



CinCor Pharma Announces Last Patient Randomized in Phase 2 HALO Trial and Initiation of Long-Term Extension Study for Baxdrostat, a Selective Aldosterone Synthase Inhibitor, in Uncontrolled Hypertension

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Open Label Extension Study Will Evaluate Baxdrostat for Up to 52 Weeks

Topline Data for Phase 2 HALO Trial Expected in 2H 2022

Topline Data for Phase 2 BrighTn Trial Expected in August 2022

WALTHAM, Mass., July 26, 2022 (GLOBE NEWSWIRE) -- CinCor Pharma, Inc. ("CinCor") announced today that the last patient has been randomized in the Phase 2 HALO trial of baxdrostat (CIN-107), a highly selective aldosterone synthase inhibitor, in patients with uncontrolled hypertension. CinCor also announced initiation of an open-label extension study of patients enrolled in HALO with uncontrolled hypertension to evaluate the long-term safety of baxdrostat for up to 52-weeks.

"Despite being on one or more different classes of antihypertensive agents, approximately 50 million Americans still fail to achieve blood pressure control. Baxdrostat is designed to selectively reduce aldosterone production, potentially offering a new mechanism that directly targets a key underlying [cause of hypertension](#)," said Mason Freeman, M.D., Chief Medical Officer at CinCor. "HALO is intended to evaluate whether baxdrostat can lower elevated blood pressure in patients with uncontrolled hypertension despite taking one or more antihypertensive agents. Baseline plasma hormone levels linked to hypertension, specifically aldosterone, will also be assessed to determine whether specific biomarkers can predict blood pressure responses and also help us identify the patients most likely to benefit from baxdrostat. Patient data from the open-label extension study are expected to provide long-term safety and tolerability of baxdrostat."

Marc de Garidel, Chief Executive Officer at CinCor, added, "HALO includes patients who fail to achieve blood pressure control while on up to two antihypertensive agents, potentially broadening the hypertension opportunity of baxdrostat. We are pleased to announce the initiation of our open-label extension study and, with the randomization of the last patient in HALO, we believe we remain on track to report initial topline data for HALO in the second half of 2022. In addition, we look forward to sharing initial topline BrighTn results in August."

The [HALO](#) trial is an ongoing Phase 2 randomized, double-blind, placebo-controlled, multicenter, parallel-group, clinical trial designed to assess the safety and efficacy of baxdrostat in subjects taking up to two antihypertensive agents at their maximally tolerated dosages. The HALO trial completed enrollment with 249 patients randomized. The primary endpoint of the trial is the change in systolic blood pressure (SBP) after eight weeks of treatment. Background antihypertensive therapy will be discontinued after eight weeks and patients will only take baxdrostat for four additional weeks to characterize monotherapy responses and to enable long-term safety assessments of the drug in the open label extension study that follows the HALO trial. Topline data from the HALO trial is expected in the second half of 2022, and the open-label extension trial is expected to be completed in the second half of 2023.

About CinCor

CinCor, founded in 2018, is a clinical-stage biopharmaceutical company with a mission to bring innovation to the pharmaceutical treatment of hypertension and other cardio-renal diseases. Its lead asset, [baxdrostat \(CIN-107\)](#), a highly selective, oral small molecule inhibitor of aldosterone synthase, is in clinical development for the [treatment of hypertension](#) and primary aldosteronism.

About Baxdrostat (CIN-107)

Baxdrostat (CIN-107) is a highly selective, oral small molecule inhibitor of aldosterone synthase, the enzyme responsible for the synthesis of aldosterone in the adrenal gland, in development for patient populations with significant unmet medical needs, including treatment-resistant hypertension and primary aldosteronism. Hypertension, which is defined by the American College of Cardiology and the American Heart Association as resting blood pressure above 130/80 mm Hg, is generally acknowledged to be one of the most common preventable risk factors for premature death worldwide. Though often asymptomatic, hypertension significantly increases the risk of heart disease, stroke, and kidney disease, amongst other diseases. It is estimated that as much as 20% of the global population suffers from hypertension, including nearly one-half of the adult population in the U.S., or 116 million hypertensive patients.

Forward-Looking Statements

This press release contains certain forward-looking statements, including, but not limited to, statements related to CinCor's business in general; the results and timing of CinCor's ongoing and planned clinical trials, including HALO and the open-label extension study; the anticipated timing of disclosure of data and results of clinical trials and studies, including for HALO and the open-label extension study; the progress of CinCor's research and development programs and clinical trials and studies, including enrollment and retention in clinical trials and studies; plans for initiating future clinical trials and studies; the therapeutic potential of baxdrostat (CIN-107), including its potential to be an effective treatment for patients with uncontrolled hypertension; CinCor's clinical milestones and pipeline; expectations with respect to regulatory matters; expectations with respect to potential market size; and other statements that are not historical facts. Because such statements are subject to risks and uncertainties, actual results may differ from those expressed or implied by such forward-looking statements. Words such as "anticipates," "believes," "expected," "intends," "plan," "may," "will," "project," "estimate," "continue," "advance," "design," and "future" or similar expressions are intended to identify forward-looking statements. These forward-looking statements are based on CinCor's current plans, objectives, estimates, expectations and intentions, involve assumptions that may never materialize or may prove to be incorrect and inherently involve significant risks and uncertainties, including factors beyond CinCor's control, that could cause actual results, performance, or achievement to differ materially and adversely from those anticipated or implied in the statements, including, without limitation, CinCor has incurred significant operating losses since its inception; CinCor has a limited operating history and no history of commercializing products; CinCor will require substantial additional funding to finance its operations; CinCor's

business is entirely dependent at this time on the success of one drug, baxdrostat; initial, interim, “top-line” and preliminary data from clinical trials announced or published from time to time may change; CinCor may not be successful in its efforts to expand its pipeline beyond baxdrostat; success in preclinical studies or earlier clinical trials may not be indicative of results in future clinical trials; enrollment and retention of patients in clinical trials could be delayed; CinCor relies and will rely on third parties to conduct, supervise and monitor existing clinical trials and potential future clinical trials; developments from the company’s competitors and the marketplace for the company’s products; and CinCor’s business, operations and clinical development timelines and plans may be adversely affected by the evolving and ongoing COVID-19 pandemic and geopolitical events, including the ongoing military conflict between Russia and Ukraine and related sanctions against Russia, and matters related thereto; and other risks and uncertainties affecting the company, including those described under the caption “Risk Factors” and elsewhere in CinCor’s Annual Report on Form 10-K for the year ended December 31, 2021 filed with the Securities and Exchange Commission (SEC) on March 22, 2022, and other filings and reports that CinCor may file from time to time with the SEC, including its quarterly report on Form 10-Q for the three months ended March 31, 2022 filed with the SEC on May 10, 2022. Other risks and uncertainties of which CinCor is not currently aware may also affect the company’s forward-looking statements and may cause actual results and the timing of events to differ materially from those anticipated. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management’s assumptions and estimates as of such date. CinCor undertakes no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise, except as may be required by law.

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