Lilly's Mirikizumab Superior to Cosentyx® (secukinumab) in a Phase 3 Study for Patients with Moderate to Severe Plaque Psoriasis

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- Mirikizumab met the primary and all key secondary endpoints versus placebo at Week 16 and all key secondary endpoints versus Cosentyx® (secukinumab) at Week 16 and Week 52, including superiority in skin clearance at Week 52

- Lilly will submit data from OASIS-1 and 2 to regulatory authorities around the world

INDIANAPOLIS, July 17, 2020 /PRNewswire/ -- Eli Lilly and Company (NYSE:LLY) announced today that mirikizumab, an investigational monoclonal antibody that binds to the p19-subunit of IL23, met the primary and all key secondary endpoints versus placebo at Week 16 (superiority) and all key secondary endpoints versus Cosentyx (secukinumab) at Week 16 (non-inferiority) and Week 52 (superiority) in the OASIS-2 study. OASIS-2 is a multicenter randomized, double-blind, placebo-controlled study comparing the efficacy and safety of mirikizumab to placebo and Cosentyx in patients with moderate to severe plaque psoriasis.

OASIS-2		
	Week 16	Week 52
	Placebo | Cosentyx (per label) | Mirikizumab (250 mg Q4W)	Cosentyx (per label) | Mirikizumab (250 mg Q4W/125 mg Q8W; 250 mg Q4W/250 mg Q8W)
sPGA(0,1)†	6.3% | 76.3% | 79.7%	68.5% | 83.1%; 83.3%
PASI 90†	6.3% | 72.8% | 74.4%	69.4% | 81.4%; 82.4%
PASI 100	1.8% | 36.6% | 37.7%	42.9% | 53.9%; 58.8%

p< 0.001 for all comparisons including non-inferiority with Cosentyx at Week 16; mirikizumab comparison with Cosentyx at Week 16 for PASI 100 not adjusted for multiplicity.

† Primary endpoints versus placebo at Week 16.

The safety profile was consistent with previously disclosed results for mirikizumab and known safety findings of other drugs in the IL23p19 class.

"The results from this study are promising to people around the world who are burdened by psoriasis and Lilly is grateful to the patients, providers and investigators for advancing science to benefit patients with immunologic conditions," said Patrik Jonsson, senior vice president and president of Lilly Bio-Medicines. "We look forward to bringing mirikizumab to market to provide patients with an additional treatment option that has the potential to provide near complete or complete skin clearance as measured by PASI 90 and PASI 100, with sustained results at 52 weeks."

The OASIS program demonstrates Lilly's continued commitment to developing new treatment options in dermatology. In addition to mirikizumab in psoriasis, Lilly is studying other treatments for atopic dermatitis and alopecia areata, a disease without an FDA-approved medicine.

"We are pleased with the positive results observed in the mirikizumab psoriasis development program (OASIS). Mirikizumab has the potential to be a meaningful treatment option for people living with psoriasis," said Andrew Blauvelt, M.D., M.B.A., president of Oregon Medical Research Center and a lead investigator in the OASIS program. "The data builds on our understanding of IL-23 inhibition in psoriasis and possible future applications."

In OASIS-2, the primary endpoints were the proportion of patients with a Static Physician's Global Assessment (sPGA) of (0,1) with at least a 2-point improvement and the proportion of patients with at least a 90 percent improvement from baseline in Psoriasis Area and Severity Index (PASI 90) at Week 16 compared to placebo. Similar endpoints were evaluated at Week 16 as key secondary endpoints compared to Cosentyx. Other key secondary endpoints compared to placebo at Week 16 include the proportion of patients with at least a 75 and 100 percent improvement from baseline in Psoriasis Area and Severity Index (PASI 75/PASI 100).

Key secondary endpoints at Week 52 compared to Cosentyx included the proportion of patients with a Static Physician's Global Assessment (sPGA) of (0,1) with at least a 2-point improvement and the proportion of patients with at least a 90 and 100 percent improvement from baseline in Psoriasis Area and Severity Index (PASI 90/PASI 100).

The most common treatment-emergent adverse events (≥5%) during the induction period (up to Week 16) were nasopharyngitis and upper respiratory infections and during the combined induction and maintenance treatment periods (up to Week 52) were nasopharyngitis, upper respiratory tract infections, headache, back pain, and arthralgia. The frequency of serious adverse events was comparable across treatment arms during the induction period (<2.5%) and combined induction and maintenance periods up to 52 weeks (<6%).

