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FOR IMMEDIATE RELEASE

Sun Pharma Announces Regulatory Filing of Tildrakizumab in Japan

- *Japan is a key market with approximately 430,000 people currently suffering from psoriasis and psoriatic arthritis*[1]
- *Filing is a significant milestone in establishing the specialty business in Japan and adds one more potential market for Tildrakizumab globally*

Mumbai, India & Tokyo, Japan, August 01, 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 that one of its wholly owned subsidiaries has filed an application for Manufacturing and Marketing Authorization of Tildrakizumab for moderate-to-severe psoriasis and psoriatic arthritis with the Pharmaceuticals and Medical Devices Agency (PMDA), Japan.

Kirti Ganorkar, EVP & Head Global Business Development, Sun Pharma said, "Sun Pharma is committed to growing its global dermatology franchise, with Tildrakizumab as its lead product. We continue to build our pipeline and capabilities in this important therapeutic area of significant unmet need. This filing in Japan is a step forward for Sun Pharma in expanding the global franchise for the product. It offers a potential new treatment option to patients who struggle everyday with the chronic nature of these aliments."

The recent acquisition of Pola Pharma (Pola) in Japan will help Sun Pharma leverage Pola's strong presence in the dermatology segment to commercialize Tildrakizumab post regulatory approval. Sun Pharma had announced the closure of the Pola acquisition in January 2019.

About Tildrakizumab-asmn

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. It was approved by USFDA in March 2018 and is being currently marketed in the US under the ILUMYA™ brand name.

It is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The US FDA approval was based on data from the pivotal Phase-3 reSURFACE clinical development program, which consisted of two randomized, double-blind, placebo-controlled trials of more than 1,800 patients across over 200 clinical trial sites.

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Results from the Phase-3 reSURFACE 1 and 2 studies were published in The Lancet in July 2017, with primary endpoints presented at the 25th European Academy of Dermatology and Venereology (EADV) Congress.

Both Phase-3 studies met the primary efficacy endpoints, with an average of 63 percent of patients receiving Tildrakizumab 100 mg achieving 75 percent of skin clearance (Psoriasis Area Sensitivity Index or PASI 75) by week 12, and 77 percent of patients achieving 75 percent skin clearance after 28 weeks (64 percent and 80 percent in reSURFACE 1, 61 percent and 74 percent in reSURFACE 2). Similarly, an average of 57 percent and 66 percent of patients receiving Tildrakizumab 100 mg had a Physician's Global Assessment (PGA) score of "clear" or "minimal" at weeks 12 and 28, respectively. Additionally, a higher number of Tildrakizumab-treated patients achieved PASI 90 and PASI 100 compared to placebo and etanercept.

Tildrakizumab has also been approved and commercialized in Australia under the ILUMYA™ brand name and in Europe under the ILUMETRI™ brand name.

IMPORTANT SAFETY INFORMATION

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

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

Tildrakizumab may increase the risk of infection. Treatment with Tildrakizumab 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 Tildrakizumab in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving Tildrakizumab 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 Tildrakizumab until the infection resolves.

Evaluate patients for TB infection prior to initiating treatment with Tildrakizumab. Do not administer Tildrakizumab to patients with active TB infection. Initiate treatment of latent TB prior to administering Tildrakizumab. Consider anti-TB therapy prior to initiation of Tildrakizumab in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving Tildrakizumab should be monitored closely for signs and symptoms of active TB during and after Tildrakizumab treatment.

Most common (≥1%) adverse reactions associated with Tildrakizumab include upper respiratory

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infections, injection site reactions, and diarrhea. Adverse reactions that occurred at rates less than 1% but greater than 0.1% in the Tildrakizumab group and at a higher rate than in the placebo group included dizziness and pain in extremity.

About the Phase-3 reSURFACE Trials

The Phase-3 studies (reSURFACE 1 and reSURFACE 2) were randomized, placebo-controlled, multicenter, three-part studies designed to demonstrate efficacy of Tildrakizumab in moderate-to-severe plaque psoriasis compared to placebo and comparative drug and to assess safety and tolerability. Part one of the studies randomized patients into three or four treatment arms, including Tildrakizumab 100 mg, Tildrakizumab 200 mg, placebo and etanercept (reSURFACE 2 only). After Week 12, patients on placebo were then re-randomized into Tildrakizumab 100 mg and 200 mg treatment arms to proceed into part two of the studies. Finally, in part three of the reSURFACE 1 study, responders (PASI ≥75) and partial responders (PASI ≥50 and PASI <75) to Tildrakizumab were re-randomized after Week 28 to continue the same treatment, a different dose of Tildrakizumab or placebo. Partial and non-responders to etanercept were treated with Tildrakizumab 200 mg in part three of the reSURFACE 2 study. Patients with guttate, erythrodermic, or pustular psoriasis were excluded.

About Psoriasis

Psoriasis is a chronic immune disease that appears on the skin, affecting approximately 125 million people worldwide.[2] The non-contagious disorder speeds the growth cycle of skin cells[4] and results in thick scaly areas of skin.[3] The most common form, affecting about 80 to 90 percent of people with psoriasis, is called plaque psoriasis.[4] It appears as red, raised areas of skin covered with flaky white scales which may be itchy and painful and can crack and bleed.[4] Twenty percent of people with plaque psoriasis are considered moderate-to-severe[4], and many continue to struggle with the ongoing, persistent nature of this chronic disease.

About Sun Pharma, Merck & Co., Inc., Kenilworth, NJ, USA, Agreement

Sun Pharmaceutical Industries Ltd.'s wholly owned subsidiary licensed worldwide rights to Tildrakizumab from a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, in 2014. Funded by a Sun Pharma subsidiary, Merck & Co., Inc., Kenilworth, NJ, USA is responsible for the completion of Phase-3 trials in patients with moderate-to-severe plaque psoriasis and submission of a Biologics License Application to the United States Food and Drug Administration (FDA), as well as manufacturing finished goods to support Sun Pharma's initial product launch. Sun Pharma will be responsible for all post-approval regulatory activities, including subsequent submissions, pharmacovigilance, post approval studies, manufacturing and commercialization of the approved product. Sun Pharma will also be responsible for all regulatory, pharmacovigilance, post approval studies, manufacturing and commercialization of approved products for all non-U.S. markets. Merck & Co., Inc., Kenilworth, NJ, USA is eligible to receive milestone payments and royalties on

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sales of Tildrakizumab.

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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