Concert Pharmaceuticals Announces Results from CTP-692 Phase 2 Trial in Patients with Schizophrenia

February 1, 2021

CTP-692 Did Not Achieve Primary Endpoint Assessing Positive and Negative Syndrome Scale (PANSS) Total Score at 12 Weeks

LEXINGTON, Mass.--(BUSINESS WIRE)--Feb. 1, 2021-- Concert Pharmaceuticals, Inc. (NASDAQ:CNCE) today announced that its Phase 2 clinical trial to evaluate CTP-692 as an adjunctive treatment in patients with schizophrenia did not meet the primary endpoint or other secondary endpoints. CTP-692 is a deuterated form of D-serine, an endogenous amino acid that is a co-agonist of the NMDA receptor.

"The body of evidence in the field supporting D-serine as an adjunctive treatment for schizophrenia was compelling and led us to advance CTP-692 into a Phase 2 proof of concept study. Unfortunately, we didn't see the results we hoped for to support continuation of this program. Going forward, we will focus our internal resources on the advancement of CTP-543, which is currently in Phase 3 evaluation for the treatment of alopecia areata, and evaluation of additional pipeline candidates," stated Roger Tung, Ph.D., President and Chief Executive Officer of Concert Pharmaceuticals. "We believe that we conducted a well-designed, well-controlled study and extend our gratitude to the patients, caregivers and investigators for their participation in the CTP-692 Phase 2 study. It's our hope that these learnings will support future research to address the important need to improve the symptom domains of schizophrenia."

The Phase 2 trial was a double-blind, randomized, placebo-controlled study to evaluate the safety and efficacy of CTP-692. The primary endpoint of the trial was the change in the Positive and Negative Syndrome Scale (PANSS) total score at 12 weeks compared to baseline. A total of 325 patients, already on a stable course of an antipsychotic medication, were randomized to receive 1, 2 or 4-gram doses of CTP-692 or placebo once-daily. CTP-692 did not show a statistically significant improvement over placebo at any of the doses. Additionally, no significant improvements were observed in either the positive or negative symptoms subscales of the PANSS scale at any of the CTP-692 doses evaluated.

In the Phase 2 trial, treatment with CTP-692 was generally well tolerated. The adverse events reported were predominantly mild in severity and equally distributed across the dose groups, including placebo.

Key data slides are available in the Investors section of Concert's website at: https://ir.concertpharma.com/events-presentations.

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 clinical development of CTP-543 and CTP-692, 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.

View source version on businesswire.com: https://www.businesswire.com/news/home/20210201005232/en/

Justine Koenigsberg (Investors)
Concert Pharmaceuticals, Inc.
(781) 674-5284
ir@concertpharma.com

Kathryn Morris (Media)
The Yates Network
(914) 204-6412
kathryn@theyatesnetwork.com

Source: Concert Pharmaceuticals, Inc.