



FOR IMMEDIATE RELEASE

ILUMYA™ (tildrakizumab-asmn) 3-Year Data Demonstrates Sustained Skin Clearance in Patients with Moderate-to-Severe Plaque Psoriasis

- *Wide-Range of ILUMYA™ Data Shared at American Academy of Dermatology 2019 Annual Meeting Provides New Insights on Long-Term Use*
- *Multiple One-Year Data Analyses Show Impact of ILUMYA™ Across Different Types of Patients*
- *Analyses Also Show ILUMYA™ Among Most Cost-Effective Options Compared to Other Biologics*

Mumbai, India and Princeton, NJ, March 1, 2019 – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma” and includes its subsidiaries and/or associate companies) today announced that one of its wholly owned subsidiaries presented new ILUMYA™ (tildrakizumab-asmn) clinical insights at the 2019 American Academy of Dermatology (AAD) Annual Meeting, including long-term data showing sustained skin clearance in some patients living with moderate-to-severe plaque psoriasis after three years of ongoing treatment with ILUMYA™.^{1,2}

These findings from the Phase 3 reSURFACE 1 and reSURFACE 2 studies showed sustained response by some patients over time and ILUMYA™ was well tolerated with low rates of adverse events. After up to 5 years of treatment, all prespecified adverse events were reported at rates <1.6 and <1.3 events per 100 patient-years in reSURFACE 1 and reSURFACE 2, respectively. Of the adverse events of interest, severe infections (1.2 and 1.5 events per 100 patient-years, respectively) and malignancies (1.2 and 0.5 events per 100 patient-years, respectively) were the most frequently reported.^{1,2}

Psoriasis Area Sensitivity Index (PASI) Responses Consistently Achieved Over Time in Patients with Moderate-to-Severe Plaque Psoriasis Who Were Treated with ILUMYA™ 100 mg^{1,2}				
	reSURFACE 1 Study (NCT01722331)		reSURFACE 2 Study (NCT01729754)	
	Week 64	Week 160	Week 52	Week 148
PASI 75	209 (88%)	173 (84%)	346 (92%)	285 (89%)
PASI 90	128 (54%)	118 (58%)	262 (70%)	206 (64%)
PASI 100	73 (31%)	51 (25%)	131 (35%)	113 (35%)
Discontinued*	n/a	73 (14%)	n/a	113 (16%)

*The most common reasons for discontinuation of ILUMYA™ was patient withdrawal, adverse events, lost to follow-up and physician decisions

The U.S. FDA approval of ILUMYA™ for adults with moderate-to-severe plaque psoriasis, who are candidates for systemic or phototherapy, is based on 64-week and 52-week reSURFACE data.

“It’s very encouraging to see these effective response rates with ILUMYA™ over a three-year period, because as clinicians we’re often faced with the challenge of finding the right treatment that addresses



the chronic nature of plaque psoriasis. We're also starting to learn more about which patients ILUMYA™ may be a fit for," said Dr. Andrew Blauvelt, board-certified dermatologist and President of Oregon Medical Research Center. "In a one-year analysis we saw that ILUMYA™ showed similar results of skin clearance in both patients who were new to biologic therapy and those who had previously been treated with another biologic. Furthermore, with its HCP administration model ILUMYA™ supports treatment adherence and may be a good treatment option for patients who are starting their first biologic treatment or those who have failed previous therapy."

Results from bio-naïve and bio-experienced patients showed that treatment with ILUMYA™ achieved a PASI ≥ 50 response at Week 28 and was maintained or continued to increase at Week 52, regardless of the patient's previous exposure to biologic treatment.³

Furthermore, additional one-year data analyses presented during the 2019 AAD Annual Meeting show that ILUMYA™ is similarly effective and safe for moderate-to-severe plaque psoriasis patients who have the common condition metabolic syndrome and those who do not.^{4,5} People with psoriasis are predisposed to metabolic syndrome, and psoriasis has been shown to increase the prevalence of metabolic syndrome by three-fold.⁶ Patients with moderate-to-severe plaque psoriasis treated with ILUMYA™ 100 mg who achieved PASI 75 at Week 52 were comparable between those with metabolic syndrome (84% [0.04]) and without (90% [0.02]) and reported similar adverse events, with no reports of cardiovascular events or diabetes worsening by metabolic syndrome status.^{4,5} The most common treatment-emergent adverse event was infection, occurring in 50.6% [n=40] of patients with metabolic syndrome and 53.1% [n=154] of patients without. The most commonly reported serious adverse events (>1.5% of patients with ≥ 1 SAE) in patients with metabolic syndrome were gastrointestinal and cardiac disorders.⁵

"As we expand our knowledge and understanding of the potential ILUMYA™ has for different patients, we're excited to see the clinically meaningful benefits this treatment option may continue to offer," said Abhay Gandhi, President and Chief Executive Officer, Sun Pharmaceutical Industries, Inc. "These insights are promising news for patients and clinicians, and we're committed to helping those with moderate-to-severe psoriasis for whom ILUMYA™ may be a good treatment option."

