEZE-AD program. Lilly previously announced results for BREEZE-AD1 and BREEZE-AD2 earlier this year.

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), and mirikizumab, 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 will receive regulatory approval, 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, 2019.

² Olumiant Prescribing Information, 2018.

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 September, 2019.

⁵ Skin conditions by the numbers. American Academy of Dermatology website. <https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers>. Accessed September, 2019.

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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The Lilly logo is rendered in a vibrant red, flowing script font. The letters are interconnected, with the 'L' and 'i' being particularly prominent. The overall style is elegant and classic, characteristic of the pharmaceutical company's branding.

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