Late-Breaking Phase 3 Data at AAD 2023 Show Oral Investigational Medicine Deuruxolitinib Significantly Improved Scalp Hair Regrowth in Alopecia Areata

March 18, 2023

MUMBAI, India and PRINCETON, N.J. , March 18, 2023 /PRNewswire/ -- Concert Pharmaceuticals ("Concert"), a company recently acquired by Sun Pharmaceutical Industries Limited (including its subsidiaries and/or associated companies, "Sun Pharma"), today announced the presentation of data from its Phase 3 clinical trial, THRIVE-AA2. The presentation highlights THRIVE-AA2 study results evaluating the oral investigational medicine deuruxolitinib in adult patients with moderate to severe alopecia areata, an autoimmune disorder that results in patchy or complete scalp hair loss. The THRIVE-AA2 data are being presented by Brett King, M.D, Ph.D., Department of Dermatology, Yale University School of Medicine and clinical investigator of THRIVE-AA2, during the American Academy of Dermatology's (AAD) 2023 Annual Meeting Late Breaking News Session.

The primary efficacy endpoint for THRIVE-AA2 was the percentage of patients achieving an absolute Severity of Alopecia Tool (SALT) score of 20 or less at week 24 of treatment compared to placebo. As previously disclosed in the positive topline results reported by Concert, significant improvements in scalp hair regrowth were achieved at 24 weeks for patients taking 8 mg twice-daily and 12 mg twice-daily doses of deuruxolitinib. The AAD presentation includes new data from the THRIVE–AA2 study showing the ability of deuruxolitinib to achieve near-complete or complete scalp hair regrowth, with 21% (8 mg twice-daily) and 35% (12 mg twice-daily) of patients, compared with 0% receiving placebo, achieving a SALT score of 10 or less after 24 weeks.

The Phase 3 data presented at AAD include a comprehensive review of the THRIVE-AA2 results and further elaborate the topline data reported in August 2022:

- The primary efficacy endpoint for THRIVE-AA2 was the percentage of patients achieving an absolute SALT score of 20 or less at Week 24 of treatment.
- A statistically significant proportion of patients treated with either 8 mg twice-daily or 12 mg twice-daily of deuruxolitinib experienced greater scalp regrowth compared to placebo. The proportion of patients achieving a SALT score of 20 or less (meaning 20 percent or less scalp hair loss) was 38.3 percent in the 12 mg twice-daily dose group and 33.0 percent in the 8 mg twice-daily dose group, compared to 0.8 percent of patients in the placebo group, at the 24-week endpoint. The treatment difference for both dose groups of deuruxolitinib relative to placebo was statistically significant ($p<0.0001$).
- The key secondary endpoints were the percentage of responders on a Satisfaction of Hair Patient Reported Outcome (SPRO) scale at Week 24 and the percentage of patients achieving absolute SALT scores of 20 or less at each of Weeks 20, 16, 12 and 8. 47% of patients in the 8 mg twice-daily group and 52% of patients in the 12 mg twice-daily group reported being "satisfied" or "very satisfied," as compared to 2% of patients in the placebo group. The treatment difference for both groups relative to placebo was statistically significant. SALT scores of 20 or less at Weeks 20, 16 and 12 were statistically significant in both dose groups.
- The safety profile seen with deuruxolitinib in THRIVE-AA2 was consistent with previous studies. The most common (≥5%) side effects in any dose group were COVID-19 infection, nasopharyngitis, increased blood creatine kinase levels, acne and headache. No pulmonary embolisms or deep vein thromboses were observed in the trial. Two patients treated with the 8 mg twice-daily dose and two patients treated with the 12 mg twice-daily dose developed herpes zoster (shingles). Five serious adverse events were reported in five patients, with one in the 8 mg twice-daily dose group that was assessed as possibly related to treatment.

"These data are highly encouraging and support the potential of deuruxolitnib to regrow hair on the scalp, eyebrows and eyelashes in patients with alopecia areata, and in many cases with a rapid onset of effect," stated Dr. King. "We are pleased by the consistency of the Phase 3 results generated in the THRIVE-AA clinical program," said James V. Cassella, PhD, Chief Development Officer of Concert. "Based on the strength of the THRIVE-AA2 data along with data from the THRIVE-AA1 trial and the continuation of our Breakthrough Therapy designation, deuruxolitinib has the potential to be a best-in class treatment option for alopecia areata. We look forward to filing our deuruxolitinib New Drug Application with the Food and Drug Administration next quarter and bringing this potential new treatment option to patients living with alopecia areata as soon as possible."

Details from the oral presentation, entitled "Results from THRIVE-AA2: A Double Blind, Placebo-Controlled Phase 3 Clinical Trial of Deuruxolitinib (CTP-543), an Oral JAK Inhibitor, in Adult Patients With Moderate to Severe Alopecia Areata," is available in the Scientific Presentations section of Concert's website.

About THRIVE-AA2

THRIVE-AA2 (NCT04797650) was a randomized, double-blind, placebo-controlled clinical trial in 517 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-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 was approximately 87.9 (corresponding to approximately 12% average scalp hair coverage).

These data, along with data from the first Phase 3 clinical trial, THRIVE-AA1, are intended to form the basis of a New Drug Application (NDA) planned to be submitted to the U.S. Food and Drug Administration (FDA) in the first half of 2023.

About Deuruxolitinib and Alopecia Areata

Deuruxolitinib is an investigational oral selective inhibitor of Janus kinases JAK1 and JAK2. The U.S. Food and Drug Administration recently maintained Breakthrough Therapy designation for deuruxolitinib for the treatment of adult patients with moderate to severe alopecia areata and previously granted Fast Track designation for deuruxolitinib for the treatment of 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 treatment options available for alopecia areata.

Disclaimer:

Statements in this "Document" describing the Company's objectives, projections, estimates, expectations, plans or predictions or 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. The Company undertakes no 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.

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.)

About Sun Pharmaceutical Industries, Inc.

Sun Pharmaceutical Industries, Inc. (Sun Pharma) is a wholly-owned subsidiary of Sun Pharmaceutical Industries Limited (SPIL). SPIL is the world's fourth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business and a skilled team enables it to deliver high-quality products, trusted by customers and patients in over 100 countries across the world, at affordable prices. Its global presence is supported by manufacturing facilities spread across six continents and approved by multiple regulatory agencies, coupled with a multi-cultural workforce comprising over 50 nationalities. SPIL fosters excellence through innovation supported by strong R&D capabilities across multiple R&D centers, with investments of approximately 6% of annual revenues in R&D. For further information, please visit www.sunpharma.com/usa & follow us on Twitter.

On March 6, Sun Pharma announced the successful completion of its acquisition of Concert Pharmaceuticals, Inc., a late-stage clinical biopharmaceutical company that is developing deuruxolitinib, a novel, deuterated, oral JAK1/2 inhibitor, for the potential treatment of adult patients with moderate to severe alopecia areata. For additional information on the acquisition, please read the acquisition closure press release.

SOURCE Sun Pharma