



**FOR IMMEDIATE RELEASE**

## **Sun Pharma's Phase 3 Clinical Studies Evaluating Tildrakizumab 100 mg (ILUMYA®) in Active Psoriatic Arthritis Meet their Primary Endpoint**

- *The INSPIRE-1 and INSPIRE-2 trials are Phase 3 studies assessing the efficacy and safety of tildrakizumab 100 mg (ILUMYA) in adults with active psoriatic arthritis (PsA)*
- *Both pivotal studies met their primary endpoint with statistically significant improvements based on ACR20 response rates at Week 24 with tildrakizumab 100 mg (ILUMYA) compared to placebo*
- *These results support the potential regulatory submission of ILUMYA for the treatment of active psoriatic arthritis in the US*

**MUMBAI, India & PRINCETON, N.J., July 21, 2025** – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or affiliated companies, “Sun Pharma”) today announced top-line results from two Phase 3 clinical studies evaluating the efficacy and safety of tildrakizumab 100 mg (ILUMYA®) administered over 24 weeks for treatment of active psoriatic arthritis.

Treatment with tildrakizumab 100 mg (ILUMYA) resulted in greater improvements in PsA signs and symptoms at Week 24 compared to treatment with placebo. Both the INSPIRE-1 and INSPIRE-2 studies achieved the primary endpoint, with a higher proportion of patients in the INSPIRE-1 and INSPIRE-2 studies treated with tildrakizumab achieving ACR20 responses at week 24, compared to those receiving placebo ( $p < 0.05$ ).

"We are excited to share that both the INSPIRE-1 and INSPIRE-2 clinical trials have successfully met their primary endpoints. These top-line results reinforce the therapeutic potential of ILUMYA as a treatment option for patients with active psoriatic arthritis. We extend our sincere gratitude to the patients, healthcare professionals and administrators whose contributions made the studies possible. We look forward to sharing the complete clinical data in the near future," said Marek Honczarenko, MD, PhD, Senior Vice President and Head of Global Specialty Development at Sun Pharma.

Safety data in the studies was consistent with the well-documented safety profile of ILUMYA, which is approved for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. No new safety signals were identified in the INSPIRE-1 and INSPIRE-2 studies.

Findings from the INSPIRE studies will be presented at upcoming medical conferences and published in a peer-reviewed medical journal. Use of tildrakizumab 100 mg (ILUMYA) in psoriatic arthritis is not approved, and its safety and efficacy have not been evaluated by regulatory authorities.



### **About the INSPIRE-1 and INSPIRE-2 Phase 3 studies**

The INSPIRE-1 and INSPIRE-2 are both 52-week global, multicenter, randomized, double-blind, single-dose, placebo-controlled Phase 3 studies aimed at assessing the efficacy and safety of tildrakizumab 100 mg (ILUMYA®) in adult patients with active psoriatic arthritis. The INSPIRE-1 enrolled patients having prior exposure to an anti-TNF agent while the INSPIRE-2 enrolled anti-TNF naïve patients. A total of over 800 adult patients were enrolled for the two studies from clinical sites in the US, Europe and Asia. Patients were randomized to receive either tildrakizumab 100 mg (ILUMYA®) or placebo. An induction dose was not administered in either study. Study participants were permitted to use concomitant methotrexate or leflunomide, provided the dose remained stable throughout the trial. In the INSPIRE-1 and INSPIRE-2 studies, tildrakizumab 100 mg (ILUMYA®) was administered at Week 0 and then every 12 weeks. In contrast, in Phase 3 studies for chronic plaque psoriasis, the treatment schedule included doses in Week 0, Week 4, and then every 12 weeks thereafter. ILUMYA® is approved by the regulatory Agencies for the indication of chronic plaques psoriasis.

The primary endpoint for both studies is the proportion of participants achieving an ACR20 response at Week 24. The key secondary efficacy endpoints at 24 weeks include ACR50, ACR70, and PASI75 and improvement. Learn more about the studies at [clinicaltrials.gov](http://clinicaltrials.gov) (INSPIRE-1 NCT04314544 and INSPIRE-2 NCT04314531).

The ACR20 is a composite measure defined as a 20 percent improvement in both the number of tender and number of swollen joints and a 20 percent improvement in three of the following five criteria: patient global assessment, physician global assessment, functional ability measure (most often HAQ-DI), visual analog pain scale, and erythrocyte sedimentation rate or C-reactive protein (CRP). ACR50 and ACR70 are the same measurement with improvement levels of 50 percent and 70 percent, respectively.

### **About Psoriatic Arthritis (PsA)**

Psoriatic arthritis (PsA) is a chronic (long-lasting or recurring) disease related to the immune system. It causes swelling, pain, and stiffness in joints and entheses (places where tendons and ligaments connect to bones).[1] Psoriatic arthritis can develop at any age.[2] Psoriatic arthritis can occur regardless of the severity of psoriasis (mild, moderate, or severe). Roughly 1 in 3 people living with psoriasis also have psoriatic arthritis [3]; typically, with psoriasis developing before psoriatic arthritis.[2] While as many as 2.4 million Americans live with psoriatic arthritis, more than 15% of people living with psoriasis may also have undiagnosed psoriatic arthritis.[4]

### **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 and other countries.

## **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**

Cases of angioedema and urticaria occurred in ILUMYA-treated patients 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.

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## 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 [Full Prescribing Information](#) and [Medication Guide](#)

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

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 about 20% 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 workforce drawn from over 50 nations. For further information, please visit [www.sunpharma.com](http://www.sunpharma.com) and follow us on [LinkedIn](#) & [X](#) (Formerly Twitter).

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### **References**

1. National Psoriasis Foundation. About Psoriatic Arthritis. 2025.
2. Ritchlin CT, Colbert RA, Gladman DD. Psoriatic Arthritis [published correction appears in N Engl J Med. 2017 May 25;376(21):2097]. N Engl J Med. 2017;376(10):957-970. doi:10.1056/NEJMra1505557
3. Mease PJ, Gladman DD, Papp KA, et al. Prevalence of rheumatologist-diagnosed psoriatic arthritis in patients with psoriasis in European/North American dermatology clinics. J Am Acad Dermatol. 2013;69(5):729-735. doi:10.1016/j.jaad.2013.07.023
4. Villani AP, Rouzaud M, Sevrain M, et al. Prevalence of undiagnosed psoriatic arthritis among psoriasis patients: Systematic review and meta-analysis. J Am Acad Dermatol. 2015;73(2):242-248. doi:10.1016/j.jaad.2015.05.001

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