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Scrip Symbol: SUNPHARMA

BSE Limited
Scrip Code: 524715

Subject: Press Release – Sun Pharma Presents New Clinical Efficacy and Safety Data in Severe Dermatological Conditions at the 2024 European Academy of Dermatology and Venereology (EADV) Congress

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Enclosed herewith is a copy of the Press Release about Sun Pharma presenting new clinical efficacy and safety data at the 2024 European Academy of Dermatology and Venereology (EADV) Congress, which shall be released after this intimation.

For **Sun Pharmaceutical Industries Limited**

Anoop Anjanikumar Deshpande

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FOR IMMEDIATE RELEASE

Sun Pharma Presents New Clinical Efficacy and Safety Data in Severe Dermatological Conditions at the 2024 European Academy of Dermatology and Venereology (EADV) Congress

New data demonstrate improved hair satisfaction in more than 95% of patients taking deuruxolitinib and clinically meaningful improvements in depression and anxiety from baseline to Week 24

Studies also confirm dose optimization, with results demonstrating greater response with 8 mg tablets twice-daily as compared to higher once-daily dosing

MUMBAI, India & PRINCETON, N.J., September 26, 2024 – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715 (together with its subsidiaries and/or affiliated companies, "Sun Pharma") today announced that it will present abstracts across its dermatology portfolio at the 33rd European Academy of Dermatology and Venereology (EADV) Congress being held in Amsterdam, Netherlands from September 25-28, 2024.

Three abstracts, accepted for podium and poster presentation, will highlight clinical efficacy and safety data of LEQSELVI™ (deuruxolitinib) 8 mg tablets, an oral selective inhibitor of Janus Kinases (JAK) JAK1 and JAK2 approved by the U.S. Food and Drug Administration for the treatment of adults with severe alopecia areata (AA). Notably, data presented in the podium presentation (FC04.04) found a greater proportion (95%) of patients taking deuruxolitinib 8 mg twice a day showed improvement in their hair satisfaction scores, compared to baseline over the 24-week period. Satisfaction with hair regrowth is imperative, as a significant number of patients with AA experience depression and anxiety due to the visible nature of the disease.[1] The company will also share results in two additional posters for deuruxolitinib, which showed clinically meaningful improvement in anxiety and depression among patients taking deuruxolitinib to treat their severe AA (P2022) as well as dose optimization for deuruxolitinib at 8 mg (P2081).

"Deuruxolitinib targets the immune mechanisms behind alopecia areata, providing patients with an effective treatment option," said Arash Mostaghimi, MD, MPA, MPH, FAAD, Vice Chair, Clinical Trials and Innovation and Director, Inpatient Dermatology, Brigham and Women's Hospital. "As a dermatologist, I find these data particularly encouraging because it addresses the physical effects of hair loss, which can, in turn, address the significant emotional and mental health challenges that patients often face."

Additionally, 12 poster presentations will underscore the clinical efficacy and safety of ILUMYA® (tildrakizumab) in moderate-to-severe plaque psoriasis. These data also include research from interim data analysis from real-world settings.

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The following abstracts representing the dermatology portfolio will be presented at the 33rd EADV Congress:

Deuruxolitinib

- **Podium Presentation [FC04.04]:** Change in patient-reported hair satisfaction during deuruxolitinib treatment of severe alopecia areata: Pooled data from the Phase 3 THRIVE-AA1 and THRIVE-AA2 trials (Presentation Time: September 26 at 16:30-16:40)
- **Poster Presentation [P2022]:** Improvement in anxiety and depression in adult patients with severe alopecia areata treated with deuruxolitinib: Pooled data from the THRIVE-AA1 and THRIVE-AA2 Phase 3 trials
- **Poster Presentation [P2081]:** Optimization of deuruxolitinib dosing in adult patients with alopecia areata: Results from a randomized, parallel-group, multicenter, Phase 2 trial

