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FOR IMMEDIATE RELEASE

U.S. FDA Approves LEQSELVI™ (deuruxolitinib), an Oral JAK Inhibitor for the Treatment of Severe Alopecia Areata

LEQSELVI delivered statistically significant efficacy across two Phase 3 clinical trials.

At baseline, the average patient had only 13% scalp hair coverage. At week 24, one-third of those patients experienced 80% scalp hair coverage.

MUMBAI, India and PRINCETON, N.J., July 25, 2024 – Sun Pharmaceutical Industries Limited (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, “Sun Pharma” and includes its subsidiaries or associate companies) today announced that the U.S. Food and Drug Administration (FDA) approved LEQSELVI™ (deuruxolitinib) 8 mg tablets for the treatment of adults with severe alopecia areata.¹

Alopecia areata affects around 700,000 people in the United States, and 300,000 have severe alopecia areata.^{2,3} Alopecia often leads patients to self-treat before seeking professional help, driven by dissatisfaction with the slow progress of existing treatments.^{4,5}

“LEQSELVI offers a new and effective solution that will significantly enhance options for long-suffering patients battling severe alopecia areata and their physicians,” said Abhay Gandhi, CEO, North America Business, Sun Pharma. “Our fast-growing dermatology business is excited to add this novel treatment to its portfolio.”

Alopecia areata is a common autoimmune disease in which hair loss is thought to occur due to the collapse of immune privilege, leading to the immune system targeting the hair follicles and causing sudden hair loss on the scalp, face and sometimes other areas of the body.^{4,5} LEQSELVI is a new, twice-daily oral selective inhibitor of Janus Kinases (JAK) JAK1 and JAK2. As a JAK inhibitor, LEQSELVI interrupts the pathways thought to contribute to hair loss in severe alopecia areata.¹

“We welcome the approval of LEQSELVI as a significant step for the alopecia areata community,” said Nicole Friedland, President and CEO, National Alopecia Areata Foundation (NAAF). “Alopecia areata is an autoimmune disease, with significant physical, emotional and financial impacts that go beyond hair loss. Today’s announcement empowers the alopecia community with even more choices, to which NAAF is committed, and provides another important option for those living with severe alopecia areata.”

The approval is based on data from two multicenter, randomized, double-blind, placebo-controlled Phase 3 clinical trials THRIVE-AA1 and THRIVE-AA2, which enrolled a total of 1,220 patients with alopecia areata who had at least 50% scalp hair loss as measured by Severity of Alopecia Tool (SALT) for more

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than six months. Data were also collected from two open-label, long-term extension trials in which patients were eligible to enroll upon completion of the 24-week trials.

At study baseline, the average patient had only 13% of their scalp hair coverage. In the trials, at 24 weeks, the primary endpoint was met, with more than 30% of patients taking LEQSELVI experiencing 80% or more scalp hair coverage (SALT \leq 20).¹ The number of patients taking LEQSELVI and achieving a SALT score of \leq 20 showed a consistent upward trend with no plateau through 24 weeks.¹ Additionally, up to 25% of patients had almost all of their scalp hair back at 24 weeks (\geq 90% coverage).¹

“For many people with severe alopecia areata, early intervention with effective treatment is critical,” said Natasha Mesinkovska, MD, PhD, Associate Professor and Vice Chair for Clinical Research of Dermatology, University of California, Irvine, and investigator in the LEQSELVI clinical development program. “An oral JAK that delivers proven results will be impactful for the alopecia areata community.”

Across the Phase 2 dose-ranging study and Phase 3 randomized, placebo-controlled trials, few patients (3.1%) receiving LEQSELVI 8 mg twice daily were discontinued from the trials due to adverse reactions.¹ In clinical trials, more than 100 people continued taking deuruxolitinib for more than three years.¹

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.

“We are pleased with the timely approval of LEQSELVI by the U.S. FDA,” said Marek Honczarenko, MD, PhD, Senior Vice President, Head of Development, Sun Pharma. “This validates our team’s capability to effectively bring treatments from research and development to approval in a way that is meaningful for physicians and patients. I want to thank all the investigators and patients for their participation in the clinical trials.”

Sun Pharma is committed to delivering support to the alopecia areata community and will introduce an access program to help eligible patients get started and stay on track with their treatment. Please visit www.LEQSELVI.com for additional information.

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.^{3,6,7} The scalp is the most commonly affected area, but any hair-bearing

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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 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.

Important Safety Information

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;

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- 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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Disclaimer

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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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