Sun Pharmaceutical Industries Ltd.
SUN HOUSE, CTS No. 201 B/1,
Western Express Highway, Goregaon (E),
Mumbai 400063, India
Tel.: (91-22) 4324 4324 Fax.: (91-22) 4324 4343
CIN: L24230GJ1993PLC019050
www.sunpharma.com

FOR IMMEDIATE RELEASE

Sun Pharma Announces Long-term Insights into the Clinical Use of ILUMYA™ (tildrakizumab-asmn) in a Cross Section of People Living with Moderate-to-Severe Plaque Psoriasis

- *With 20 presentations at the American Academy of Dermatology (AAD) Virtual Meeting Experience 2020, Sun Pharma is dedicated to offering ongoing clinical support and continued development of ILUMYA*

- *Long-term ILUMYA data analysis demonstrated continued improvement and sustained response rates in moderate-to-severe plaque psoriasis and offers clinical insights into bio naïve patient population subset*

- *Six additional presentations identified potential of ILUMYA in patients who are more difficult to treat, including those with metabolic syndrome and those over 65 years of age*

- *Updated cost analysis reveals ILUMYA is still among the most cost-effective first-line treatments for moderate-to-severe plaque psoriasis*

Mumbai, India and Princeton, NJ, June 13, 2020 – 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 further evidence of the long-term use and cost-effectiveness of ILUMYA™ (tildrakizumab-asmn) in moderate-to-severe plaque psoriasis at the American Academy of Dermatology (AAD) Virtual Meeting Experience 2020.

Long-term analyses of the reSURFACE 1 and 2 extension studies found that ILUMYA offers sustained and improved results in patients with moderate-to-severe plaque psoriasis who received treatment for up to four years with no new safety concerns recorded.[1,2] Furthermore, the safety profile of ILUMYA was reconfirmed in a five-year analysis that demonstrated low and similar exposure-adjusted incidence rates of malignancies from year four to year five. A majority of malignancies were singular events with similar incidence rates as seen in the general US population.[3]

Another post-hoc analysis of 335 patients who were predominately bio naïve showed that those who achieved PASI 50 or higher after 6 months of treatment with ILUMYA saw continued improvement and sustained response rates when they maintained treatment for up to three years. Those patients who achieved PASI ≥90 at week 28 had rapid improvements as early as week 4.[4]

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Mean Percent Change from Baseline PASI Score Over Time			
	Week 28 (n)	**Week 52 (n)**	**Week 148 (n)**
PASI 50-74 at Week 28	64.4% (34)	79.4% (34)	81.4% (22)
PASI 75-89 at Week 28	83.5% (79)	83.8% (78)	94.8% (63)
PASI 90-99 at Week 28	95% (131)	85.3% (131)	92.4% (117)
PASI 100 at Week 28	100% (91)	98% (90)	95.4% (81)

*95% confidence interval | Data are as observed and sample size at each study week is based on subjects with non-missing data.

ILUMYA 100 mg was well-tolerated, with a low rate of adverse events (AEs) that were comparable or numerically lower than placebo or etanercept based upon exposure-adjusted rates for many AE categories. The most common (≥1%) adverse reactions associated with ILUMYA are upper respiratory infections, infection site reactions, and diarrhea.

"Notably, 85 percent of the patients included in our analysis had never used a biologic before even though they have been living with psoriasis for over a decade," said lead investigator Kim Papp, M.D., Ph.D., founder and president of Probity Medical Research in Waterloo, Ontario, Canada. "This tells dermatologists that ILUMYA will treat different types of patients who have moderate-to-severe plaque psoriasis. ILUMYA is a good treatment option to consider for treatment naïve patients; for patients having inadequate response to topicals or who are intolerant to or not responding well to oral treatments; and for any patient in need of a new treatment to address the chronic nature of this disease."