Tildrakizumab

- **Poster Presentation [P3221]:** Comparative Efficacy and Safety of Tildrakizumab for Moderate-to-Severe Plaque Psoriasis: Systematic Literature Review (SLR) and Network Meta-Analysis (NMA)
- **Poster Presentation [P3177]:** Efficacy and safety of tildrakizumab through Week 28 in patients with early vs late-onset moderate-to-severe plaque psoriasis: A post hoc analysis of reSURFACE 1 and reSURFACE 2
- **Poster Presentation [P3274]:** Improving the well-being of patients with moderate to severe plaque psoriasis and involvement of impactful areas with Tildrakizumab*
- **Poster Presentation [P3348]:** Effectiveness and Nail Assessment in Psoriasis and Psoriatic Arthritis (NAPPA) of tildrakizumab patients with nail psoriasis: 52-week results from the phase IV POSITIVE Austrian subset*
- **Poster Presentation [P3343]:** Effectiveness of tildrakizumab in patients with moderate-to-severe psoriasis located in special areas: 52-week results from the POSITIVE study*
- **Poster Presentation [P3341]:** High effectiveness of tildrakizumab in bio-naïve and bio-experienced patients with moderate-to-severe psoriasis: 52-week results from the POSITIVE study*
- **Poster Presentation [P3340]:** High effectiveness of tildrakizumab regardless of baseline characteristics in patients with moderate-to-severe psoriasis: 52-week results from the POSITIVE study*
- **Poster Presentation [P3188]:** Patient-reported well-being using tildrakizumab for psoriasis in a real-world setting: 52-week interim data of the phase IV POSITIVE study*
- **Poster Presentation [P3339]:** Safety of tildrakizumab in patients with moderate-to-severe psoriasis: 52-week data from the phase IV POSITIVE study*
- **Poster Presentation [P3346]:** Effectiveness of tildrakizumab for itch, pain, and fatigue in patients with moderate-to-severe psoriasis: 52-week results from the real-world POSITIVE study*
- **Poster Presentation [P3347]:** Quality of life, work productivity and treatment satisfaction with tildrakizumab in moderate-to-severe psoriasis patients: 52-week interim data of the real-world POSITIVE study*

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- **Poster Presentation [P3344]:** (ENCORE) Impact of patient psoriasis on partner well-being in a real-world setting: 52- week interim data of the phase IV POSITIVE study*

** Indicates data sponsored by Almirall; Sun Pharma and Almirall operate under a licensing agreement on the development and commercialization of tildrakizumab for psoriasis in Europe*

About LEQSELVI™ and alopecia areata

LEQSELVI (deuruxolitinib) 8 mg tablets is an oral selective inhibitor of Janus kinases JAK1 and JAK2 approved for the treatment of adult patients with severe alopecia areata. Alopecia areata is an autoimmune disease in which the immune system attacks hair follicles, resulting in partial or complete loss of hair on the scalp and body. Alopecia areata may affect up to 2.5% of the United States and global population during their lifetime.[2,3,4] The scalp is the most commonly affected area, but any hair-bearing site can be affected alone or together with the scalp. Onset of the disease can occur throughout life and affects both women and men. Alopecia areata can be associated with serious psychological consequences, including anxiety and depression. There are currently limited approved treatment options available for alopecia areata.

About THRIVE-AA1 and THRIVE-AA2 trial design

THRIVE-AA1 and THRIVE-AA2 (NCT04518995 and NCT04797650) were randomized, double-blind, placebo-controlled clinical trials in 1223 adult patients ages 18-65 with severe alopecia areata at sites in the U.S., Canada and Europe evaluating the regrowth of scalp hair after 24 weeks of dosing using the Severity of Alopecia Tool (SALT) score. Patients were randomized to receive either 8 mg twice daily or 12 mg twice daily of deuruxolitinib or placebo for 24 weeks. The primary endpoint was the percentage of patients achieving a SALT score of 20 or less at 24 weeks. Patients enrolled in THRIVE-AA1 and THRIVE-AA2 were required to have at least 50 percent scalp hair loss due to alopecia areata, as measured by SALT. A SALT score of 100 represents total scalp hair loss, whereas a score of 0 represents no scalp hair loss. The average baseline SALT score across all patients in THRIVE-AA1 and THRIVE-AA2 was approximately 85.9 and 87.9 respectively.

LEQSELVI Important Safety Information

Please click here for full Prescribing Information Including BOXED WARNING and Medication Guide.

Indications and Usage
LEQSELVI (deuruxolitinib) is a Janus kinase (JAK) inhibitor indicated for the treatment of adults with severe alopecia areata.

Limitations of Use
LEQSELVI is not recommended for use in combination with other JAK inhibitors, biologic immunomodulators, cyclosporine or other potent immunosuppressants.

Contraindications
LEQSELVI is contraindicated in patients who are CYP2C9 poor metabolizers or who are using moderate or strong CYP2C9 inhibitors.

Warnings

Serious Infections
Increased risk of serious bacterial, fungal, viral and opportunistic infections including tuberculosis (TB) that may lead to hospitalization or death. Interrupt treatment with LEQSELVI if a serious infection occurs until the infection is controlled. Test for latent TB before and during therapy; treat latent TB prior to use. Monitor all patients for active TB during treatment, even patients with initial negative, latent TB test.

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Mortality
Higher rate of all-cause mortality, including sudden cardiovascular death with another Janus kinase inhibitor (JAK) vs. TNF blockers in rheumatoid arthritis (RA) patients. LEQSELVI is not approved for use in RA patients.

