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National Stock Exchange of India Limited
Scrip Symbol: SUNPHARMA

BSE Limited
Scrip Code: 524715

Press Release – Sun Pharma Presents LEQSELVI™ (deuruxolitinib) Data Highlighting Clinical Efficacy & Durability for Treatment of Alopecia Areata at the 2024 Fall Clinical Dermatology Conference

Enclosed herewith is a copy of the Press Release about Sun Pharma presented new data highlighting the clinical efficacy and safety of LEQSELVI™ (deuruxolitinib) 8 mg tablets at the 44th Annual Fall Clinical Dermatology Conference, 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 LEQSELVI™ (deuruxolitinib) Data Highlighting Clinical Efficacy & Durability for Treatment of Alopecia Areata at the 2024 Fall Clinical Dermatology Conference

Data at 68 weeks of treatment with LEQSELVI showed ongoing and clinically meaningful improvement in scalp hair regrowth

Study finds that doctors and patients prefer fast time to onset and proven efficacy in JAK inhibitor options, regardless of dosing schedule

MUMBAI, India and PRINCETON, N.J, October 25, 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 presented new data highlighting the clinical efficacy and safety of LEQSELVI™ (deuruxolitinib) 8 mg tablets at the 44th Annual Fall Clinical Dermatology Conference, being held October 24-27, 2024, in Las Vegas, Nevada. LEQSELVI 8 mg tablets was approved by the U.S. Food and Drug Administration for the treatment of adults with severe alopecia areata (AA) earlier this year. LEQSELVI, a JAK inhibitor, treats alopecia areata at the source and is clinically proven to deliver statistically significant efficacy.

LEQSELVI data presented at Fall Clinical includes pooled long-term results from open-label extension (OLE) studies showing ongoing and clinically meaningful improvements in scalp hair regrowth in adults with AA taking LEQSELVI for up to 68 weeks. To determine long-term efficacy, the Severity of Alopecia Tool (SALT) scores were analyzed using two methods: Last Observation Carried Forward (LOCF) and As Observed (AO). At the end of the qualifying trial period at Week 24, 32.6% of patients receiving LEQSELVI 8 mg BID (twice daily) achieved a SALT ≤20 score; the percentage of SALT 20 responders increased to 48.8% (LOCF analysis) and 76.6% (AO analysis) at Week 68 of the OLE studies. Additionally, 99.6% (282 patients) maintained their response to LEQSELVI 8 mg BID (as defined by sustaining a SALT ≤50 after achieving SALT ≤20 during the OLE studies as of the cutoff date).

"This research provides insight into the durability of response experienced with LEQSELVI 8 mg twice daily, adding to a growing body of evidence highlighting the benefits of this treatment for those living with severe alopecia areata," said Brett King, MD, PhD. "These data highlight an important role for deuruxolitinib in the care of patients living with this disease."

In addition to the OLE study, two posters presented at Fall Clinical capture patient and clinician feedback for the treatment of AA which confirm the preference for treatment options with fast time to onset and proven efficacy, irrespective of dosing schedules. In the blinded treatment scenario displaying profiles of LEQSELVI, baricitinib and ritlecitinib, patients and clinicians chose the profile of LEQSELVI as the preferred therapeutic option.

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"As we continue to grow the Sun Pharma dermatology portfolio, the data presented at Fall Clinical support a growing body of clinical evidence which show LEQSELVI is an effective treatment option for those living with severe alopecia areata," said Marek Honczarenko, MD, PhD, Senior Vice President and Head of Global Development at Sun Pharma. "We're excited to share these important data with the dermatology community and look forward to seeing patients living with alopecia areata access this innovative treatment option."

LEQSELVI may cause serious side effects including serious infections, malignancies, thrombosis, gastrointestinal perforations, and certain laboratory abnormalities. There also may be an increased risk of mortality and major cardiovascular events. LEQSELVI should not be used in patients who are CYP2C9 poor metabolizers or who are taking moderate or strong CYP2C9 inhibitors. In placebo-controlled trials, the three most common adverse events were headache (12.4% as compared to 9.4% with placebo), acne (10% as compared to 4.3% with placebo), and nasopharyngitis (8.1% as compared to 6.7% with placebo). Please see full Prescribing Information, including BOXED WARNING and Medication Guide, and see below for Important Safety Information.

For more information about LEQSELVI, visit LEQSELVI.com.

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.[1,2,3] 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.

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.

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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.

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.

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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.

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.

References

1. Benigno M. A Large Cross-Sectional Survey Study of the Prevalence of alopecia areata in the United States, Clinical, Cosmetic and Investigational Dermatology 2020.
2. Lee HH et al. Epidemiology of alopecia areata, ophiasis, totalis, and universalis: A systematic review and meta-analysis, J Am Acad Dermatol. 2020 Mar; 82(3): 675-682.
3. Fricke et al. Epidemiology and burden of alopecia areata: a systematic review, Clin Cosmet Investig Dermatol. 2015 Jul 24;8: 397-403.

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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).

Disclaimer: Statements in this "document" describing Sun Pharma's objectives, projections, estimates, expectations, plans or predictions, 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. Sun Pharma does not undertake any obligation to update or revise forward-looking statements to reflect developments or circumstances that arise or to reflect the occurrence of unanticipated developments/circumstances after the date hereof.

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