Concert Pharmaceuticals Completes Enrollment in THRIVE-AA2 Phase 3 Clinical Trial Evaluating CTP-543 for Alopecia Areata

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LEXINGTON, Mass.--(BUSINESS WIRE)--Jan. 4, 2022-- Concert Pharmaceuticals, Inc. (NASDAQ: CNCE) today announced that it has completed patient enrollment in THRIVE-AA2, the second Phase 3 clinical trial to evaluate the efficacy and safety of CTP-543, an oral Janus kinase (JAK) inhibitor, in adult patients with moderate to severe alopecia areata.

The THRIVE-AA clinical program includes two international Phase 3 studies, THRIVE-AA1 and THRIVE-AA2. Enrollment in the THRIVE-AA1 trial was completed in October 2021, and topline data is expected in the second quarter of 2022. Topline data from the THRIVE-AA2 trial is expected in the third quarter of 2022.

"With both of our Phase 3 trials now fully enrolled and progressing toward completion, our focus will be on efficiently moving to data read out and preparing our New Drug Application, which we plan to submit to the FDA in the first half of 2023," said James V. Cassella, Ph.D., Chief Development Officer of Concert Pharmaceuticals. "There is a tremendous need for viable treatment options for individuals with alopecia areata, and we would like to express our sincere gratitude to the patients who volunteered for our clinical trials to further the development of CTP-543 as a potential therapeutic for this significant autoimmune disease."

About the THRIVE-AA2 Study

THRIVE-AA2 (NCT04797650) is a randomized, double-blind, placebo-controlled clinical trial in adult patients 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 Severity of Alopecia Tool (SALT). Key aspects of THRIVE-AA2 include:

- Patient characteristics: adults age 18-65 years with ≥ 50% hair loss are eligible for the study;
- Enrollment size: 517 patients;
- Dosing: 8 mg twice-daily or 12 mg twice-daily of CTP-543 or placebo for 24 weeks; and
- Primary endpoint: percent of patients achieving a SALT score ≤ 20 at Week 24.

Further information about the THRIVE-AA clinical trials is available on www.clinicaltrials.gov.

About CTP-543 and Alopecia Areata

CTP-543 is an investigational oral selective inhibitor of Janus kinases JAK1 and JAK2. The U.S. Food and Drug Administration (FDA) has granted CTP-543 Breakthrough Therapy designation for the treatment of adult patients with moderate to severe alopecia areata and 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 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 no drugs approved by the FDA for the treatment of alopecia areata.

The FDA selected alopecia areata as one of eight new disease areas that it focused on under its Patient-Focused Drug Development Initiative (PFDDI) in 2016-2017. The goal of the PFDDI is to bring patient perspectives into an earlier stage of product development. Following the FDA's Patient-Focused Drug Development meeting held in September 2017 on alopecia areata, the FDA summarized the input shared by patients and patient representatives in a Voice of the Patient report. Additional information on the PFDDI is available online.

About Concert

Concert Pharmaceuticals is a clinical stage biopharmaceutical company that is developing small molecule drugs that it discovered through the application of its DCE Platform® (deuterated chemical entity platform). Selective incorporation of deuterium into known molecules has the potential, on a case-by-case basis, to provide better pharmacokinetic or metabolic properties, thereby enhancing their clinical safety, tolerability or efficacy. Concert's lead product candidate is in late-stage development for the treatment of alopecia areata, a serious autoimmune dermatological condition. Concert is also assessing a number of earlier-stage pipeline candidates. For more information please visit www.concertpharma.com or follow us on Twitter at @ConcertPharma or on 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 CTP-543, the timing of availability of clinical trial data and the timing of regulatory filings, 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 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 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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