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29 June 2020.

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

Please find enclosed herewith our Press Release relating to Ilumya approval in Japan, 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

Ashok I. Bhuta
Compliance Officer

Encl: as above

FOR IMMEDIATE RELEASE

Sun Pharma announces Japan MHLW approval of ILUMYA™ for the treatment of Plaque Psoriasis

Mumbai, India & Tokyo, Japan, June 29, 2020 – 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 one of its wholly-owned subsidiaries has received approval from the Ministry of Health, Labour and Welfare (MHLW), Japan for ILUMYA (tildrakizumab) for the treatment of plaque psoriasis in adult patients who have an inadequate response to conventional therapies. Japan has approximately 430,000 people currently suffering from psoriasis¹.

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

Junichi Nakamichi, Country Head, Sun Pharma Japan, said, “ILUMYA is the first innovative drug that Sun Pharma plans to launch in Japan. It was extensively tested in Japanese patients as part of ILUMYA’s global clinical development program. The drug offers a new treatment option with only one injection every 12 weeks for Japanese patients who struggle everyday with the chronic nature of plaque psoriasis. It showed sustained efficacy for over 4 years and has safety profiles over 4 years with low rates of severe infections, malignancies and MACEs. This approval adds a biologic product to our existing strong dermatology portfolio in Japan. We will leverage Sun Pharma Japan’s robust marketing network to make ILUMYA, a safe and efficacious product, available to dermatologists and patients in Japan.”

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.

The MHLW approval of ILUMYA for the treatment of 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). 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.

After 64-week base study of reSURFACE 1, a total of 120 Japanese patients entered the reSURFACE 1 extension study and 101 patients completed the extension study for 148 weeks.

IMPORTANT SAFETY INFORMATION

ILUMYA is contraindicated in patients with a previous serious hypersensitivity reaction to ILUMYA 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 125 million people worldwide². The non-contagious disorder speeds the growth cycle of skin cells² and results in thick scaly areas of skin³. The most common form, affecting about 80 to 90 percent of people with psoriasis, is called plaque psoriasis⁴. It appears as red, raised areas of skin covered with flaky white scales which may be itchy and painful and can crack and bleed³. Twenty percent of people with plaque psoriasis are considered moderate-to-severe, and many continue to struggle with the ongoing, persistent nature of this chronic disease.

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About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across 6 continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 7% of annual revenues in R&D. For further information, please visit www.sunpharma.com & follow us on Twitter @SunPharma_Live.

References:

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2. National Psoriasis Foundation. Facts about psoriasis. www.psoriasis.org/sites/default/files/for-media/MediaKit.pdf. Accessed on February 22, 2018.
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4. Menter A, Gottlieb A, Feldman SR, Van Voorhees AS et al. Guidelines of care for the management of psoriasis and psoriatic arthritis: Section 1. Overview of psoriasis and guidelines of care for the treatment of psoriasis with biologics. J Am Acad Dermatol 2008 May; 58(5):826-50.

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