



FOR IMMEDIATE RELEASE

Sun Pharma Announces British Journal of Dermatology Publication on ILUMYA® (tildrakizumab-asmn), the First IL-23 Inhibitor to Complete Five Years of Continuous Treatment in Moderate-to-Severe Plaque Psoriasis

- *In an analysis of the Phase 3 ReSURFACE 1 and 2 study data, ILUMYA (tildrakizumab-asmn) demonstrated progressive and sustained skin clearance and continued to show a durable safety profile through five years*
- *The results showed ILUMYA provided a durable safety profile regardless of baseline level of skin disease, age, or background illness, including in patients with metabolic syndrome*
- *This publication sets a new benchmark as the first and longest complete dataset of an IL-23 inhibitor published in a peer-reviewed medical journal*

Princeton, NJ, March 11, 2021 – Sun Pharmaceutical Industries Inc., USA (Sun Pharma) today announced the publication of five-year Phase 3 efficacy and safety results for ILUMYA® (tildrakizumab-asmn) based on a pooled analysis of the ReSURFACE 1 and ReSURFACE 2 extension studies in the [British Journal of Dermatology](#). Patients with moderate-to-severe plaque psoriasis who received ILUMYA maintained consistent, high levels of skin clearance with no new safety signals reported through five years of continuous treatment. This is the longest complete dataset of an IL-23 inhibitor reported to date with a total ILUMYA exposure of more than 5,400 patient-years.

In an analysis of the pooled reSURFACE 1 and reSURFACE 2 extension study data, patients could receive 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. The results showed moderate-to-severe plaque psoriasis patients who responded at Week 28 had well maintained efficacy as assessed by relative clinical improvement and extent of disease activity through Week 244. In patients who were treated with ILUMYA 100 mg, the median improvement from baseline Psoriasis Area and Severity Index (PASI) score was 94.3% and 65.5% of patients achieved Physician's Global Assessment (PGA) 0/1 at Week 244. Furthermore, patients achieved a median absolute PASI score of 1.1 on the 72-point PASI disease activity scale at Week 244, which indicates patients treated with ILUMYA had low residual disease following treatment. Absolute PASI scores are used in clinical trials to assess efficacy and can provide an indication of the extent of residual disease after treatment.^{1,2}



ILUMYA 100 mg was well-tolerated during the Phase 3 trials. The three adverse reactions (AEs) 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 incidence rates of severe infections, malignancies, major adverse cardiovascular events, and AEs in patients over 65 years of age, were comparable throughout 5 years of treatment, and no new safety signals were observed.

"We are proud to publish five-year data reinforcing our understanding that a high level of sustained skin clearance and a durable safety profile is achievable with ILUMYA, regardless of baseline level of skin disease, age or background illnesses," said Abhay Gandhi, CEO, Sun Pharma, North America. "These impressive results underscore our commitment to patients living with moderate-to-severe plaque psoriasis by providing further assurance of the long-term efficacy and safety of ILUMYA."

ILUMYA is approved for adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and is being evaluated for other possible uses. Visit www.ILUMYA.com to learn more about the ILUMYA SUPPORT Lighting 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](#).

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 once every 12 weeks. Researchers evaluated PASI responses and PGA score of 0 or 1 with ≥ 2 grade reduction from baseline and incidence rates for 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 Pharma's legal entity 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.

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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 Ltd., 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 Inc., USA

Sun Pharma is a wholly owned subsidiary of Sun Pharmaceutical Industries Limited (SPIL). SPIL 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. SPIL 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 & follow us on Twitter [@SunPharma Live](https://twitter.com/SunPharma_Live).

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2. Gordon K. B., et al. (2020) Disease activity and treatment efficacy using patient-level Psoriasis Area and Severity Index scores from tildrakizumab phase 3 clinical trials. *Journal of Dermatological Treatment*.