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Western Express Highway, Goregaon (E),  
Mumbai 400063, India  
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CIN: L24230GJ1993PLC019050  
www.sunpharma.com



**21 September 2018.**

National Stock Exchange of India Ltd,  
Exchange Plaza, 5th Floor,  
Plot No. C/1, G Block,  
Bandra Kurla Complex,  
Bandra (East),  
Mumbai – 400 051.

BSE Limited,  
Market Operations Dept.  
Phiroze Jeejeebhoy Towers,  
Dalal Street,  
Mumbai - 400 001.

Dear Sirs,

**Sub: Press Release**

We are pleased to enclose herewith our Press Release relating to Australian TGA approval of ILUMYA™, which we shall be releasing after sending this letter to you. This is for your information and record.

Thanking you,

Yours faithfully,  
For Sun Pharmaceutical Industries Ltd

A handwritten signature in blue ink, appearing to read "A. I. Bhuta".

Ashok I. Bhuta  
Compliance Officer

Encl: as above

**FOR IMMEDIATE RELEASE**

**Sun Pharma announces Australian TGA approval of ILUMYA™  
(tildrakizumab) for treatment of moderate-to-severe plaque psoriasis**

**Mumbai, India, September 21, 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 Sun Pharma has received the Australian Therapeutic Goods Administration (TGA) approval for its speciality product, ILUMYA™ (tildrakizumab) for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy.

ILUMYA™ selectively binds to the p19 subunit of IL-23 and inhibits its interaction with the IL-23 receptor leading to inhibition of the release of proinflammatory cytokines and chemokines. ILUMYA™ is administered at a dose of 100 mg by subcutaneous injection every 12 weeks after the completion of initial doses at weeks 0 and 4. ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any of the excipients in ILUMYA™, and in patients with clinically important active infections, e.g. active tuberculosis.

"We are pleased to have received this approval and look forward to bringing ILUMYA™ to dermatologists and patients in Australia," said **Hellen De Kloet, Business Head, Western Europe & Australia, Sun Pharma**. "We are launching a patient support program to assist patients prescribed with ILUMYA™. The program is designed to supplement the support offered by doctors in their practice or in hospital departments." she added.

The ILUMYA™ patient support program offers self-injection training by a registered nurse, dose reminders, injection consumables and a patient support help line.

ILUMYA™ is one of the key specialty products of Sun Pharma and it was approved by US FDA in March 2018 while the European Commission approved it in September 2018.

In Australia, the number of severe chronic plaque psoriasis patients receiving treatment through the Pharmaceutical Benefit Scheme (PBS) with biologics, increased by more than 60% between 2014 and 2016. However, the number treated was less than 30% of the severely affected population. The total PBS expenditure on biologics for chronic plaque psoriasis (at published prices) was A\$121 million in 2016<sup>1</sup>.

The TGA approval of ILUMYA™ for the treatment of adults with moderate-to-severe plaque psoriasis was supported by data from the pivotal Phase-3 reSURFACE clinical development program. In the two multicentre, randomized, double-blind, placebo-controlled trials (reSURFACE 1 and reSURFACE 2), 1862 adult patients were enrolled and treated with ILUMYA™ (N=1238), etanercept (N=313) or placebo (N=310). Results from these studies were published in The Lancet in July 2017, with primary endpoints presented at the 25th European Academy of Dermatology and Venereology (EADV) Congress. Both Phase-3 studies met the primary efficacy endpoints, demonstrating significant clinical improvement with ILUMYA™ 100 mg compared to placebo or etanercept when measured by at least 75 percent

reduction in baseline psoriasis severity (Psoriasis Area Sensitivity Index or PASI 75) and Physician's Global Assessment (PGA) score of "clear" or "minimal" at week 12 after two doses.

The most common adverse reactions observed with ILUMYA™ in the pooled data from one Phase 2 and two Phase 3 studies in psoriasis patients for the placebo controlled period (16 weeks for the Phase 2 study and 12 weeks for the Phase 3 studies) were nasopharyngitis, headache, and site injection pain. Most adverse reactions were considered mild and no adverse reaction led to discontinuation of treatment in >1% of patients.

## References

1. Post-market review of the use of biologics in the treatment of severe chronic plaque psoriasis (CPP) – Ratified minutes April 2018 PBAC meeting - Agenda item 7  
<http://www.pbs.gov.au/info/reviews/post-market-biologics>

### **The Full Australian Product Information can be accessed here:**

<https://www.ebs.tga.gov.au/ebs/picmi/picmirepository.nsf/pdf?OpenAgent&id=CP-2018-PI-02292-1&d=201809121016933>

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

Sun Pharmaceutical Industries Ltd.'s wholly owned subsidiary licensed worldwide rights to ILUMYA™ 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 ILUMYA™.

### **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,

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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](http://www.sunpharma.com) & follow us on Twitter @SunPharma\_Live.

### **Contacts**

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