

**FOR IMMEDIATE RELEASE**

## **Sun Pharma Announces Data from Tildrakizumab Clinical Development Program to be Presented at the 2017 American Academy of Dermatology Meeting**

*Analyses from Pivotal Phase-3 reSURFACE Trials Offer Evidence for the Potential of the Investigational IL-23 Inhibitor Tildrakizumab as a Treatment Option for People with Moderate-to-Severe Psoriasis*

**Mumbai, India and Princeton, New Jersey, March 1, 2017** – Sun Pharmaceutical Industries Ltd (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, "Sun Pharma" and includes its subsidiaries or associate companies) today announced that several new analyses from Phase-1 and the pivotal Phase-3 clinical trials (reSURFACE 1 and 2) of tildrakizumab, an investigational IL-23p19 inhibitor being evaluated for the treatment of moderate-to-severe plaque psoriasis, will be presented at the 2017 Annual American Academy of Dermatology (AAD) Meeting taking place March 3-7 in Orlando, Florida.

"Not all people with psoriasis respond to currently available therapies or are able to maintain long-term symptom control. We are looking forward to sharing new and continued insights about tildrakizumab at AAD and upcoming meetings," said Jesper Jensen, Executive Vice President, Biologics and Dermatology, Sun Pharma. "With origins in dermatology that stretch back more than 30 years, we are committed to patients suffering from skin conditions. At Sun Dermatology, we care to make a difference."

Tildrakizumab data analyses being presented at AAD include:

- **Tildrakizumab, a Selective Anti-IL-23 Monoclonal Antibody, Is Effective in Subjects With Chronic Plaque Psoriasis Who Do Not Adequately Respond to Etanercept – Poster 5252** (Pearls of the Symposium Session on Friday, March 3<sup>rd</sup> from 2:30 PM to 2:40 PM)
- **Efficacy of Tildrakizumab, an Anti-IL23p19 Monoclonal Antibody, Stratified by Prior Exposure to Biologics in a Randomized, Placebo-Controlled Phase 3 Clinical Trial – Poster 5111** (Psoriasis & Other Papulosquamous Disorders Section on Sunday, March 5<sup>th</sup> from 9:20 AM to 9:25 AM)
- **Maintenance of Treatment Response in Chronic Plaque Psoriasis Patients Continuing Treatment or Discontinuing Treatment With Tildrakizumab in a 64-Week, Randomized Controlled, Phase 3 Trial – Poster 4855** (Psoriasis & Other Papulosquamous Disorders Section on Sunday, March 5<sup>th</sup> from 11:35 AM to 11:40 AM)
- **The Effect of Tildrakizumab, a High-Affinity, Selective Anti-IL23p19 Monoclonal Antibody, on Cytochrome P450 Metabolism – Poster 4792** (Pharmacology Section on Sunday, March 5<sup>th</sup> from 12:55 PM to 1:00 PM)

Over 1,800 patients across more than 200 clinical sites participated in the tildrakizumab Phase-3 pivotal trials (reSURFACE 1 and 2). Data were presented for the first time demonstrating results through 28 weeks of treatment at the European Academy of Dermatology and Venerology (EADV) Congress in October 2016. Regulatory filings for tildrakizumab in the U.S. and Europe are proceeding as planned.

### **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 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.

### **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.

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### **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.

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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 49 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 31 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

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