



**FOR IMMEDIATE RELEASE**

## **Sun Pharma to Announce Late-Breaking Results for Investigational IL-23p19 inhibitor, Tildrakizumab, Achieves Primary End Point in Both Phase-3 Studies in Patients with Moderate-to-Severe Plaque Psoriasis**

*Pivotal Data of the Targeted IL-23p19 Antibody to be Presented for the First Time at the 25<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Congress*

**Mumbai, India and Princeton, New Jersey, October 1, 2016** – Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies, through its wholly owned subsidiary) today will announce late-breaking data from two pivotal Phase-3 clinical trials (reSURFACE 1 and 2) achieving the primary endpoint with tildrakizumab, an investigational IL-23p19 inhibitor, in patients with moderate-to-severe plaque psoriasis at the 25<sup>th</sup> European Academy of Dermatology and Venereology (EADV) Congress in Vienna, Austria. As indicated in a previous press release, top line results from these studies were announced on May 4, 2016.

The Phase-3 data results through week 28 are being presented for the first time as part of the “Late Breaking News” Session at the premier European dermatology conference where the latest in research and developments in the field are presented each year. Tildrakizumab clinical trials included over 1,800 patients from more than 200 clinical trial sites worldwide.

In the trials, an average of 63 percent of patients achieved 75 percent of skin clearance (Psoriasis Area Sensitivity Index or PASI 75) by week 12 after only two injections, and 77 percent achieved 75 percent skin clearance after 28 weeks and three injections of the 100 mg dose of tildrakizumab (64 percent and 80 percent in reSURFACE1, 61 percent and 74 percent in reSURFACE2). Similarly, an average of 57 percent and 66 percent of patients had a Physician’s Global Assessment (PGA) score of “clear” or “minimal” with the 100 mg dose at weeks 12 and 28 respectively.

Those receiving the 200 mg dose also saw an average of 64 percent and 78 percent of patients achieving PASI 75 at weeks 12 and 28 respectively. Also, 59 percent and 69 percent of the patients had PGA score of “clear” or “minimal” at weeks 12 and 28 respectively.

The data further showed that a higher number of patients on tildrakizumab achieved PASI 90 and 100 compared to placebo and etanercept. An average of 37 percent and 36 percent of patients on tildrakizumab achieved PASI 90 at week 12 with the 100 mg dose and 200 mg dose respectively which increased to 54 percent and 59 percent at week 28. Correspondingly, an average of 13 percent on tildrakizumab achieved PASI 100 at week 12 regardless of dose with an increase to 24 percent for the 100 mg dose and 30 percent for the 200 mg dose at week 28.

The overall safety profile of tildrakizumab in both Phase-3 clinical trials was consistent with the safety data observed in previously reported studies. The incidences of severe infections, malignancies, and



extended major cardiovascular events (MACE) were low and similar across treatment groups (1-3 percent).

"For patients with psoriasis, their condition is always top of mind and they struggle on a daily basis with the often debilitating effects of this chronic condition. In our studies, we saw that the targeted effects of tildrakizumab significantly improved skin clearance offering a potential new treatment option for many patients with quarterly dosing," said Dr. Kristian Reich, Professor of Dermatology at the Georg-August-University Göttingen and inflammation specialist at the Dermatologikum Hamburg in Germany.

"We are excited about these Phase-3 tildrakizumab results that further validate the central role of IL-23 as a key regulatory cytokine and treatment target in psoriasis. Tildrakizumab has the potential to be a new treatment that helps people living with moderate-to-severe psoriasis," said Jesper Jensen, Executive Vice President, Biologics and Dermatology, Sun Pharma. "At Sun Dermatology, we care to make a difference and seek to match our products and solutions making them accessible and available to patients and health care providers with unmet needs."

Additional findings from the Phase-3 clinical trials will be presented at upcoming scientific meetings and the preparations for regulatory submissions in both the U.S. and Europe are proceeding. In July 2016, Sun Pharma had announced a strategic licensing agreement with Almirall S.A (Spain) on the development and commercialization of tildrakizumab for psoriasis in Europe.

### **About Psoriasis**

Psoriasis is a chronic immune disease that appears on the skin. It affects an estimated 7.5 million people in the U.S. and approximately 125 million people worldwide<sup>1</sup>. It is a non-contagious disorder that speeds the growth cycle of skin cells<sup>1</sup> and results in thick scaly areas of skin<sup>2</sup>. The most common form of psoriasis, called plaque psoriasis, appears as red, raised areas of skin covered with flaky white scales, which may be itchy and painful and can crack and bleed<sup>2</sup>. Despite existing treatment options, many people with plaque psoriasis continue to struggle with the ongoing, persistent nature of this chronic disease impacting their everyday lives.

