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FOR IMMEDIATE RELEASE

Sun Pharma Presents Long-term Study Results that Show Significant Skin Clearance with ILUMYA® (tildrakizumab-asmn) Maintained Over Four Years in People with Moderate-to-Severe Plaque Psoriasis

- *Additional data show people with and without metabolic syndrome respond similarly to ILUMYA treatment with comparable, positive results*

- *These results were presented at the 28th European Academy of Dermatology and Venereology Congress (EADV) in Madrid, Spain*

Mumbai, India and Princeton, NJ, October 9, 2019 – Sun Pharmaceutical Industries Ltd. (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" including its subsidiaries and/or associate companies) today announced that one of its wholly owned subsidiaries presented long-term follow-up data from ILUMYA® (tildrakizumab-asmn) Phase 3 reSURFACE 1 and 2 trials at the 28th European Academy of Dermatology and Venereology Congress (EADV) in Madrid, Spain.

The data showed that the significant response rates seen in the initial 52 and 64 weeks, respectively, were maintained over four years for people with moderate-to-severe plaque psoriasis, with more than half of participants achieving at least 90 percent skin clearance (Psoriasis Area Sensitivity Index (PASI) 90) and no new safety concerns recorded.[1,2] Additional study analyses showed that the 75 to 100 percent skin clearance achieved with ILUMYA treatment over three years was sustained equally in people with and without metabolic syndrome,[3,4] a common condition in people with psoriasis.[5]

"Psoriasis is an individualized condition and it can be a challenge for clinicians to prescribe a medicine that's effective over time, especially for patients with co-morbid conditions like metabolic syndrome," said Jeffrey Crowley, M.D., Bakersfield Dermatology, Bakersfield, California. "These data provide confidence that ILUMYA can help patients with moderate-to-severe plaque psoriasis, regardless of metabolic syndrome, achieve and maintain significant skin clearance over the long-term."

Eligible participants in the ILUMYA Phase 3 reSURFACE 1 and 2 trials who remained on treatment for the open-label extension studies received ILUMYA for a total of 208 weeks (reSURFACE 1) and 200 weeks (reSURFACE 2).[1,2] After four years, ILUMYA treatment led to significant and durable observed improvements in PASI and Physician Global Assessment (PGA) scores – key measures of disease severity.[1,2]

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- ILUMYA 100 mg (reSURFACE 1, reSURFACE 2):
  - PASI 75: 82 percent, 89 percent
  - PASI 90: 56 percent, 64 percent
  - PASI 100: 28 percent, 35 percent
  - Percentage of participants with favorable PGA response: 58 percent, 65 percent

ILUMYA 100 mg was well-tolerated, with a low rate of adverse events (AEs) that were comparable or numerically lower than placebo based upon exposure-adjusted rates for many AE categories.[1,2]

Researchers also analyzed the reSURFACE 1 and reSURFACE 2 studies to glean insights into whether ILUMYA's efficacy was similar in people with metabolic syndrome (defined as elevated blood pressure, body mass index/obesity, triglycerides and glucose and low HDL cholesterol levels), as this co-morbid condition can negatively affect people's response to most biologic psoriasis medicines.[6] This post-hoc analysis showed that the skin clearance levels achieved and sustained with ILUMYA 100 mg at three years were comparable in participants with and without metabolic syndrome.[3,4]

- reSURFACE 1:
  - PASI 75: 69 percent with metabolic syndrome; 71 percent without metabolic syndrome
  - PASI 90: 42 percent with metabolic syndrome; 51 percent without metabolic syndrome
  - PASI 100: 27 percent with metabolic syndrome; 23 percent without metabolic syndrome

- reSURFACE 2:
  - PASI 75: 73 percent with metabolic syndrome; 79 percent without metabolic syndrome
  - PASI 90: 57 percent with metabolic syndrome; 60 percent without metabolic syndrome
  - PASI 100: 34 percent with metabolic syndrome; 32 percent without metabolic syndrome

Three-year adverse event rates usually associated with metabolic syndrome, such as infections, cardiovascular events or complications of diabetes, were no different in study participants with and without metabolic syndrome.[3,4]

"Moderate-to-severe psoriasis is a lifelong condition, and at Sun Pharma we're committed to helping people find treatment options that work consistently over time, regardless of any co-morbid conditions, to help manage the frustrating symptoms that for so many years are a part of everyday life," said Alan Mendelsohn, M.D., Associate Vice President, Dermatology Medical Affairs, Sun Pharma. "ILUMYA has been proven to provide significant skin clearance that begins soon after initial use and is maintained for years, with just four doses a year following two starter doses, without demonstrating any new or increased risk of safety events."

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About the Studies

reSURFACE 1 Extension Study
reSURFACE 1 was a three-part, double-blind, randomized, controlled, 64-week study that evaluated ILUMYA 100 mg and 200 mg at weeks 0 and 4, and every subsequent 12 weeks in adults with moderate-to-severe chronic plaque psoriasis. 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 64) were eligible to enroll in the extension study and continued on the same ILUMYA dose once every 12 weeks. Researchers evaluated PASI and PGA response (score of 0 or 1 with ≥2 grade reduction from baseline) and incidence rates for prespecified adverse events, including severe infections, cardiovascular events and drug-related hypersensitivities.

reSURFACE 2 Extension Study
reSURFACE 2 was a three-part, double-blind, randomized, controlled, 52-week study that compared the safety and efficacy of ILUMYA 100 mg and 200 mg to placebo and etanercept 50 mg. At Week 12, patients with at least a 50 percent improvement in PASI 50 at base study completion on ILUMYA 100 or 200 mg were eligible to enroll in the extension study and continued on the same ILUMYA dose every 12 weeks. Partial and non-responders to etanercept were converted to treatment with ILUMYA 200 mg, while responders (PASI ≥75) were discontinued. Researchers evaluated PASI and PGA response (score of 0 or 1 with ≥2 grade reduction from baseline) and incidence rates for prespecified adverse events, including severe infections, cardiovascular events and drug-related hypersensitivities.

reSURFACE 1 and reSURFACE 2 Post-Hoc Analyses
Post-hoc analyses of reSURFACE 1 and reSURFACE 2 were conducted to evaluate changes in ILUMYA's efficacy in people with and without metabolic syndrome, which was previously defined as those who met the National Cholesterol Education Program-Adult Treatment Panel III criteria (including elevated blood pressure, body mass index [BMI], triglycerides, and glucose). Researchers stratified efficacy results – determined by proportion of patients with at least PASI 75 and absolute and median percent PASI change from baseline – up to week 148 in both studies.

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 under the brand name ILUMETRI™ in Europe.

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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.

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 (≥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.

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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 second 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 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. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

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References

1. Crowley J, et al. Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 1. Presented at the European Academy of Dermatology and Venereology Congress (EADV), October 2019.
2. Langley RG, et al. Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 2. Presented at EADV, October 2019.
3. Lebwohl MG, et al. Tildrakizumab Efficacy by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 3-Year Data from the Phase 3 reSURFACE 1 Study. Presented at EADV, October 2019.
4. Gottlieb AB, et al. Tildrakizumab Efficacy by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 3-Year Data from the Phase 3 reSURFACE 2 Study. Presented at EADV, October 2019.
5. Gisondi P, et al. *Clin Dermatol*. 2018;36(1):21-28.
6. Jacobi A, et al. *Int J Dermatol*. 2016;55(3):296-302.

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