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www.sunpharma.com



**23 October 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.  
**Scrip Code: SUNPHARMA**

**BSE Limited,**  
Market Operations Dept.  
Phiroze Jeejeebhoy Towers,  
Dalal Street,  
Mumbai - 400 001.  
**Scrip Code: 524715**

Dear Sirs,

**Sub: Press Release**

We are pleased to enclose herewith our Press Release relating to availability of ILUMYA™ (tildrakizumab-asmn) in the United States, 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 the Availability of ILUMYA™ (tildrakizumab-asmn) in the United States for the Treatment of Moderate-to-Severe Plaque Psoriasis**

*New Insights on the Cost-Effectiveness of ILUMYA™ Presented Today  
at the Academy of Managed Care Pharmacy Nexus 2018 Meeting*

**Mumbai, India and Princeton, NJ, October 23, 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 moderate-to-severe psoriasis treatment ILUMYA™ (tildrakizumab-asmn) 100 mg/mL is now available in the United States. ILUMYA™ is an injectable interleukin-23 (IL-23) inhibitor approved by the FDA for the treatment of moderate-to-severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy.<sup>1</sup> ILUMYA™ injections are administered by a healthcare provider every 12 weeks, following starter doses at Week 0 and Week 4.

“The availability of ILUMYA™ is an important milestone for Sun Pharma as we expand our specialty medicine portfolio in the U.S. ILUMYA™ offers a new, safe and effective treatment option for people who are still struggling to manage their moderate-to-severe plaque psoriasis,” said Abhay Gandhi, Chief Executive Officer, Sun Pharma, North America. “We understand the importance of patient and physician choice, and are committed to making ILUMYA™ among the most cost-effective treatments on the market today.”

“For nearly 20 years, my psoriasis has disrupted my life in many ways. I never imagined the impact of dealing with flaking and peeling skin,” said Mary Robinson, a tildrakizumab clinical trial participant. “After a couple doses of ILUMYA™ my skin started to improve, and I’m encouraged by the ongoing results that help me keep my psoriasis under control.”

A pooled analysis of the Phase-3 studies presented recently at the European Academy of Dermatology and Venerology (EADV) Congress demonstrated the clinical results of ILUMYA™ 100 mg/mL were sustained over a three-year period, and the medicine was well-tolerated with very low drug-related serious adverse events and discontinuation rates.<sup>2</sup> Most common ( $\geq 1\%$ ) adverse reactions associated with ILUMYA™ 100 mg treatment are upper respiratory infections, infection site reactions, and diarrhea.<sup>1</sup>

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“We saw that nine out of 10 patients who achieved 75 percent skin clearance, or PASI 75, at Week 28 after three doses of ILUMYA™ 100 mg maintained their skin clearance after three years on treatment. Skin clearance was also sustained over the long-term in 67.6 percent of patients who had reached PASI 90 after the first three doses of ILUMYA™,” said study investigator Dr. Andrew Blauvelt, board-certified dermatologist and President of Oregon Medical Research Center. “These long-term data tell us that quarterly maintenance dosing of ILUMYA™ offers clinically meaningful benefits over time, which is promising news for patients and clinicians.”

Additional analyses presented today at Academy of Managed Care Pharmacy (AMCP) Nexus 2018 used the 10-year Markov model to demonstrate the cost-effectiveness of ILUMYA™ as a first-line treatment. The data results demonstrated that ILUMYA™ is among the most cost-effective options compared to non-targeted treatments such as apremilast. Furthermore, ILUMYA™ was more cost-effective than other biologic options including secukinumab, guselkumab, ixekizumab, adalimumab, ustekinumab and etanercept.<sup>3,4</sup>

Sun Pharma is working closely with relevant stakeholders to ensure ILUMYA™ is accessible to patients with moderate-to-severe psoriasis across the U.S. who may benefit from this new treatment option.

