



## **FOR IMMEDIATE RELEASE**

# Almirall and Sun Pharma enter into a License Agreement for Tildrakizumab in Europe for Psoriasis

- Relationship Builds on Tildrakizumab Clinical Success and Leverages Almirall Capabilities in Europe
- First IL-23p19 Antibody to Meet Primary Endpoints in Pivotal Phase-3 Clinical Trials in Patients with Moderate-to-Severe Plaque Psoriasis

Mumbai, India and Barcelona, Spain July 27, 2016 – Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies), and its wholly owned subsidiary and Almirall (Spanish Stock Exchange ticker: ALM) today announced a licensing agreement on the development and commercialization of tildrakizumab for psoriasis in Europe. Tildrakizumab is an investigational IL-23p19 inhibitor currently being evaluated in patients with moderate-to-severe plaque psoriasis.

Under terms of the license agreement, Almirall will pay Sun Pharma an initial upfront payment of US \$50 million. Phase-3 studies of tildrakizumab have recently been completed. Sun Pharma will be eligible to receive development and regulatory milestone payments and, additionally, sales milestone payments and royalties on net sales, the terms of which are confidential. Almirall will be 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 continue to lead development of tildrakizumab for other indications, where Almirall will have right of first negotiation for certain indications in Europe.

"Sun Pharma is committed to growing our dermatology franchise, with tildrakizumab as our lead investigational compound. We continue to build our pipeline and capabilities in this important therapeutic area of significant unmet need. We are proud to be partnering with a regional leader in dermatology, like Almirall, to bring tildrakizumab to the European market," said Dilip Shanghvi, Managing Director, Sun Pharma. "This agreement with Almirall follows the recent announcement that tildrakizumab is the first IL-23p19 inhibitor to demonstrate positive results in Phase-3 clinical trials and is another step towards preparing for future regulatory milestones that will potentially enable us to bring a new treatment option to patients with moderate-to-severe plaque psoriasis."

"This agreement with Sun Pharma allows us to add a novel biologic for treatment of psoriasis to our extensive dermatology portfolio," said Jorge Gallardo, President of Almirall. "This is an exciting time for the treatment of psoriasis, a disease which can take both a physical and emotional toll on patients' lives. Emerging new investigational drugs, like tildrakizumab, are increasingly targeted and will potentially offer patients and physicians another alternative."

Additionally, the license agreement has a provision for possible co-promotion agreement at some point in the future, subject to certain conditions.





## **Tildrakizumab Phase-3 trial outcome**

In May 2016, the two pivotal Phase-3 clinical trials of tildrakizumab met their primary endpoints for both evaluated doses with topline results shared via a separate press release. The co-primary efficacy endpoints 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. Additionally, the second study 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.

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.

#### **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 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 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 that often has a debilitating impact not only on their bodies but their everyday lives.

## References

- 1. National Psoriasis Foundation. Facts about psoriasis. https://www.psoriasis.org/sites/default/files/formedia/MediaKit.pdf. Accessed on June 27, 2016.
- 2. National Psoriasis Foundation. About Psoriasis. https://www.psoriasis.org/about-psoriasis. Accessed on June 27, 2016.

## 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 13 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 & follow us on Twitter @SunPharma\_Live

#### **About Almirall**

Almirall is a global company based in Barcelona dedicated to providing valuable medicines and medical devices through its R&D, agreements and alliances. Our work covers the whole of the drug value chain. A consolidated growth allows us to devote our talent and efforts towards specialty areas and particularly to further grow as a leading Dermatology player. We are a specialist company, enabling us to accomplish the purpose of providing innovative products wherever they are needed.

Founded in 1943, Almirall is listed on the Spanish Stock Exchange (ticker: ALM) and it has become a source of value creation for society due to its vision, and the commitment of its long-standing major shareholders. In 2015, Almirall revenues totaled 769 million euros and, with more than 1,800 employees, it has become a trusted presence across Europe, as well as in the USA.

For more information, please visit www.almirall.com.

## **Contacts: Sun Pharma**

Nimish Desai Frederick Castro

Tel +91 22 4324 4324, Xtn 2778 Tel Direct +91 22 4324 2778 Tel Direct +91 22 4324 2777

Tel Direct +91 22 4324 2778 Tel Direct +91 22 4324 2777 Mobile +91-98203 30182 Mobile +91 99206 65176

E mail nimish.desai@sunpharma.com E mail frederick.castro@sunpharma.com

FleishmanHillard Faith Moresco

Tel +1 646-659-0642

E mail faith.moresco@fleishman.com





**Contacts: Almirall** 

Media contact: Cohn & Wolf

Adriana Ibarguen adriana.ibarguen@cohnwolfe.com Tel.: (+34) 91 531 57 23 **Investor Relation contact:** Almirall

Pablo Divasson del Fraile Tel.: (+34) 93 291 30 87

#### Disclaimer

This document includes only summary information and does not intend to be comprehensive. Facts, figures and opinions contained herein, other than historical, are "forward-looking statements". These statements are based on currently available information and on best estimates and assumptions believed to be reasonable by the Companies. These statements involve risks and uncertainties beyond the Companies' control. Therefore, actual results may differ materially from those stated by such forward-looking statements. The Companies expressly disclaim any obligation to review or update any forward-looking statements, targets or estimates contained in this document to reflect any change in the assumptions, events or circumstances on which such forward-looking statements are based unless so required by applicable law.