Six additional long-term analyses showed ILUMYA offers similar efficacy and safety results in patients with metabolic syndrome or patients who are over 65 years of age, factors that may make treatment more complex.[5,6,7,8,9,10] Metabolic syndrome has a higher prevalence in patients with moderate-to-severe psoriasis compared to the overall population and an impact on response rates to many anti-TNF and IL-17 treatments.[8] The analyses found that metabolic syndrome had minimal effect on the positive results seen in people treated with ILUMYA for up to three years and there was no increase in cardiac events or worsening of diabetes, compared to those without metabolic syndrome.

Furthermore, a 10-year cost analysis study revealed that ILUMYA is among the most cost-effective first-line therapies for treating moderate-to-severe plaque psoriasis and is more cost-effective than many other biologics, including risankizumab, secukinumab, guselkumab, ixekizumab, adalimumab, ustekinumab, etanercept, or certolizumab pegol.[11]

"It is exciting to share this wealth of clinical insights that continue to confirm the potential of ILUMYA to manage moderate-to-severe plaque psoriasis effectively and safely across different types of patients and as a cost-effective, first-line biologic treatment option," said Alan Mendelsohn, M.D., Associate Vice President, Dermatology Medical Affairs, Sun Pharma. "We are dedicated to continue

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bringing insights and support on the use of ILUMYA in daily clinical practice as well as exploring its potential for people living with other chronic autoimmune diseases."

ILUMYA is approved for adults with moderate-to-severe plaque psoriasis and is being evaluated for other possible uses. See ongoing studies below for more information.[12,13] Visit www.ILUMYA.com to learn more about the ILUMYA SUPPORT Lighting the Way™ program that helps patients get started with treatment, understand cost and saving options, and connect with experts and others living with plaque psoriasis.

Please click here for Full Prescribing Information and Medication Guide.

Notable ILUMYA Analyses Presented at the AAD Virtual Meeting Experience 2020

- Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 1 (Abstract #15904). E-Poster.
- Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 2 (Abstract #15910). E-Poster.
- Rates of Malignancies Through 5 Years of Tildrakizumab Exposure in 2 Phase 3 Clinical Trials (Abstract #15966). E-Poster.
- Early and Maintained Response Levels in Psoriasis Patients Treated with Tildrakizumab (Abstract #17113). E-Poster.
- Effect of Metabolic Syndrome on Efficacy and Safety in Patients with Psoriasis Treated with Etanercept or Tildrakizumab: Post Hoc Analysis of 2 Phase 3 Clinical Studies (Abstract #15914). E-Poster.
- Tildrakizumab Efficacy by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 3-Year Data from the Phase 3 reSURFACE 1 Study (Abstract #15938). E-Poster.
- Safety of Tildrakizumab in Patients with Preexisting Metabolic Syndrome: Long-Term Data from the Post Hoc Analysis of 2 Phase 3 Clinical Studies (Abstract #15960). E-Poster.
- Relationship of Serum Glucose to Efficacy and Safety of Tildrakizumab Treatment for Psoriasis in Patients with and without Metabolic Syndrome from reSURFACE 1 and reSURFACE 2 (Abstract #15920). E-Poster.
- Tildrakizumab Efficacy by Metabolic Syndrome Status in Psoriasis: Post Hoc Analysis of 3-Year Data from the Phase 3 reSURFACE 2 Study (Abstract #15950). E-Poster.
- *Long-term safety of tildrakizumab in patients 65 years of age or older with moderate-to-severe psoriasis: pooled analysis through 3 years (148 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials (Abstract #13632). E-Poster.
- Clearance of Head Involvement in Plaque Psoriasis with Tildrakizumab Treatment in the Phase 3 reSURFACE 1 Study (Abstract #15953). E-Poster.
- Randomized, 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 (Abstract #15964). E-Poster.

