

**Sun Pharmaceutical Industries Limited**

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**31 October 2020.**

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 5-year sustained efficacy and safety results for ILUMYA® 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 Limited

Ashok I. Bhuta  
Compliance Officer

Encl: as above

**FOR IMMEDIATE RELEASE**

## **Sun Pharma Announces 5-Year Sustained Efficacy and Safety Results for ILUMYA® (tildrakizumab-asmn) in Patients with Moderate-to-Severe Plaque Psoriasis**

- *ILUMYA is the first IL-23 inhibitor to complete five years of study based on a pooled analysis of two Phase 3 efficacy and safety extension trials in moderate-to-severe plaque psoriasis<sup>1</sup>*
- *Results presented in a late-breaking oral presentation highlighted that ILUMYA delivered progressive and sustained skin clearance per PASI 75/90/100 responses and absolute <1/<3/<5 scores<sup>1</sup>*
- *Additional data results presented provide insight into the positive long-term safety profile for ILUMYA through five years<sup>2</sup>*

**Mumbai, India and Princeton, NJ, October 31, 2020** – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma” including its subsidiaries and/or associate companies) today announced that one of its wholly owned subsidiaries presented positive, five-year Phase 3 data for ILUMYA® (tildrakizumab-asmn) from the combined reSURFACE 1 and reSURFACE 2 extension studies. Patients with moderate-to-severe plaque psoriasis who continued to receive ILUMYA through five years of continuous treatment maintained consistent and extensive skin clearance with no new safety issues reported.<sup>1</sup> These data were presented for the first time at the 29<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Virtual Congress.

“These results are important as we now have five-year data reinforcing our understanding that ILUMYA may provide patients with sustained skin clearance and a well understood safety profile that was comparable to placebo,” said Richard Langley, M.D., FRCPC, professor of medicine and director of research, Department of Medicine, Dalhousie University. “ILUMYA is a valued option for patients in the treatment of moderate-to-severe plaque psoriasis, and these findings are reassuring for physicians and their patients living with this chronic disease.”

In an analysis of the pooled reSURFACE 1 and reSURFACE 2 extension studies, patients received ILUMYA 100 mg or 200 mg through five years of continuous treatment. ILUMYA 100 mg is approved in the U.S., Japan and Australia, and 200 mg is additionally approved under the brand name ILUMETRI™ in Europe. In patients who were treated with ILUMYA 100 mg, clear or almost clear skin

(PASI 90) was achieved by 65.9% of patients and 32.8% of patients achieved completely clear skin (PASI 100) at Week 244. The standard goal of treatment, a PASI 75 response, was achieved by 88.7% of patients at Week 244.<sup>1</sup> The long-term analyses also showed absolute PASI <1/<3/<5 scores at Week 28 (50.8%, 85.1% and 96.4%, respectively) were sustained through Week 244 (47.7%, 78.8% and 88.7%, respectively).<sup>1</sup> Absolute PASI scores can provide an indication of the extent of residual disease after treatment. Achievement of an absolute PASI score of <3 has been proposed as comparable to a PASI 90 response, which is equivalent to clear or almost clear skin.<sup>3</sup>

ILUMYA 100 mg was well-tolerated during the Phase 3 trials. The three adverse reactions that occurred more frequently than placebo and  $\geq 1\%$  in clinical trials were upper respiratory infections (14% vs. 12%), injection site reactions (3% vs. 2%) and diarrhea (2% vs. 1%). Furthermore, the analysis demonstrated similar exposure-adjusted incidence rates of malignancies throughout five years of study. A majority of malignancies were singular events with similar incidence rates as seen in the general US population.<sup>2</sup>

“These impressive results show that ILUMYA keeps working year-on-year, maintaining a high level of skin clearance and a durable safety profile regardless of baseline level of skin disease, age or background illnesses,” said Abhay Gandhi, CEO, Sun Pharma, North America. “Patients living with moderate-to-severe plaque psoriasis need therapies they can use over long periods of time without loss of efficacy, and we are pleased these data show that ILUMYA is a sustainable choice for patients over the long term.”

ILUMYA is approved for adults with moderate-to-severe plaque psoriasis and is being evaluated for other possible uses. See ongoing studies below for more information. Visit [www.ILUMYA.com](http://www.ILUMYA.com) to learn more about the ILUMYA SUPPORT Lighting the Way<sup>®</sup> 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](#).

### **Notable ILUMYA Analyses Presented at the 2020 EADV Virtual Congress**

- Long-term efficacy and safety of tildrakizumab for moderate-to-severe psoriasis: pooled analyses of two randomised Phase 3 clinical trials (reSURFACE 1 and reSURFACE 2) through 5 years (Abstract #3115). Late-breaking Oral Presentation.
- \*Long-term safety profile of tildrakizumab: Incidence of malignancies over 5 years of treatment in patients with moderate-to-severe psoriasis from reSURFACE 1 and reSURFACE 2 Phase 3 trials. (Abstract #1718). E-Poster.
- \*Long-term safety of tildrakizumab in patients over 65 years of age with moderate-to-severe plaque psoriasis: pooled analysis through 5 years (256 weeks) from reSURFACE 1 and reSURFACE 2 Phase 3 trials. (Abstract #722). E-Poster.

