

FOR IMMEDIATE RELEASE

Sun Pharma Announces Positive Results of Two Pivotal Phase-3 Clinical Trials of Tildrakizumab in Patients with Moderate-to-Severe Plaque Psoriasis

First IL-23p19 Therapeutic Antibody Meets Primary Endpoints in Both Placebo-Controlled Studies and Secondary Endpoint in Active-Comparator Etanercept Arm

Mumbai, May 04, 2016: Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies) today announced that two pivotal Phase-3 clinical trials evaluating the efficacy and safety of the investigational IL-23p19 inhibitor antibody tildrakizumab (MK-3222) in patients with moderate-to-severe plaque psoriasis met their primary endpoints for both evaluated doses.

The co-primary efficacy endpoints of the placebo controlled studies (MK-3222-010 and MK-3222-011) were: the proportion of participants 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 overall safety profile of tildrakizumab in both Phase-3 clinical trials was consistent with the safety data observed in previously reported studies.

The second study (MK-3222-011) also included an etanercept comparator arm, with a key secondary endpoint comparing tildrakizumab and etanercept on PASI 75 and PGA. Tildrakizumab 200mg was superior to etanercept on both PASI 75 and PGA endpoints at week 12, while the 100 mg dose showed superiority to etanercept on PASI 75 only.

"Tildrakizumab is the first IL-23p19 inhibitor to demonstrate positive results in Phase-3 clinical trials for the treatment of moderate-to-severe plaque psoriasis, further validating the importance of the role of IL-23 in psoriasis. We are encouraged by these results and the potential to provide a new treatment option to patients with moderate-to-severe plaque psoriasis, a disease that often takes both a physical and emotional toll on their lives," stated Dilip Shanghvi, Managing Director, Sun Pharma. "We would like to thank the over 1,800 patients who participated as well as the investigators at more than 200 clinical sites."

"While there are existing treatment options for psoriasis, many patients continue to struggle with the debilitating impact this chronic disease can have on their bodies, their lives and their families," said Kim Papp, MD, clinical trial investigator and president, Probitry Medical Research, Inc. "Tildrakizumab works by selectively targeting IL-23, specifically the p19 component of the cytokine. Blocking this key cytokine helps control the pathogenic cells responsible for the inflammatory process of psoriasis. These new data are encouraging and support the potential of tildrakizumab as a new treatment option for patients."

The preparations for submission of a Biologics License Application to the U.S. Food and Drug Administration are proceeding. The detailed findings from the Phase-3 clinical trials will be presented at upcoming scientific meetings.

Tildrakizumab Study Design

Tildrakizumab Phase-3 studies 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. Psoriasis Area Severity Index (PASI) and Physician Global Assessment (PGA) were the primary endpoints in the studies. 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. 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."

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

Sun Pharmaceutical Industries Ltd.'s wholly owned subsidiary, acquired worldwide rights to tildrakizumab from Merck, known as MSD outside the United States and Canada, in 2014. Funded by 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.

About Tildrakizumab

Tildrakizumab is an investigational humanized, anti-IL-23p19 monoclonal antibody designed to selectively block the cytokine IL-23. Evidence from human genetics studies suggest that inhibition of IL-23 may provide an approach for the treatment of some inflammatory conditions.

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 worldwide¹. 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 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 bleed². Currently, there is no cure for psoriasis¹.

About Sun Pharma's Dermatology Franchise

Sun Pharma is committed to bringing patients new treatment options for dermatologic conditions with unmet needs such as psoriasis, acne and actinic keratosis. In addition to the investigational candidate tildrakizumab, an investigational anti-IL-23p19 monoclonal antibody, Sun Pharma's branded dermatology business is comprised of several products including Absorica® and Levulan®. Sun Pharma, along with its subsidiaries is ranked fourth in dermatology prescription volume within the U.S per IMS.

References

1. National Psoriasis Foundation. Facts about psoriasis. <https://www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf>. Accessed on March, 17, 2016.
2. National Psoriasis Foundation. About Psoriasis. <https://www.psoriasis.org/about-psoriasis>. Accessed on March, 17, 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 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 2015 are approximately US\$ 4.5 billion, of which US contributes US\$ 2.2 billion. In India, the company enjoys leadership across 12 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 7% of annual revenues. For further information please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

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