

FOR IMMEDIATE RELEASE

Sun Pharma and China Medical System Holdings enter into a License Agreement for Tildrakizumab in Greater China

- *Relationship gives Sun Pharma access to Greater China market for Tildrakizumab*
- *China to become a key market in future with more than 6.5 million^{4,5} people currently suffering from psoriasis and psoriatic arthritis*
- *Tildrakizumab enjoys patent protection in China*

Mumbai, India June 27, 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 entered into a licensing agreement with a subsidiary of China Medical System Holdings Ltd. (CMS) for the development and commercialization of Tildrakizumab, an innovative biologic product, for psoriasis and psoriatic arthritis in Greater China (including Mainland China, Hong Kong Special Administrative Region, Macao Special Administrative Region and Taiwan).

Under terms of the license agreement, CMS will pay Sun Pharma an initial upfront payment, regulatory and sales milestone payments, and royalties on net sales, the terms of which are confidential. CMS will be responsible for development, regulatory filings and commercialization of the product in China. The initial tenure of the agreement shall be 15 years from the first commercial sale of Tildrakizumab in Greater China, and may be extended for additional 3 years’ subject to certain conditions defined in the agreement.

“This licensing agreement marks our entry into the Greater China market which is the second largest pharmaceutical market globally. Sun Pharma is committed to growing its 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. We are excited to be partnering with a leading pharmaceutical company like CMS to offer Tildrakizumab as an alternative treatment for psoriasis and psoriatic arthritis in Greater China,” said Dilip Shanghvi, Managing Director, Sun Pharma.

About Tildrakizumab-asmn

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. 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.

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 ($\geq 1\%$) adverse reactions associated with Tildrakizumab 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 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.¹ The non-contagious disorder speeds the growth cycle of skin cells³ and results in thick scaly areas of skin.² The most common form, affecting about 80 to 90 percent of people with psoriasis, is called plaque psoriasis.³ It appears as red, raised areas of skin covered with flaky white scales which may be itchy and painful and can crack and bleed.³ Twenty percent of people with plaque psoriasis are considered moderate-to-severe³, 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 sales of Tildrakizumab.

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



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

About CMS

CMS is a well-established, innovation-driven specialty pharma company with focus on sales and marketing in China. CMS is committed to offering competitive products and services to meet China's unmet medical needs with a strong and professional sales and marketing network as well as a promotion platform covering the whole Chinese market. It is listed on the Hong Kong Stock Exchange (867.HK). For more information, please see <https://en.cms.net.cn/CmsNewWebEn/Index.aspx>

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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