The full OASIS-2 study results will be disclosed at future congresses. Phase 3 clinical trials are ongoing for mirikizumab in inflammatory bowel diseases (IBD) including ulcerative colitis and Crohn's disease, an area where there are limited treatment options and patients are currently underserved. After pausing enrollment due to the COVID-19 pandemic, these studies have resumed enrolling patients. Lilly expects topline results for the Phase 3 induction data in ulcerative colitis in the spring of 2021 and for the Phase 3 Crohn's data in 2022.

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 the OASIS-2 Trial
OASIS-2 is a multicenter randomized, double-blind, placebo-controlled study comparing the efficacy and safety of mirikizumab to placebo and Cosentyx (secukinumab) in patients with moderate to severe plaque psoriasis. 1,465 patients were randomized in the study in a 4:4:4:1 ratio to one of the following induction and maintenance period treatments: a) 250 mg mirikizumab at Weeks 0, 4, 8, 12 followed by 250 mg every 8 weeks (Q8W) starting at Week 16; b) 250 mg mirikizumab at Weeks 0, 4, 8, 12 followed by 125 mg Q8W starting at Week 16; c) 300 mg secukinumab at Weeks 0, 1, 2, 3, 4, followed by 300 mg Q4W starting at Week 4; d) placebo at Weeks 0, 4, 8, 12, followed by 250 mg mirikizumab every 4 weeks (Q4W) starting at Week 16 through Week 32 followed by Q8W thereafter. Dosing was via subcutaneous injection for all treatments.

About Moderate to Severe Plaque Psoriasis
Psoriasis is a chronic disease that occurs when the immune system sends out faulty signals that speed up the growth cycle of skin cells, causing raised, red, scaly patches to appear on the skin.[1] Psoriasis affects approximately 125 million people worldwide, approximately 20 percent of whom have moderate to severe plaque psoriasis.[1,2] There are five types of psoriasis. The most common form of psoriasis, plaque psoriasis, appears as raised, red patches covered with a silvery white buildup of dead skin cells.[1]

About Lilly in Immunology
Lilly is bringing our heritage of championing groundbreaking, novel science to immunology and is driven to change what's possible for people living with autoimmune diseases. There are still significant unmet needs, as well as personal and societal costs, for people living with a variety of autoimmune diseases and our goal is to minimize the burden of disease. Lilly is investing in leading-edge clinical approaches across our immunology portfolio in hopes of transforming the autoimmune disease treatment experience. We've built a deep pipeline and are focused on advancing cutting-edge science to find new treatments that offer meaningful improvements to support the people and the communities we serve.

About Eli Lilly and Company
Lilly is a global healthcare leader that unites caring with discovery to create medicines that make life better for people around the world. We were founded more than a century ago by a man committed to creating high-quality medicines that meet real needs, and today we remain true to that mission in all our work. Across the globe, Lilly employees work to discover and bring life-changing medicines to those who need them, improve the understanding and management of disease, and give back to communities through philanthropy and volunteerism. To learn more about Lilly, please visit us at www.lilly.com and www.lilly.com/newsroom/social-channels. P-LLY

This press release contains forward-looking statements (as that term is defined in the Private Securities Litigation Reform Act of 1995) about mirikizumab as a potential treatment for moderate to severe plaque psoriasis and inflammatory bowel diseases including ulcerative colitis and Crohn's disease, and reflects Lilly's current belief. As with any pharmaceutical product, there are substantial risks and uncertainties in the process of development and commercialization. Among other things, there can be no guarantee that future study results will be consistent with the results to date, that mirikizumab will receive regulatory approvals, or be commercially successful. For further discussion of these and other risks and uncertainties, see Lilly's most recent Form 10-K and Form 10-Q filings with the United States Securities and Exchange Commission. Except as required by law, Lilly undertakes no duty to update forward-looking statements to reflect events after the date of this release.

[1] About Psoriasis. National Psoriasis Foundation website. https://www.psoriasis.org/about-psoriasis. Accessed April 2020.
[2] Skin conditions by the numbers. American Academy of Dermatology website. https://www.aad.org/media/stats/conditions/skin-conditions-by-the-numbers. Accessed April 2020.

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