

**FOR IMMEDIATE RELEASE**

## **Sun Pharma Announces US FDA Filing Acceptance of Biologics License Application (BLA) For Tildrakizumab**

*Tildrakizumab is being evaluated for treatment of moderate-to-severe plaque psoriasis*

**Mumbai, INDIA and New Jersey, USA, May 24, 2017** – Sun Pharmaceutical Industries Ltd (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries or associate companies) announces the U.S. Food and Drug Administration (FDA) acceptance of the Biologics License Application (BLA) for tildrakizumab. The FDA filing acceptance follows the acceptance of the regulatory filing of tildrakizumab by the European Medicines Agency (EMA) in March 2017. Tildrakizumab is an investigational IL-23p19 inhibitor being evaluated for the treatment of moderate-to-severe plaque psoriasis. The BLA filing for tildrakizumab was submitted by Merck & Co., Inc., Kenilworth, NJ, USA.

**According to Abhay Gandhi, CEO - North America Business, Sun Pharma,** *"At Sun Dermatology, we are committed to making a difference in the lives of patients and healthcare providers. The acceptance of the regulatory filing by the U.S. FDA marks a significant milestone as we seek to advance for tildrakizumab as a potential new treatment option for people who continue to struggle everyday with the chronic nature of psoriasis."*

The BLA filing for tildrakizumab with the U.S. FDA is based on two pivotal Phase III trials (reSURFACE 1 and 2) which included over 1,800 patients across more than 200 clinical trial sites, including some patients who have been treated with tildrakizumab for up to three and a half years. Data from these trials were most recently [presented](#) at the 2017 American Academy of Dermatology (AAD) Annual Meeting in March and previously [presented](#) at the 25<sup>th</sup> European Academy of Dermatology and Venereology Congress. Future presentations and publications of the reSURFACE Phase-3 pivotal trials will include more scientific insights on the data to week 52 and beyond. The clinical trials are designed to evaluate safety and efficacy for up to five years, and to date, some clinical trial participants have been treated with tildrakizumab for up to three and half years.

### **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.

### **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. Phase-3 tildrakizumab data provide further evidence for the role of the IL-23 pathway in helping to control the inflammatory process of psoriasis.

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

Tildrakizumab Phase-3 studies (reSURFACE 1 and 2) are 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 200mg, tildrakizumab 100mg, placebo and etanercept (reSURFACE 2 only). After Week 12 patients on placebo and etanercept were then re-randomized into tildrakizumab 200mg and 100mg treatment arms to proceed into part two of the studies. Finally, in part three of the studies, responders (PASI  $\geq$ 75) and partial responders (PASI  $\geq$ 50 and PASI <75) were re-randomized after Week 28 continue the same treatment, a different dose of tildrakizumab or placebo.

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 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 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. For further information, please visit [www.sunpharmaderm.com](http://www.sunpharmaderm.com)

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

Sun Pharmaceutical Industries Ltd.'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.

### **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.

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



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**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, 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 42 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 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 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**

**Media**

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)

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

**FleishmanHillard (PR Agency | US)**

**Sarah Connolly**

Tel +1 212-453-2034  
Mobile +1 347-559-3671  
E mail [sarah.connolly@fleishman.com](mailto:sarah.connolly@fleishman.com)