Malignancy
Malignancies have occurred in patients treated with LEQSELVI. Higher rate of lymphomas and lung cancers with another JAK inhibitor vs. TNF blockers in RA patients.

Major Adverse Cardiovascular Events
Higher rate of MACE (defined as cardiovascular death, myocardial infarction, and stroke) with another Janus kinase inhibitor (JAK) vs. TNF blockers in rheumatoid arthritis (RA) patients.

Thrombosis
Thrombosis, including PE, DVT & CVT, has occurred in patients treated with LEQSELVI. Increased incidence of pulmonary embolism, venous and arterial thrombosis with another JAK inhibitor vs. TNF blockers.

Increased risk of serious adverse reactions in CYP2C9 poor metabolizers or with concomitant use of moderate or strong CYP2C9 inhibitors
Do not treat patients who are CYP2C9 poor metabolizers or patients taking a moderate or strong CYP2C9 inhibitor with LEQSELVI.

Gastrointestinal Perforations
GI perforations have occurred in patients treated with LEQSELVI. Monitor patients who may be at increased risk for gastrointestinal perforation. Evaluate promptly patients presenting with new onset abdominal symptoms.

Lipid elevations, anemia, neutropenia, and lymphopenia
Monitor for changes in lipids, hemoglobin, neutrophils, and lymphocytes.

Immunizations
Avoid use of live vaccines during or immediately prior to LEQSELVI treatment. Prior to initiating LEQSELVI, it is recommended that patients be brought up to date with all immunizations.

Dosage
The recommended dosage of LEQSELVI for the treatment of severe alopecia areata is 8 mg orally twice daily, with or without food.

Before treatment with LEQSELVI, perform the following evaluations:

- CYP2C9 genotype & use of moderate or strong CYP2C9 inhibitors;
- Active and latent tuberculosis evaluation;
- Viral hepatitis screening;
- Complete blood count (LEQSELVI treatment is not recommended in patients with an absolute lymphocyte count (ALC) <500 cells/mm3 absolute neutrophil count (ANC) <1,000 cells/mm3, or hemoglobin level <8 g/dl).

Adverse Reactions
Most common adverse reactions (≥1%) are headache, acne, nasopharyngitis, blood creatine phosphokinase increased, hyperlipidemia, fatigue, weight increased, lymphopenia, thrombocytosis, anemia, skin and soft tissue infections, neutropenia, and herpes.

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Use in Specific Populations
Based on animal studies, LEQSELVI may cause fetal harm during pregnancy. Pregnant women should be advised of a risk to the fetus. Consider pregnancy planning and prevention for women of reproductive potential. LEQSELVI should not be used by women who are breastfeeding until one day after the last dose.

LEQSELVI should not be used by patients with severe renal impairment or severe hepatic impairment.

ILUMYA Important Safety Information

Please click here for Full Prescribing Information and Medication Guide.

INDICATION

ILUMYA (tildrakizumab-asmn) is indicated for the treatment of adults with moderate-to-severe plaque psoriasis who are candidates for systemic therapy or phototherapy.

CONTRAINDICATIONS

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

WARNINGS AND PRECAUTIONS:

Hypersensitivity: Cases of angioedema and urticaria occurred in ILUMYA-treated subjects in clinical trials. If a serious allergic reaction occurs, discontinue ILUMYA immediately and initiate appropriate therapy.

Infections: 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 consider discontinuation of ILUMYA until the infection resolves.

Pretreatment Evaluation for Tuberculosis: Evaluate patients for tuberculosis (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 treatment.

Immunizations: Prior to initiating therapy with ILUMYA, consider completion of all age-appropriate immunizations according to current immunization guidelines. Patients treated with ILUMYA should not receive live vaccines.

Adverse Reactions: The most common (≥1 %) adverse reactions associated with ILUMYA treatment that were more frequent than in the placebo group are upper respiratory infections, injection-site
reactions, and diarrhea.

To report SUSPECTED ADVERSE REACTIONS, contact Sun Pharmaceutical Industries, Inc. at 1-800-818-4555 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

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About Sun Pharmaceutical Industries Limited. (CIN - L24230GJ1993PLC019050)

Sun Pharma is the world's leading specialty generics company with a presence in specialty, generics and consumer healthcare products. It is the largest pharmaceutical company in India and is a leading generic company in the U.S. as well as global emerging markets. Sun Pharma's high-growth global specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 18% of company sales. The company's vertically integrated operations deliver high-quality medicines, trusted by physicians and consumers in over 100 countries. Its manufacturing facilities are spread across six continents. Sun Pharma is proud of its multicultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on LinkedIn & X (Formerly Twitter).

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