### **About Tildrakizumab Phase-3 reSURFACE Trial Design**

Tildrakizumab Phase-3 studies (reSURFACE 1 and 2) are randomized, placebo-controlled, multicenter 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. The co-primary efficacy endpoint of the two placebo controlled studies were the proportion of patients with Psoriasis Area Sensitivity Index 75 (PASI 75) response at week 12 compared to placebo and the proportion of participants with a Physician's Global Assessment (PGA) score of clear or minimal with at least a 2 grade reduction from baseline at week 12 compared to placebo. The reSURFACE 2 also included an etanercept comparator arm, with a key secondary endpoint comparing tildrakizumab and etanercept on PASI 75 and PGA. Other co-secondary endpoint of both placebo controlled studies included PASI 90 and PASI 100 responses at week 12 and PASI 75, 90 and 100 and PGA responses from baseline at Week 28. PGA measures lesion thickness, erythema and scaling across all of a patient's psoriasis lesions in order to determine the disease activity on a six-point scale from "clear" to "severe." A PASI score is a measure of psoriatic plaque redness, scaling and thickness and extent of the involvement in each region of the body. Treatment efficacy is often measured by reduction of PASI from baseline (i.e. 75 percent reduction is known as PASI 75), a 90 percent reduction is known as PASI 90 and PASI 100 is total clearance of skin disease.



### **About Tildrakizumab**

Tildrakizumab is an investigational humanized, anti-IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23. With this precise targeting, tildrakizumab has the potential to help control the pathogenic cells responsible for the inflammatory process of psoriasis with limited impact on the rest of the immune system.

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

Sun Pharma's wholly owned subsidiary, acquired worldwide rights to tildrakizumab from Merck (through a Merck subsidiary) known as MSD outside the United States and Canada, in 2014. Funded by a Sun Pharma subsidiary, Merck is responsible for the completion of Phase-3 trials in patients with mild-to-moderate plaque psoriasis and, as appropriate, submission of a Biologics License Application to the United States Food and Drug Administration (FDA). Merck is also responsible for manufacturing finished goods to support Sun Pharma's initial product launch. Post-approval in the U.S., Sun Pharma will be responsible for all other 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 is eligible to receive milestone payments and royalties on sales of tildrakizumab. The agreement between Sun Pharma and Almirall remains subject to the exclusive license agreement between Sun Pharma and Merck.

### **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 for psoriasis in Europe. Under terms of the license agreement, Almirall is able to lead European studies, and participate in larger Global clinical studies for psoriasis indication subject to the terms of the Sun Pharma – Merck 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 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 license agreement between Sun Pharma and Merck.

### **About Sun Dermatology**

Sun Pharma is committed to expanding our dermatology portfolio to bring healthcare providers and patients around the world more treatment options and ongoing support for conditions with high unmet medical needs like 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 the investigational candidate tildrakizumab, an investigational anti-IL-23p19 monoclonal antibody, Sun Dermatology is comprised of several branded products indicated for the treatment of acne and actinic keratosis with a focus on other dermatologic conditions with unmet needs such as psoriasis and atopic dermatitis.



## References

1. National Psoriasis Foundation. Facts about psoriasis. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed on June 27, 2016.
2. National Psoriasis Foundation. About Psoriasis. <https://www.psoriasis.org/about-psoriasis>. Accessed on June 27, 2016.
3. Reich K, et al. Tildrakizumab, selective IL-23p19 antibody, in the treatment of chronic plaque psoriasis: results from two randomized, controlled, Phase 3 trials (reSURFACE 1 and reSURFACE 2) [abstract]. Presented as a late breaking abstract at the European Academy of Dermatology and Venereology 2016. October 1, 2016.

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## **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 47 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2016 are approximately US\$ 4.3 billion, of which US contributes US\$ 2.1 billion. In India, the Company enjoys leadership across 12 different classes of doctors with 32 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 4 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 over 8% of annual revenues. For further information please visit [www.sunpharma.com](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live

## **Contacts: Sun Pharma**

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](mailto:nimish.desai@sunpharma.com)

Frederick Castro  
Tel +91 22 4324 4324, Xtn 2777  
Tel Direct +91 22 4324 2777  
Mobile +91 99206 65176  
E mail [frederick.castro@sunpharma.com](mailto:frederick.castro@sunpharma.com)

FleishmanHillard (PR Agency)  
Faith Moresco  
Tel +1 646-659-0642  
E mail [faith.moresco@fleishman.com](mailto:faith.moresco@fleishman.com)