Please click here for [Full Prescribing Information](#) and [Medication Guide](#). For more information about ILUMYA™, please visit [www.ilumya.com](http://www.ilumya.com).

### **About ILUMYA™ (tildrakizumab-asmn)**

ILUMYA™ (tildrakizumab-asmn) is a humanized IgG1/k monoclonal antibody designed to selectively bind to the p19 subunit of interleukin-23 (IL-23) and inhibit its interaction with the IL-23 receptor, leading to inhibition of the release of pro-inflammatory cytokines and chemokines.

ILUMYA™ is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy. The U.S. Food and Drug Administration approval is based on data from the pivotal Phase-3 reSURFACE clinical development program, which consisted of two randomized, double-blind, placebo-controlled trials of more than 1,800 patients across over 200 clinical trial sites.

ILUMYA™ has also been approved in Australia, and in Europe under the brand name ILUMETRI™.

### **IMPORTANT SAFETY INFORMATION**

ILUMYA™ is contraindicated in patients with a previous serious hypersensitivity reaction to tildrakizumab or to any other excipients.

Cases of angioedema and urticaria occurred in ILUMYA™-treated subjects in clinical trial. If a serious hypersensitivity reaction occurs, discontinue ILUMYA™ immediately and initiate appropriate therapy.

ILUMYA™ may increase the risk of infection. Treatment with ILUMYA™ should not be initiated in patients with a clinically important active infection until the infection resolves or is adequately treated. Consider the risks and benefits of treatment prior to prescribing ILUMYA™ in patients with a chronic infection or a history of recurrent infection. Instruct patients receiving ILUMYA™ to seek medical help if signs or symptoms of clinically important chronic or acute infection occur. If a patient develops a clinically important or serious infection, or is not responding to standard therapy, closely monitor and discontinue ILUMYA™ until the infection resolves.

Evaluate patients for TB infection prior to initiating treatment with ILUMYA™. Do not administer ILUMYA™ to patients with active TB infection. Initiate treatment of latent TB prior to administering ILUMYA™. Consider anti-TB therapy prior to initiation of ILUMYA™ in patients with a past history of latent or active TB in whom an adequate course of treatment cannot be confirmed. Patients receiving ILUMYA™ should be monitored closely for signs and symptoms of active TB during and after ILUMYA™ treatment.

Most common ( $\geq 1\%$ ) adverse reactions associated with ILUMYA™ include upper respiratory infections, injection site reactions, and diarrhea. Adverse reactions that occurred at rates less than 1% but greater than 0.1% in the ILUMYA™ group and at a higher rate than in the placebo group included dizziness and pain in extremity.

### **About Psoriasis**

Psoriasis is a chronic immune disease that appears on the skin, affecting approximately 8 million Americans<sup>5</sup> and 125 million people worldwide<sup>6</sup>. The non-contagious disorder speeds the growth cycle of skin cells<sup>5</sup> and results in thick scaly areas of skin<sup>7</sup>. The most common form, affecting about 80 to 90 percent of people with psoriasis, is called plaque psoriasis<sup>8</sup>. It appears as red, raised areas of skin covered with flaky white scales which may be itchy and painful and can crack and bleed<sup>7</sup>. Twenty percent of people with plaque psoriasis are considered moderate-to-severe<sup>8</sup>, and many continue to struggle with the ongoing, persistent nature of this chronic disease.

### **About Sun Dermatology**

Sun Dermatology (the branded dermatology division of a wholly owned subsidiary of Sun Pharma) is committed to expanding its dermatology portfolio to bring healthcare providers and patients around the world more treatment options and ongoing support for conditions like moderate-to-severe plaque psoriasis. Sun Pharma, along with its subsidiaries, is ranked fourth in dermatology prescription volume within the U.S. per IQVIA and is fifth largest specialty generic pharmaceutical company globally. In addition to ILUMYA™, Sun Dermatology is comprised of several branded products with a focus on other dermatologic conditions.

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

## **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.

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