Concert Pharmaceuticals Maintains Deuruxolitinib Breakthrough Therapy Designation from FDA for the Treatment of Alopecia Areata

February 15, 2023

LEXINGTON, Mass.--(BUSINESS WIRE)--Feb. 15, 2023-- Concert Pharmaceuticals, Inc. today announced that, after a recent review of deuruxolitinib clinical data by the U.S. Food and Drug Administration (FDA), the FDA determined that deuruxolitinib will maintain its Breakthrough Therapy designation. Deuruxolitinib, an oral Janus kinase (JAK) inhibitor, is being developed for the treatment of adult patients with moderate to severe alopecia areata.

In light of the FDA approval of a different JAK inhibitor as the first treatment for alopecia areata, the FDA previously notified Concert that it was reviewing the Breakthrough Therapy designation previously granted for deuruxolitinib. At the FDA's request, Concert submitted additional clinical data and justification to support the continued eligibility of deuruxolitinib for the designation. The FDA has now informed Concert that, after reviewing these data, the Breakthrough Therapy designation criteria continue to be met at this time.

The FDA grants Breakthrough Therapy designation for drug candidates that treat a serious or life-threatening condition where preliminary clinical evidence indicates that the drug candidate may demonstrate substantial improvement on a clinically significant endpoint(s) over available therapies. Whether the improvement over available therapy is substantial is a matter of judgment and depends on both the magnitude of the treatment effect, which could include duration of the effect, and the importance of the observed clinical outcome. In general, the preliminary clinical evidence should show a clear advantage over available therapy.

The FDA originally granted Breakthrough Therapy designation to deuruxolitinib for the treatment of adult patients with moderate to severe alopecia areata in 2020, which was supported by positive data from a Phase 2 clinical trial. The additional information that Concert submitted to support the continued maintenance of the Breakthrough Therapy designation for deuruxolitinib included the positive data from two Phase 3 clinical trials.

About Deuruxolitinib and Alopecia Areata

Deuruxolitinib is an investigational oral selective inhibitor of Janus kinases JAK1 and JAK2. In addition to Breakthrough Therapy designation for the treatment of adult patients with moderate to severe alopecia areata, the FDA has granted deuruxolitinib Fast Track designation 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 approximately 1.5 million Americans at any given time.[1] 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.

About Concert

Concert Pharmaceuticals is a late-stage clinical biopharmaceutical company that is developing deuruxolitinib (CTP-543), a novel, deuterated, oral JAK1/2 inhibitor. Concert has successfully completed two Phase 3 trials with deuruxolitinib in adults with alopecia areata, a serious autoimmune dermatological disease. The Company is also evaluating the use of deuruxolitinib in other indications and assessing a number of earlier-stage pipeline candidates. For more information, please visit www.concertpharma.com or follow us on Twitter, Instagram or LinkedIn.

Cautionary Note on Forward Looking Statements

Any statements in this press release about our future expectations, plans and prospects, including, among others, statements about our expectations regarding the development of deuruxolitinib, and any other statements containing the words “anticipate,” “believe,” “continue,” “could,” “estimate,” “expect,” “intend,” “may,” “plan,” “potential,” “predict,” “project,” “should,” “target,” “will,” “would” and similar expressions, constitute forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995. Actual results may differ materially from those indicated by such forward-looking statements as a result of various important factors, including: the uncertainties inherent in the initiation, timing and design of future clinical trials, the availability and timing of data from ongoing and future clinical trials and the results of such trials, whether preliminary results, including safety profiles, from a clinical trial will be predictive of the final results of that trial or whether results of early clinical trials will be indicative of the results of later clinical trials, expectations for the timing of the submission of a New Drug Application, the availability of regulatory approvals and other factors discussed in the “Risk Factors” section of our most recent Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission and in other filings that we make with the Securities and Exchange Commission. In addition, any forward-looking statements included in this press release represent our views only as of the date of this release and should not be relied upon as representing our views as of any subsequent date. We specifically disclaim any obligation to update any forward-looking statements included in this press release.

[1] Benigno M. Clinical, Cosmetic and Investigational Dermatology 2020

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