

#### FOR IMMEDIATE RELEASE

# ILUMYA<sup>®</sup> (tildrakizumab-asmn) Found Effective for Treatment of Moderate-to-Severe Plaque Psoriasis Affecting Nails in Study Presented at 2025 AAD Conference

Data Presented at American Academy of Dermatology Shows Significant Improvement in Moderate-to-Severe Nail Psoriasis with No New Safety Signals

**Princeton, NJ, March 7, 2025** – Sun Pharmaceutical Industries, Inc., USA, a wholly owned subsidiary of Sun Pharmaceutical Industries Limited (Sun Pharma), today presented the results of a Phase 3b, randomized, double-blind, placebo-controlled clinical trial evaluating the safety and efficacy of ILUMYA<sup>®</sup> (tildrakizumab-asmn) for the treatment of moderate-to-severe psoriasis affecting the nails. The study, which included 99 patients with moderate-to-severe plaque psoriasis, found that ILUMYA significantly improved nail psoriasis severity compared to placebo, marking forward progress in addressing this difficult-to-treat condition.

This trial showed that:

- Patients treated with ILUMYA demonstrated a significantly higher rate of 75% improvement from baseline in the Nail Psoriasis Severity Index (mNAPSI 75) at Week 28 (25.5% mNAPSI 75 response rate vs. 4.5% in the placebo group; P=0.003).
- 29.4% of patients treated with ILUMYA achieved normal nails or nails with minimal psoriasis (ViSENPsO<sup>®</sup> score of 0 or 1), compared to 4.2% in the placebo group (P = 0.0008). ViSENPsO is a clinical tool used for detecting and assessing psoriasis including a visual medical scale to evaluate nail psoriasis severity and Patient Global Assessment (PGA) questionnaires.
- The safety profile was consistent with the known safety profile of ILUMYA, and no serious adverse events related to ILUMYA treatment occurred in this clinical trial.

"Nail psoriasis is understood as a difficult to treat population, and many current therapies fall short of providing lasting relief or are slow to produce results," said Dr. Paul Yamauchi, MD, lead investigator of the ILUMYA study. "While other IL-23 inhibitors do not have a dedicated study to evaluate efficacy in nail psoriasis, these trial results clearly demonstrate the promise for ILUMYA to ease discomfort and improve patient outcomes."

Nail psoriasis impacts approximately 50% of patients living with plaque psoriasis and can have an increased negative impact on quality of life.<sup>1</sup> Effective, long-term treatments for nail psoriasis have

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been limited due to the complicated nature of the treatment area, making the condition difficult to manage.

"Psoriasis affecting the nails can have a profound impact on a patient's daily life, causing both physical discomfort and emotional distress. Although highly prevalent in people with plaque psoriasis, nail psoriasis has been challenging to treat," said Marek Honczarenko, M.D., PhD, Senior Vice President, Head of Development, Sun Pharma, North America. "As a company dedicated to developing innovative therapies which help improve quality of life for patients, these data, along with our existing data in scalp psoriasis, reinforces the benefits of ILUMYA in difficult to treat populations."

The most common ( $\geq$ 1%) adverse reactions associated with ILUMYA treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea. The results of this study contribute to the growing body of evidence supporting ILUMYA as a promising treatment for patients living with moderate-to-severe plaque psoriasis, including those with scalp and nail involvement.

## About ILUMYA (tildrakizumab-asmn)

ILUMYA (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. 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<sup>®</sup> in Europe, where it is marketed by Almirall.

# INDICATIONS AND USAGE

ILUMYA (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

## CONTRAINDICATIONS

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

## **IMPORTANT SAFETY INFORMATION**

#### WARNINGS AND PRECAUTIONS Hypersensitivity

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

## Infections

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 consider discontinuation of ILUMYA until the infection resolves.

## **Pretreatment Evaluation for Tuberculosis**

Evaluate patients for tuberculosis (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 treatment.

## Immunizations

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.

## **Adverse Reactions**

The most common ( $\geq$ 1%) adverse reactions associated with ILUMYA treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site reactions, and diarrhea.

# Please see <u>Full Prescribing Information</u>.

## About Sun Pharmaceutical Industries Limited

Sun Pharma is the world's leading specialty generics company with a presence in specialty, generics and consumer healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the U.S. as well as global emerging markets. Sun Pharma's high-growth global specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multicultural

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workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com/usa & follow us on Twitter @SunPharma\_

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## References

1. https://www.psoriasis.org/hands-feet-nails/