

FOR IMMEDIATE RELEASE

Sun Pharma Announces U.S. FDA Approval of ILUMYA™ (tildrakizumab-asmn) for the Treatment of Moderate-to-Severe Plaque Psoriasis

Mumbai, India and Princeton, NJ, March 21, 2018 – 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 the U.S. Food and Drug Administration (FDA) has approved ILUMYA™ (tildrakizumab-asmn) for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. ILUMYA™ selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor leading to inhibition of the release of pro-inflammatory cytokines and chemokines. ILUMYA™ is administered at a dose of 100 mg by subcutaneous injection every 12 weeks, after the completion of initial doses at weeks 0 and 4. ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients.

“With the approval of ILUMYA™ and our long-standing commitment in dermatology, we are focused on making a difference for people living with moderate-to-severe plaque psoriasis,” said Abhay Gandhi, President and Chief Executive Officer, North America, Sun Pharma. “We are committed to working with all relevant stakeholders to make ILUMYA™ available to appropriate people with plaque psoriasis.”

The FDA approval of ILUMYA™ for the treatment of adults with moderate-to-severe plaque psoriasis was supported by data from the pivotal Phase-3 reSURFACE clinical development program. In the two multicenter, randomized, double-blind, placebo-controlled trials (reSURFACE 1 and reSURFACE 2), 926 adult patients were treated with ILUMYA™ (N=616) or placebo (N=310). Results from these 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, demonstrating significant clinical improvement with ILUMYA™ 100 mg compared to placebo when measured by at least 75 percent of skin clearance (Psoriasis Area Sensitivity Index or PASI 75) and Physician’s Global Assessment (PGA) score of “clear” or “minimal” at week 12 after two doses.

Efficacy Primary Endpoint at Week 12 in Adults with Plaque Psoriasis (NRI*)				
	reSURFACE 1 Study (NCT01722331)		reSURFACE 2 Study (NCT01729754)	
	ILUMYA 100 mg n=309	Placebo n=154	ILUMYA 100 mg n=307	Placebo n=156
PGA of “clear” (0) or “minimal” (1)†	179 (58%)	11 (7%)	168 (55%)	7 (4%)
PASI 75†	197 (64%)	9 (6%)	188 (61%)	9 (6%)
PASI 90	107 (35%)	4 (3%)	119 (39%)	2 (1%)
PASI 100	43 (14%)	2 (1%)	38 (12%)	0 (0%)

* NRI = Non-Responder Imputation † Co-Primary Endpoints

Of the patients in the reSURFACE 1 study 74 percent (229 patients) achieved 75 percent skin clearance at week 28 after three doses, and 84 percent of patients who continued receiving ILUMYA™ 100 mg maintained PASI 75 at week 64 compared to 22 percent of patients who were re-randomized to placebo. In addition, 69 percent of the patients receiving ILUMYA™ 100 mg who had a PGA score of “clear” or “minimal” at week 28 maintained this

response at week 64 compared to 14 percent of patients who were re-randomized to placebo.

Full Prescribing Information and Medication Guide for ILUMYA are attached.

PDF: <http://www.sunpharma.com/Media/Press-Releases/ILUMYA%20US%20Prescribing%20Information.pdf>

PDF: <http://www.sunpharma.com/Media/Press-Releases/ILUMYA%20US%20Medication%20Guide.pdf>

IMPORTANT SAFETY INFORMATION (continued)

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.

Evaluate patients for TB infection prior to initiating treatment with ILUMYA™. Initiate treatment of latent TB prior to administering ILUMYA™. Monitor patients for signs and symptoms of active TB during and after ILUMYA™ treatment. Do not administer ILUMYA™ to patients with active TB infection.

Prior to initiating ILUMYA™, consider completion of all age-appropriate immunizations according to current immunization guidelines. Avoid use of live vaccines in patients treated with ILUMYA™.

Most common ($\geq 1\%$) 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 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 ILUMYA™ 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 ILUMYA™ 100 mg, ILUMYA 200 mg, placebo and etanercept (reSURFACE 2 only). After Week 12, patients on placebo were then re-randomized into ILUMYA™ 100 mg and 200 mg treatment arms to proceed into part two of the studies. Finally, in part three of the studies, responders (PASI ≥ 75) and partial responders (PASI ≥ 50 and PASI < 75) to ILUMYA™ were re-randomized after Week 28 to continue the same treatment, a different dose of ILUMYA™ or placebo. Partial and non-responders to etanercept were treated with ILUMYA™ 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. It is a non-contagious disorder that speeds the growth cycle of skin cells¹ and results in thick scaly areas of skin². The most common form, affecting about 80 to 90 percent of people living with psoriasis, is called plaque psoriasis³. It appears as red, raised areas of skin covered with flaky white scales, which may be itchy and painful and can crack and bleed². Many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease.

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About Sun Dermatology

Sun Dermatology (the branded dermatology division of a wholly owned subsidiary of Sun Pharma) 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 Pharma, along with its subsidiaries, is ranked fourth in dermatology prescription volume within the U.S. per IMS and is fifth largest specialty generic pharmaceutical company globally. In addition to ILUMYA™, Sun Dermatology is comprised of several branded products indicated for the treatment of acne and actinic keratosis with a focus on other dermatologic conditions.

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

Sun Pharmaceutical Industries Ltd.'s wholly owned subsidiary licensed worldwide rights to ILUMYA™ from a subsidiary of Merck & Co., Inc., Kenilworth, NJ, USA, in 2014. Funded by a Sun Pharma subsidiary, Merck & Co., Inc., Kenilworth, NJ, USA was responsible for the completion of Phase-3 trials 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 ILUMYA™.

About Sun Pharma, Almirall S.A, Europe, Agreement

Sun Pharma and its wholly owned subsidiary and Almirall (Spanish Stock Exchange ticker: ALM) closed on July 2016 a licensing agreement on the development and commercialization of tildrakizumab-asmn for psoriasis in Europe. Under the terms of the licensing agreement, Almirall is able to lead European studies, and participate in larger Global clinical studies for plaque psoriasis indication subject to the terms of the Sun Pharma – Merck & Co., Inc., Kenilworth, NJ, USA agreements, as well as certain cost sharing agreements. Sun Pharma will be eligible to receive development and regulatory milestone payments and, additionally, sales milestone payments and royalties on net sales. Sun Pharma will continue to lead development of tildrakizumab-asmn for other indications, where Almirall will have right of first negotiation for certain indications in Europe. The agreement between Sun Pharma and Almirall remains subject to the exclusive licensing agreement between Sun Pharma and Merck & Co., Inc., Kenilworth, NJ, USA.

About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fifth 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 150 countries across the world. Sun Pharma's global presence is supported by 41 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 3 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 8% of annual revenues. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

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References

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3. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. *J Am Acad Dermatol* 2008 May; 58(5):826-50.

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- *If you are changing jobs, please send us your new email id. We would like to be in touch with you and keep you updated on happenings at Sun Pharma.*

We would be happy to host one-on-one, group and telephone meetings for updates on the Company. If you wish to setup such a meeting, feel free to get in touch with us. In-person meetings can be at our office or elsewhere depending on mutual convenience. Our contact details:

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