Sun Pharmaceutical Industries, Inc.
Sun House, Plot No. 201 B/1, Western
Express Highway Goregaon (E)
Mumbai – 400 063, Maharashtra, INDIA
Tel.: (91-22) 4324 4324
Fax.: (91-22) 4324 4343
Website : www.sunpharma.com
Email : secretarial@sunpharma.com
CIN : L24230GL1883PLC019050

FOR IMMEDIATE RELEASE

Sun Pharma Announces US FDA Acceptance of Supplemental Biologics License (sBLA) Application for ILUMYA® (tildrakizumab-asmn) for the Treatment of Adults with Active Psoriatic Arthritis

If the sBLA is approved, expansion into psoriatic arthritis would build on the established clinical experience of ILUMYA as an IL-23 inhibitor for moderate-to-severe plaque psoriasis; FDA decision expected by October 29, 2026

With 1 in 3 psoriasis patients developing psoriatic arthritis, Sun Pharma remains committed to better serving patients living with psoriatic disease

Mumbai, INDIA and Princeton, NJ, March 16, 2026 – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries and/or associated companies) announced that the US Food and Drug Administration (FDA) has accepted for review the supplemental Biologics License Application (sBLA) for ILUMYA for the treatment of adults with active psoriatic arthritis. The FDA regulatory action date for this sBLA is expected by October 29, 2026.

"For many people living with psoriatic disease, joint symptoms often add another layer of burden," says Rick Ascroft, CEO, Sun Pharma North America. "As we continue to strengthen Sun Pharma's innovative portfolio, we look forward to working with the FDA throughout the review process. As the only HCP-administered IL-23 biologic, our ambition is that ILUMYA becomes a differentiated first-choice advanced systemic treatment for active psoriatic arthritis."

If approved, this would mark a new indication for ILUMYA following its US FDA approval in 2018 for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. Scalp and nail plaque psoriasis sBLAs were approved in April 2024, and December 2025, respectively. ILUMYA has also received marketing authorization from over 55 worldwide health authorities since its original approval, including in India, Japan, the European Union, China, Australia and Canada.

Since its approval, ILUMYA has supported nearly 140,000 patients worldwide with durable skin clearance and a well-characterized safety profile through 5 years of clinical follow-up. Additionally, real-world experience has shown strong adherence and persistence, helping patients stay on treatment long-term. ILUMYA has been endorsed widely by dermatologists in the US and globally as a trusted and effective treatment for adults with moderate-to-severe plaque psoriasis.

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The sBLA is based on the results from the INSPIRE-1 and INSPIRE-2 Phase 3 clinical studies evaluating the efficacy and safety of ILUMYA in adult patients with active psoriatic arthritis. Top-line findings from these studies were reported in July 2025. Further details of the studies will be shared at a future congress.

Sun Pharma appreciates the tireless contributions of the participating clinical sites and the participants involved in the PsA investigational clinical trial program.

ILUMYA may cause serious side effects, including serious allergic reactions. Do not take ILUMYA if allergic to it. Seek emergency medical help right away for an allergic reaction. ILUMYA may increase risk of infections and lower ability to fight them. Call a doctor about any infection. Before starting, a doctor will check for infections and tuberculosis (TB). Consult a doctor before vaccinations; avoid live vaccines. Most common side effects are upper respiratory infections, injection site reactions, and diarrhea.

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, placebo-controlled Phase 3 studies aimed at assessing the efficacy and safety of tildrakizumab 100 mg (ILUMYA®) in adult patients with active psoriatic arthritis.

Learn more about the studies at clinicaltrials.gov (INSPIRE-1 NCT04314544 and INSPIRE-2 NCT04314531).

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. ILUMYA has also been approved for moderate-to-severe plaque psoriasis in India, Australia, Canada, China and Japan, and under the brand name ILUMETRI® in Europe, where it is marketed by Almirall.

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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 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

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The most common (≥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.

About Sun Pharmaceutical Industries Limited (CIN - L24230GJ1993PLC019050):
Sun Pharma is the world's leading specialty generics company with a presence in innovative medicines, 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 Innovative Medicines 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 and follow us on LinkedIn & X (Formerly Twitter).

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INVESTOR/MEDIA CONTACTS:

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Email : secretarial@sunpharma.com
CIN : L24230GL1883PLC019050

Investors:
Dr. Abhishek Sharma
Tel + 91 22 4324 4324, Ext 2929
Tel Direct + 91 22 43242929
Mobile + 91 98196 86016
E-mail abhi.sharma@sunpharma.com

Media:
Gaurav Chugh
Tel +91 22 4324 4324, Ext 5373
Tel Direct +91 22 4324 5373
Mobile +91 98104 71414
E-mail
gaurav.chugh@sunpharma.com

U.S. Media:
Jeremy Allen
Mobile: +1 640 230 1397
E-mail: jeremy.allen@sunpharma.com