Additional analyses presented today used the 10-year Markov model to demonstrate the cost-effectiveness of ILUMYA™ as a first-line treatment. The data results demonstrated that ILUMYA™ is among the most cost-effective options compared to other biologic options including secukinumab, guselkumab, ixekizumab, adalimumab, ustekinumab, and etanercept.^{7,8}

Visit www.Ilumya.com to learn more about the ILUMYA SUPPORT Light The Way™ program that helps patients get started with treatment, understand cost and saving options, and connect with experts and others living with plaque psoriasis.

Please click here for [Full Prescribing Information](#) and [Medication Guide](#).

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About ILUMYA™ (tildrakizumab-asmn)

ILUMYA™ (tildrakizumab-asmn) is a humanized IgG1/k monoclonal antibody designed to selectively bind to the p19 subunit of interleukin-23 (IL-23) and inhibit its interaction with the IL-23 receptor, leading to inhibition of the release of pro-inflammatory cytokines and chemokines.

ILUMYA™ is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The U.S. Food and Drug Administration approval is based on data from the pivotal Phase-3 reSURFACE clinical development program, which consisted of two randomized, double-blind, placebo-controlled trials of more than 1,800 patients across over 200 clinical trial sites.

ILUMYA™ has also been approved in Australia, and in Europe under the brand name ILUMETRI™.

IMPORTANT SAFETY INFORMATION

ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any other excipients.

Cases of angioedema and urticaria occurred in ILUMYA™-treated subjects in clinical trial. If a serious hypersensitivity reaction occurs, discontinue ILUMYA™ immediately and initiate appropriate therapy.

ILUMYA™ may increase the risk of infection. Treatment with ILUMYA™ should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to prescribing ILUMYA™ in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILUMYA™ to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue ILUMYA™ until the infection resolves.

Evaluate patients for TB infection prior to initiating treatment with ILUMYA™. Do not administer ILUMYA™ to patients with active TB infection. Initiate treatment of latent TB prior to administering ILUMYA™. Consider anti-TB therapy prior to initiation of ILUMYA™ in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving ILUMYA™ should be monitored closely for signs and symptoms of active TB during and after ILUMYA™ treatment.

Most common ($\geq 1\%$) adverse reactions associated with ILUMYA™ include upper respiratory infections, injection site reactions, and diarrhea. Adverse reactions that occurred at rates less than 1% but greater than 0.1% in the ILUMYA™ group and at a higher rate than in the placebo group included dizziness and pain in extremity.

About the Phase-3 reSURFACE Trials

The Phase-3 studies ([reSURFACE 1](#) and [reSURFACE 2](#)) were randomized, placebo-controlled, multicenter, three-part studies designed to demonstrate efficacy of ILUMYA™ in moderate-to-severe plaque psoriasis compared to

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placebo and comparative drug and to assess safety and tolerability. Part one of the studies randomized patients into three or four treatment arms, including ILUMYA™ 100 mg, ILUMYA™ 200 mg, placebo and etanercept (reSURFACE 2 only). After Week 12, patients on placebo were then re-randomized into ILUMYA™ 100 mg and 200 mg treatment arms to proceed into part two of the studies. Finally, in part three of the reSURFACE 1 study, responders (PASI ≥75) and partial responders (PASI ≥50 and PASI <75) to ILUMYA™ were re-randomized after Week 28 to continue the same treatment, a different dose of ILUMYA™ or placebo. Partial and non-responders to etanercept were treated with ILUMYA™ 200 mg in part three of the reSURFACE 2 study. Patients with guttate, erythrodermic, or pustular psoriasis were excluded.

About Psoriasis

Psoriasis is a chronic immune disease that appears on the skin, affecting approximately 8 million Americans⁹ and 125 million people worldwide.¹⁰ The non-contagious disorder speeds the growth cycle of skin cells¹² and results in thick scaly areas of skin.¹¹ The most common form, affecting about 80 to 90 percent of people with psoriasis, is called plaque psoriasis.¹² It appears as red, raised areas of skin covered with flaky white scales which may be itchy and painful and can crack and bleed.¹² Twenty percent of people with plaque psoriasis are considered moderate-to-severe¹², and many continue to struggle with the ongoing, persistent nature of this chronic disease.

About Sun Dermatology

Sun Dermatology (the branded dermatology division of a wholly owned subsidiary of Sun Pharmaceutical Industries Inc.) is committed to expanding its dermatology portfolio to bring healthcare providers and patients around the world more treatment options and ongoing support for conditions like moderate-to-severe plaque psoriasis. Sun Pharmaceutical Industries Ltd., along with its subsidiaries, is ranked fourth in dermatology prescription volume within the U.S. per IQVIA and is the fifth largest specialty generic pharmaceutical company globally. In addition to ILUMYA™, Sun Dermatology is comprised of several branded products with a focus on various dermatologic conditions.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 100 countries across the world. Sun Pharma's global presence is supported by 44 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 10 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 3 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of approximately 8% of annual revenues. For further information, please visit www.sunpharma.com & follow us on Twitter [@SunPharma Live](https://twitter.com/SunPharmaLive).

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