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The 2020 AAD Virtual Meeting Experience is accessible via registration here.
**Abstract sponsored by Almirall who markets tildrakizumab-asmn in EU*

About the reSURFACE Extension Studies

The Phase-3 studies (reSURFACE 1 and reSURFACE 2) were randomized, placebo-controlled, multicenter, three-part studies designed to evaluate efficacy and safety of ILUMYA 100 mg and 200 mg in moderate-to-severe plaque psoriasis compared to placebo and comparative drug and to assess safety and tolerability. 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 52 or 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.

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.

IMPORTANT SAFETY INFORMATION

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

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

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 discontinue ILUMYA until the infection resolves.

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Evaluate patients for 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 ILUMYA treatment.

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.

Most common (≥1%) adverse reactions associated with ILUMYA include upper respiratory infections, injection site reactions, and diarrhea. Adverse reactions that occurred at rates less than 1% but greater than 0.1% in the ILUMYA group and at a higher rate than in the placebo group included dizziness and pain in extremity.

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. J. Crowley, et al. Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis 4-Year Results from reSURFACE 1. Presented at 2020 AAD Virtual Meeting Experience, June 2020.
2. R. Langley, et al. Efficacy and Safety of Long-Term Tildrakizumab for Plaque Psoriasis: 4-Year Results from reSURFACE 2. Presented at 2020 AAD Virtual Meeting Experience, June 2020.
3. J. Cather, et al. Rates of malignancies through 5 years of tildrakizumab exposure in reSURFACE 1 and reSURFACE 2. Presented at 2020 AAD Virtual Meeting Experience, June 2020.
4. K Papp, et al. Early and Maintained Response Levels in Psoriasis Patients Treated with Tildrakizumab. Presented at 2020 AAD Virtual Meeting Experience, June 2020.
5. A. Gottlieb, et al. Effect of Metabolic Syndrome on Efficacy and Safety in Patients with Psoriasis Treated with Etanercept or Tildrakizumab: Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and reSURFACE 2). Presented at 2020 AAD Virtual Meeting Experience, June 2020.
6. M. Lebwohl, 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 2020 AAD Virtual Meeting Experience, June 2020.
7. M. Lebwohl, et al. Safety of Tildrakizumab in Patients with Preexisting Metabolic Syndrome: Long-Term Data from the Post Hoc Analysis of 2 Phase 3 Clinical Studies (reSURFACE 1 and reSURFACE 2). Presented at 2020 AAD Virtual Meeting Experience, June 2020.
8. A. Gottlieb, 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 2020 AAD Virtual Meeting Experience, June 2020.
9. M. Lebwohl, et al. Relationship of Serum Glucose to Efficacy and Safety of Tildrakizumab Treatment for Psoriasis in Patients with and Without Metabolic Syndrome from reSURFACE 1 and reSURFACE 2. Presented at 2020 AAD Virtual Meeting Experience, June 2020.
10. V. Kerkhof, et al. Long term safety of tildrakizumab in patients 65 years of age or older with moderate to severe psoriasis: pooled analysis through 3 years (148 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials. Presented at 2020 AAD Virtual Meeting Experience, June 2020.
11. X. Jia, et al. Comparative Cost-Effectiveness for Tildrakizumab and Other Targeted Therapies for the Treatment of Moderate-to-Severe Plaque Psoriasis in the United States. Presented at 2020 AAD Virtual Meeting Experience, June 2020.

12. P. Mease, et al. Randomized, 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. Presented at 2020 AAD Virtual Meeting Experience, June 2020.
13. M. Menter, et al. Clearance of Head Involvement in Plaque Psoriasis with Tildrakizumab Treatment in the Phase 3 reSURFACE 1 Study. Presented at 2020 AAD Virtual Meeting Experience, June 2020.

Contacts:

Investors:
Nimish Desai
Tel +91 22 4324 4324, Xtn 2778
Tel Direct +91 22 4324 2778
Mobile +91-98203 30182
E mail nimish.desai@sunpharma.com

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

U.S. Media:
Vinita Alexander
Tel Direct +1 609-720-8197
Mobile +1 732-258-6725
E mail vinita.alexander@sunpharma.com