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

FOR IMMEDIATE RELEASE

Sun Pharma Announces Receipt of European Commission Approval For ILUMETRI® (tildrakizumab) By Almirall For Treatment Of Moderate-To-Severe Chronic Plaque Psoriasis

- *ILUMETRI® demonstrates lasting efficacy and safety through 3 years according to the positive results of a pooled analysis [2] of two phase-3 clinical trials*
- *With only 4 doses per year during maintenance, ILUMETRI® offers an easy and convenient dosing regimen*

Mumbai, India, September 18, 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 Almirall has received the European Commission (EC) approval for ILUMETRI® (tildrakizumab) for the treatment of adults with moderate-to-severe chronic plaque psoriasis who are candidates for systemic therapy. As indicated by Almirall, roll out of ILUMETRI® in Europe will start in the next few weeks. In July 2016, Sun Pharma out-licensed tildrakizumab to Almirall, for the development and commercialization of the product for psoriasis in Europe.

Tildrakizumab is a humanized high-affinity anti-IL-23p19 monoclonal antibody[1]. Due to its specific mechanism of action, it selectively blocks interleukin-23 (IL-23), an upstream inflammatory mediator cytokine, and acts by modifying the pathogenesis of the disease with limited impact on the rest of the immune system.

Its approval in Europe is based on the positive results from reSURFACE 1 and 2 phase-3 clinical trials[3], presented for the first time in October 2016 at the 25th European Academy of Dermatology and Venerology (EADV) Congress in Vienna (Austria). Both pivotal phase-3 clinical trials, which included over 1,800 patients from more than 200 clinical sites worldwide, showed ILUMETRI® has a high level of safety and efficacy.

According to both studies data, an average of 63% of patients achieved 75% of skin clearance (Psoriasis Area Sensitivity Index or PASI 75) by week 12 and an average of 78% at week 28. Moreover, an average of 59% of patients achieved PASI 90 and an average of 30% reached PASI 100 at week 28. Over a year, more than 92% of patients who responded to ILUMETRI® within 28 weeks maintained a PASI 75 response.

Moreover, the results of a pooled analysis through three years[2] from resurface 1 and 2 phase-3 trials show the consistent maintenance of efficacy and safety over three years of ILUMETRI® in patients with moderate-to-severe chronic plaque psoriasis who were responders at week 28. According to the data, PASI 75 responses were maintained with continued treatment with ILUMETRI® in 90% of patients up to week 148[2]. ILUMETRI® was well-tolerated with very low drug-related serious adverse events and discontinuation rates.

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 ILUMETRI®

ILUMETRI® is a humanized, anti-IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23. With this precise targeting, ILUMETRI® 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 Psoriasis

Psoriasis is a chronic immune disease that appears on the skin. It affects an estimated 7.8 million adults in Europe and approximately 125 million people worldwide[4]. It is a non-contagious disorder that accelerates the growth cycle of skin cells and results in thick scaly areas of skin. 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. Despite different treatment options existing, many people with plaque psoriasis 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.

References

1. ILUMETRI® Summary of Product Characteristics

2. Thaçi D, Iversen L, Pau-Charles I, Rozzo S, Blauvelt A, Reich K. Long-term efficacy and safety of tildrakizumab in patients with moderate-to-severe psoriasis who were responders at week 28: pooled analysis through 3 years (148 weeks) from reSURFACE 1 and reSURFACE 2 phase 3 trials. Presented at European Academy of Dermatology and Venereology, September 2018.

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.

4. Greb JE, Goldminz AM, Elder JT, et al. Psoriasis. Nat Rev Dis Primers. 2016;2:16082.

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

Disclaimer:

Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or industry conditions or events may be "forward looking statements" within the meaning of applicable securities laws and regulations. Actual results, performance or achievements could differ materially from those expressed or implied.

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 42 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 13 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 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.

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