- \*Long-term safety profile of tildrakizumab: Incidence of severe infections over 5 years of treatment in patients with moderate-to-severe psoriasis pooled analyses from reSURFACE 1 and reSURFACE 2 Phase 3 trials. (Abstract #1726). E-Poster.
- \*Long term safety profile of tildrakizumab: Incidence of confirmed extended major adverse cardiovascular events over 5 years of treatment in patients with moderate-to-severe psoriasis from reSURFACE 1 and reSURFACE 2 Phase 3 trials. (Abstract #723). E-Poster.
- \*Long-term efficacy of tildrakizumab in European patients with moderate-to-severe plaque psoriasis: 5-year results from reSURFACE 2 Phase 3 trial. (Abstract #683). E-Poster.
- \*High levels of efficacy are well maintained throughout 5 years of treatment with tildrakizumab in patients who achieved PASI <3 response at week 28: pooled analysis from reSURFACE 1 and reSURFACE 2 Phase 3 trials. (Abstract #716). E-Poster.
- \*Application of the statistical method to convert published PASI 50/75/90/100 into absolute PASI response rate in patients with moderate-to-severe plaque psoriasis treated with tildrakizumab based on data from the two pivotal Phase 3 studies, reSURFACE 1 and reSURFACE 2. (Abstract #688). E-Poster.
- \*Open-label, randomised Phase 4 study to assess the efficacy and safety of tildrakizumab in patients with moderate-to-severe plaque psoriasis who are non-responders to dimethyl fumarate therapy: TRANSITION Study design. (Abstract #65). E-Poster.
- \*Interim analysis of the non-interventional study TILOT: Effectiveness of tildrakizumab in long-term treatment of moderate-to-severe plaque psoriasis in routine practice. (Abstract #1303). E-Poster.
- \*Observational study to assess the effectiveness, safety profile and real-life prescribing and utilization patterns of tildrakizumab in patients with moderate-to-severe plaque psoriasis in routine clinical practice: SAIL study design. (Abstract #60). E-Poster.
- Efficacy and safety of tildrakizumab, a high-affinity anti-interleukin-23p19 monoclonal antibody, in patients with active psoriatic arthritis in a randomised, double-blind, placebo-controlled, multiple-dose, Phase 2b study. (Abstract #1853) E-Poster.

*\*Abstract sponsored by Amirall who markets tildrakizumab-asmn in EU.*

### **About the reSURFACE Extension Studies**

The Phase 3 studies ([reSURFACE 1](#) and [reSURFACE 2](#)) were randomized, placebo-controlled, multicenter, three-part studies designed to evaluate efficacy and safety of ILUMYA 100 mg and 200 mg in moderate-to-severe plaque psoriasis compared to placebo and comparative drug and to assess safety and tolerability. Participants with at least 50 percent improvement in PASI 50 at base study completion who received ILUMYA within 12 weeks of base study end (week 52 or 64) were eligible to enroll in the extension study and continued on the same ILUMYA dose or placebo once every 12 weeks. Researchers evaluated PASI and PGA response (score of 0 or 1 with  $\geq 2$  grade reduction from

baseline) and incidence rates for prespecified adverse events, including severe infections, cardiovascular events and drug-related hypersensitivities.

### **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, in the United States. ILUMYA has also been approved for moderate-to-severe plaque psoriasis in Australia and Japan, and under the brand name ILUMETRI in Europe.

### **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 antiTB 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.

Prior to initiating therapy with ILUMYA, consider completion of all age-appropriate immunizations according to current immunization guidelines. Patients treated with ILUMYA should not receive live vaccines.

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 Sun Dermatology**

Sun Dermatology (the branded dermatology division of Sun Pharmaceutical Industries Limited's wholly owned subsidiary, Sun Pharmaceutical Industries Inc. in the United States) is committed to expanding its dermatology portfolio to bring more treatment options and ongoing support for healthcare providers and patients around the world. For more than 30 years, it has been dedicated to advancing the science of dermatology for a variety of conditions like plaque psoriasis, severe nodular acne, minimally to moderately thick actinic keratoses of the face, scalp or upper extremities, and locally advanced basal cell carcinoma. Sun Pharmaceutical Industries Limited, along with its subsidiaries, is ranked second in dermatology prescription volume within the U.S. per IQVIA and is the fourth largest specialty generic pharmaceutical company globally.

### **About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050)**

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 6% of annual revenues in R&D. For further information, please visit [www.sunpharma.com](http://www.sunpharma.com) & follow us on Twitter [@SunPharma\\_Live](https://twitter.com/SunPharma_Live).

### **References:**

1. Thaci D., et al. Long-term efficacy and safety of tildrakizumab for moderate-to-severe psoriasis: pooled analyses of two randomised Phase 3 clinical trials (reSURFACE 1 and reSURFACE 2) through 5 years. Presented at 2020 EADV Virtual Congress, October 2020.
2. Lambert J, et al. Long-term safety profile of tildrakizumab: Incidence of malignancies over 5 years of treatment in patients with moderate-to-severe psoriasis from reSURFACE 1 and reSURFACE 2 Phase 3 trials. Presented at 2020 EADV Virtual Congress, October 2020.
3. Puig L., et al. (2013). Spanish evidence-based guidelines on the treatment of psoriasis with biologic agents, 2013. Part 1: On efficacy and choice of treatment. *Actas Dermo-Sifiliográficas*, 114(8), 694-709.

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