



FOR IMMEDIATE RELEASE

Sun Pharma Announces Late-Breaking Phase 2 Data Showing Potential of ILUMYA™ (tildrakizumab-asmn) to Improve Joint and Skin Symptoms of Psoriatic Arthritis

- *First Trial of ILUMYA™ in Patients with Psoriatic Arthritis Met Primary Efficacy Endpoint, with No Evident Safety Concerns*
- *Over 71% of Patients Treated with ILUMYA™ Achieved ACR20 Response After 24 Weeks, with Significant Improvement as Early as 8 Weeks*

Mumbai, India and Princeton, NJ, June 14, 2019 – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma” and includes its subsidiaries and/or associate companies) today announced interim results from a Phase 2 study of interleukin-23 (IL-23) inhibitor ILUMYA™ (tildrakizumab-asmn) in patients with active psoriatic arthritis that was presented in a late-breaking oral presentation at the Annual European Congress of Rheumatology (EULAR 2019) in Madrid, Spain (abstract #LB-0002).¹ The interim analysis revealed that over 71 percent of patients treated with ILUMYA™ experienced a 20 percent improvement in joint and skin symptoms (ACR20), meeting the primary endpoint of the study. The interim results showed ILUMYA™ was well tolerated with a low rate of serious treatment-emergent adverse events.

ILUMYA™ is approved in the U.S. for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy and is being investigated for psoriatic arthritis. Psoriatic arthritis, which affects up to 42 percent of people with plaque psoriasis, is an inflammatory condition that impacts both the joints and skin. It is painful, causes fatigue, and can lead to swelling and stiffness of the joints that may reduce range of motion. If left untreated, this chronic condition can lead to permanent joint damage.^{2,3,4}

“As a researcher and clinician, it’s encouraging to see these improvements in pain, joint swelling and skin plaques. Our interim findings showed that about half of the patients treated with 100 mg or 200 mg of tildrakizumab saw a 50 percent improvement in psoriatic arthritis symptoms and about a quarter saw a 70 percent improvement within 24 weeks,” said study investigator Philip J. Mease, MD, MACR, director of rheumatology research at the Swedish Medical Center/Providence St Joseph Health and clinical professor at the University of Washington School of Medicine, Seattle, WA. “These data insights are promising for patients who continue to struggle with the impact psoriatic arthritis has on their daily lives.”

The Phase 2 study interim results showed that across all patients receiving ILUMYA™, 75.3 percent experienced a 20 percent improvement in symptoms of psoriatic arthritis (ACR20) at week 24 compared to 50.6 percent of patients on placebo. The findings were similar in patients receiving 100

mg or 200 mg of ILUMYA™ on a quarterly dosing schedule. For some patients on 100 mg ILUMYA™, results were seen as early as 8 weeks. Furthermore, an average of 47.1 percent of all patients receiving ILUMYA™ achieved an ACR50 response with some results seen as early as 12 weeks, compared to 24.1 percent of patients on placebo.

The interim results also showed ILUMYA™ was well tolerated with a low and comparable rate of adverse events to placebo. Serious treatment-emergent adverse events occurred in 2.2 percent of patients treated with ILUMYA™ and 2.5 percent in those on placebo, with no patients discontinuing treatment due to these events. The most common adverse events through week 24 included common cold (nasopharyngitis), upper respiratory tract infection, and headache. There were no reports of candidiasis, inflammatory bowel disease, major adverse cardiac events, malignancy, or deaths.

“We are committed to the continued clinical development of ILUMYA™ and are pleased with the interim results in our first study for psoriatic arthritis,” said Kyle Ferguson, Business Unit Head, Vice President Sales & Marketing, Sun Pharma. “To help us determine the potential of ILUMYA™ across psoriatic disease, we are now exploring a possible Phase 3 trial for psoriatic arthritis with regulatory authorities.”

About the Phase 2 Study

This is an ongoing 52-week, double-blind Phase 2 study that is evaluating the safety and efficacy of ILUMYA™ in 450 adult patients with active psoriatic arthritis with an optional long-term extension. Patients are randomized in a 1:1:1:1:1 ratio to receive either ILUMYA™ 200 mg every four weeks, ILUMYA™ 200 mg every 12 weeks, ILUMYA™ 100 mg every 12 weeks, ILUMYA™ 20 mg every 12 weeks with dosing increase to 200 mg every 12 weeks after week 24, or placebo every four weeks with a transition to ILUMYA™ 200 mg every 12 weeks after 24 weeks. The primary endpoints are the proportion of patients achieving an ACR20 response and the rate of adverse events at 24 weeks of treatment. Additional efficacy endpoints at 24 weeks include ACR50, ACR70, PASI75, functional ability measured by health assessment questionnaire (HAQ), and enthesitis. Secondary endpoints are the proportion of patients on ILUMYA™ who achieve response at 52 weeks. Learn more about the study at [clinicaltrials.gov \(NCT02980692\)](https://clinicaltrials.gov/ct2/show/study/NCT02980692).

The ACR20 is a composite measure defined as both improvement of 20 percent in 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), 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 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 under the brand name ILUMETRI™ in Europe.

INDICATION AND IMPORTANT SAFETY INFORMATION

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.

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.

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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 click here for [Full Prescribing Information](#) and [Medication Guide](#).

About Sun Dermatology

Sun Dermatology (the branded dermatology division of a wholly owned subsidiary of Sun Pharmaceutical Industries Inc.) is committed to expanding its dermatology portfolio to bring healthcare providers and patients around the world more treatment options and ongoing support for conditions like moderate-to-severe plaque psoriasis. Sun Pharmaceutical Industries Ltd., along with its subsidiaries, is ranked fourth in dermatology prescription volume within the U.S. per IQVIA and is the fourth largest specialty generic pharmaceutical company globally. In addition to ILUMYA™, Sun Dermatology is comprised of several branded products with a focus on various dermatologic conditions.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 100 countries across the world. Sun Pharma's global presence is supported by 44 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. In India, the company enjoys leadership across 11 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of approximately 7% of annual revenues. For further information, please visit www.sunpharma.com & follow us on Twitter [@SunPharma_Live](https://twitter.com/SunPharma_Live).

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References

1. Mease PJ, et al. Randomised, Double-Blind, Placebo-Controlled, Multiple-Dose, Phase 2b Study to Demonstrate the Safety and Efficacy of Tildrakizumab, a High-Affinity Anti-Interleukin-23P19 Monoclonal Antibody, in Patients with Active Psoriatic Arthritis: An Interim Analysis. Presented at the Annual European Congress of Rheumatology (EULAR 2019), June 2019.
2. Mease PJ, et al. *J Am Acad Dermatol* 2013 Nov;69(5):729-735.
3. National Psoriasis Foundation. [About Psoriatic Arthritis](#). May 2019.
4. Arthritis Foundation. [Psoriatic Arthritis Symptoms](#). May 2019.

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