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1 March 2019.

National Stock Exchange of India Ltd, Exchange Plaza, 5th Floor, Plot No. C/1, G Block, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051. BSE Limited, Market Operations Dept. Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai - 400 001.

Dear Sirs,

Sub: Press Release

Please find enclosed herewith our Press Release relating to ILUMYA[™] (tildrakizumab-asmn) 3-Year Data Demonstrates Sustained Skin Clearance in Patients with Moderate-to-Severe Plaque Psoriasis, which we shall be releasing after sending this letter to you. This is for your information and record.

Thanking you,

Yours faithfully, For Sun Pharmaceutical Industries Ltd

Ashok I. Bhuta Compliance Officer

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Encl: as above

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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 ILUMYATM 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 Plaq Psoriasis Who Were Treated with ILUMYA TM 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

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the chronic nature of plaque psoriasis. We're also starting to learn more about which patients ILUMYATM 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 ILUMYATM 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 ILUMYATM 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 ILUMYATM achieved a PASI \geq 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 ILUMYATM 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 ILUMYATM 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 ILUMYATM 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 ILUMYATM may be a good treatment option."

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

Visit <u>www.Ilumya.com</u> 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 <u>Full Prescribing Information</u> and <u>Medication Guide</u>.

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About ILUMYA™ (tildrakizumab-asmn)

ILUMYATM (tildrakizumab-asmn) is a humanized lgG1/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.

ILUMYATM 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

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

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

ILUMYATM may increase the risk of infection. Treatment with ILUMYATM 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 ILUMYATM in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILUMYATM 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 ILUMYATM until the infection resolves.

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

Most common (\geq 1%) adverse reactions associated with ILUMYATM 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 ILUMYATM 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 (<u>reSURFACE 1</u> and <u>reSURFACE 2</u>) were randomized, placebo-controlled, multicenter, three-part studies designed to demonstrate efficacy of ILUMYATM 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 ILUMYATM 100 mg, ILUMYATM 200 mg, placebo and etanercept (reSURFACE 2 only). After Week 12, patients on placebo were then re-randomized into ILUMYATM 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 \geq 75) and partial responders (PASI \geq 50 and PASI <75) to ILUMYATM were re-randomized after Week 28 to continue the same treatment, a different dose of ILUMYATM or placebo. Partial and non-responders to etanercept were treated with ILUMYATM 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 ILUMYATM, 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 wsunpharma.com & follow us on Twitter

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References

- 1. Tyring S, et al. Efficacy and Safety of Long-term Tildrakizumab for Plaque Psoriasis: 3-Year Results From reSURFACE 1. Presented at 2019 AAD Annual Meeting, March 2019.
- 2. Gooderham M, et al, Efficacy and Safety of Long-term Tildrakizumab for Plaque Psoriasis: 3-Year Results From reSURFACE 2. Presented at 2019 AAD Annual Meeting, March 2019.
- 3. Blauvelt A, et al. Tildrakizumab Efficacy Over Time Stratified by Week-28 Response Levels and By Prior Biologic Use. Presented at 2019 AAD Annual Meeting, March 2019.
- 4. Lebwohl MG, et al. Tildrakizumab Efficacy and Drug Survival by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and reSURFACE 2). Presented at 2019 AAD Annual Meeting, March 2019.
- 5. Leonardi C, et al. Safety of Tildrakizumab in Patients with Pre-existing Metabolic Syndrome: Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and reSURFACE 2). Presented at 2019 AAD Annual Meeting, March 2019.
- 6. lkin Z, et al., The Scientific World Journal, vol. 2012, Article ID 312463, 5 pages, 2012. https://doi.org/10.1100/2012/312463.
- 7. Jia X, et al. Cost-effectiveness of Tildrakizumab in U.S. Patients with Moderate-to-Severe Plaque Psoriasis. Presented at 2019 AAD Annual Meeting, March 2019.
- 8. Jia X, et al. Comparative Cost per Time in Response for Tildrakizumab in U.S. Patients with Moderate-to-Severe Plaque Psoriasis. Presented at 2019 AAD Annual Meeting, March 2019.
- 9. National Psoriasis Foundation. Facts About Psoriasis. March 2019.
- 10. National Psoriasis Foundation. Psoriasis Around the World. March 2019.
- 11. National Psoriasis Foundation. About Psoriasis. March 2019.
- 12. Menter A, et al. J Am Acad Dermatol. 2008;58(5):826-50.

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