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14 July 2025

National Stock Exchange of India Limited
Scrip Symbol: SUNPHARMA

BSE Limited
Scrip Code: 524715

Intimation under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015 – Launch of LEQSELVI™ in the US

Press Release titled **"Sun Pharma Announces Launch of LEQSELVI™ (deuruxolitinib) in the United States for the Treatment of Severe Alopecia Areata"** is enclosed, which shall be released after this intimation.

For **Sun Pharmaceutical Industries Limited**

Anoop Anjanikumar Deshpande

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FOR IMMEDIATE RELEASE

Sun Pharma Announces Launch of LEQSELVI™ (deuruxolitinib) in the United States for the Treatment of Severe Alopecia Areata

LEQSELVI now available for prescription in U.S. nationwide, offering a new option for eligible patients

MUMBAI, India and PRINCETON, N.J., July 14, 2025 – 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 LEQSELVI™ (deuruxolitinib) 8 mg tablets is now available to healthcare providers and people living with severe alopecia areata in the U.S. LEQSELVI is indicated for the treatment of adults with severe alopecia areata.[1]

"The launch of LEQSELVI in the U.S. brings an effective, new treatment option for severe alopecia areata to eligible patients and the healthcare providers who treat them," said Richard Ascroft, CEO, Sun Pharma North America. "As a company committed to launching new therapeutic options which address the unmet needs of patients, adding LEQSELVI to our dermatology portfolio represents a key milestone for the business and an important advancement for the alopecia areata community."

With limited treatment options available to people living with severe alopecia areata in the U.S., the need for innovative therapies such as LEQSELVI remains critically important. LEQSELVI demonstrated rapid results in clinical trials with one third of patients regaining almost all of their hair by Week 24. Some patients (3%) achieved 80% or more scalp coverage as fast as 8 weeks.[1]

"The clinical evidence for LEQSELVI is truly compelling, demonstrating consistent efficacy," said Arash Mostaghimi, MD, MPA, MPH, FAAD, Vice Chair of Clinical Trials and Innovation and Associate Professor of Dermatology at Brigham and Women's Hospital. "LEQSELVI provides clinicians with an important new treatment that can deliver significant, rapid outcomes for patients with alopecia areata."

The psychosocial impact of alopecia areata can be significant. Many people living with severe alopecia areata face psychological distress, including loss of self-confidence, due to the unpredictable nature of hair loss, underscoring the importance of effective treatment solutions.[2] A medication that works fast is critical for alopecia areata patients.[5] In a recent survey, 83% of patients preferred a treatment with attributes that included speed. Fast regrowth brings back more than just hair.[3,5]

"The availability of LEQSELVI offers hope to our community, delivering a new, effective treatment option for adults living with severe alopecia areata," said Nicole Friedland, President and CEO, National Alopecia Areata Foundation (NAAF). "NAAF is thrilled to see expanded choices and increased opportunities for individuals to find an FDA-approved treatment to address hair loss caused by this autoimmune disease."

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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.[1]

Sun Pharma is committed to making LEQSELVI accessible to patients through the LEQSELVI SUPPORT™ Program, which offers eligible patients the opportunity to receive their medication for as little as $0 for up to two years. The program also provides access to a dedicated Patient Access Liaison—someone who will guide patients through the process, answer questions, and offer personalized support every step of the way. For more information about LEQSELVI, please 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 adults 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.[2,4] 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.

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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.

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.

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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.

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.

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*.

References

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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 oncodermatology 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.

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