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FOR IMMEDIATE RELEASE

Sun Pharma Announces US FDA Filing Acceptance of New Drug Application (NDA) For Deuruxolitinib

Deuruxolitinib is being evaluated for treatment of moderate to severe alopecia areata

Mumbai, INDIA and Princeton, N.J., October 06, 2023 – Sun Pharmaceutical Industries Ltd (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) has accepted the New Drug Application (NDA) for deuruxolitinib, an investigational oral selective inhibitor of Janus kinases JAK1 and JAK2, for the treatment of adults with moderate to severe alopecia areata. In the NDA, Sun Pharma has submitted 8mg twice daily regimen of deuruxolitinib for FDA review.

"At Sun, we are committed to making a difference in the lives of patients," said Abhay Gandhi, CEO - North America Business, Sun Pharma. "We believe that deuruxolitinib has the potential to be an important new treatment option for people who continue to struggle every day with the chronic nature of alopecia areata."

The NDA filing for deuruxolitinib with the U.S. FDA is based on two pivotal Phase III trials (THRIVE-AA1 and THRIVE-AA2), which included over 1200 patients across more than 135 clinical trial sites. Data from these trials were most recently presented at the 2023 American Academy of Dermatology (AAD) Annual Meeting in March and previously presented at the 31st European Academy of Dermatology and Venereology Congress. The presentations highlighted the consistent and high-level efficacy with deuruxolitinib at the 8 mg dose in both Phase 3 trials. Significant differences in achieving the clinically-meaningful SALT score ≤20 for treatment arm compared to placebo were seen as early as Week 8 and were maintained throughout the studies. Treatment with deuruxolitinib was generally well-tolerated and patient satisfaction was significantly higher for the 8mg dose compared with placebo.

"People living with alopecia areata are dealing with more than just hair loss. Alopecia areata is a chronic autoimmune disease with psychological and emotional effects, and there is still significant unmet medical need in the community," said Nicole Friedland, President and Chief Executive Officer of the National Alopecia Areata Foundation (NAAF). "We are excited that the FDA is evaluating another potential treatment option for this serious medical condition."

About deuruxolitinib and alopecia areata
Deuruxolitinib is an investigational oral selective inhibitor of Janus kinases JAK1 and JAK2.

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 treatment options available for alopecia areata.

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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 age 18-65 with moderate to 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.

References

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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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About Sun Pharmaceutical Industries Ltd. (CIN - L24230GJ1993PLC019050):

Sun Pharma is the world's fourth largest specialty generics company with presence in Specialty, Generics and Consumer Healthcare products. It is the largest pharmaceutical company in India, and is a leading generic company in the US as well as Global Emerging Markets. Sun's high growth Global Specialty portfolio spans innovative products in dermatology, ophthalmology, and onco-dermatology and accounts for over 16% 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 multi-cultural workforce drawn from over 50 nations. For further information, please visit www.sunpharma.com and follow us on Twitter @SunPharma_Live

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