CinCor Pharma Announces Positive Topline Data for Phase 2 BrigHtn Trial Evaluating Baxdrostat, its Selective Aldosterone Synthase Inhibitor, in Treatment-Resistant Hypertension

August 8, 2022

Successfully met the primary endpoint in the BrigHtn trial, delivering a 20.3 mmHg reduction in systolic blood pressure (SBP), or an 11 mmHg (p-value < 0.0001) decline on a placebo-adjusted basis, at 2 mg dose

Independent Data Review Committee determined that the trial met pre-specified statistical criteria of overwhelming efficacy at the highest dose allowing completion of the trial with 275 patients randomized

Dose-dependent reduction in SBP observed

Compelling safety and tolerability profile

Conference call and live webcast today at 8:30 AM Eastern Time

WALTHAM, Mass., Aug. 08, 2022 (GLOBE NEWSWIRE) -- CinCor Pharma, Inc. ("CinCor") announced today the topline results and successful completion of its Phase 2 BrigHtn trial evaluating the efficacy and safety of baxdrostat, a once daily potentially first-in-class, highly selective aldosterone synthase inhibitor in patients with treatment-resistant hypertension, defined as patients taking at least three blood pressure medications at their maximally tolerated doses, one of which must be a diuretic. Results showed baxdrostat met its primary endpoint and achieved statistically significant placebo-adjusted reduction in systolic blood pressure, including 11 mmHg (p-value < 0.0001) at a dose of 2 mg.

"We are thrilled to report that the BrigHtn trial has met its primary endpoint with baxdrostat demonstrating a double-digit placebo-adjusted reduction in blood pressure in patients with treatment-resistant hypertension," said Marc de Garidel, Chief Executive Officer at CinCor. "We believe these data represent an important scientific breakthrough, supporting the potential of baxdrostat to effectively emerge as a new mechanism of action in the hypertension treatment paradigm, and to potentially be the first meaningful innovation in the treatment of hypertension in decades. Treatment resistant patients represent as many as 15 million adults in the United States alone, and now CinCor looks forward to opening a new era in hypertension innovation."

"The results of BrigHtn are highly supportive for the continued development of baxdrostat as a novel antihypertensive agent," added Mason Freeman, M.D, Chief Medical Officer at CinCor. "The goal of BrigHtn was to identify effective doses of the drug and to characterize baxdrostat tolerability in the treatment-resistant hypertension patient population. The fact that these patients with very difficult-to-control hypertension responded so well to baxdrostat at both the 1 mg and 2 mg dose levels, is extremely encouraging, as is the observed tolerability of baxdrostat when used concurrently in patients on multiple background anti-hypertensive agents."

Key clinical data from BrigHtn suggests impressive efficacy and meaningful dose dependency in the treatment of patients with resistant hypertension:

- BrigHtn successfully met its primary endpoint, demonstrating a statistically significant change from baseline in mean seated SBP versus placebo for the 2 mg and 1 mg doses:
  - 20.3 mmHg SBP reduction at the 2 mg dose, or 11.0 mmHg placebo-adjusted decline ($p < 0.0001$)
  - 17.5 mmHg SBP reduction at the 1 mg dose, or 8.1 mmHg placebo-adjusted decline ($p = 0.0030$)
  - 12.1 mmHg SBP reduction at the 0.5 mg dose, or 2.7 mmHg placebo-adjusted decline ($p = 0.3110$)
- Secondary endpoint results included baxdrostat significantly lowering diastolic blood pressure (DBP) by 5.2 mmHg in the 2mg dose, and approximately 46% of patients in the 2 mg dose arm achieving blood pressure control (SBP less than 130mmHg)
- The BrigHtn trial completed enrollment with 275 patients after an Independent Data Review Committee determined that the trial had met pre-specified statistical criteria of overwhelming efficacy at the highest dose in this dose-ranging trial

Morris Brown, M.D., F. Med.Sci, Professor of Endocrine Hypertension at Barts and the London Medical School, UK, and former president of the British Hypertension Society, added, "The BrigHtn trial results represent the culmination of decades searching for a clinically safe drug which prevents synthesis of aldosterone, but not the similar adrenal gland hormone, cortisol. These impressive results suggest that baxdrostat lowered blood pressure in the BrigHtn trial by more than the reduction observed for spironolactone, as my colleagues and I reported in the PATHWAY-2 study in a similar patient group. For the first time in hypertension, the BrigHtn trial demonstrated that a dose-dependent reduction in blood pressure is accompanied by a dose-dependent reduction in a major cause of hypertension, confirming indeed the importance of aldosterone as a remediable factor in resistance to other commonly used drugs."

Key clinical safety and tolerability findings of baxdrostat support a safe and well-tolerated profile

- No drug related serious adverse events (SAEs) observed or major safety concerns were reported across all three dose cohorts tested after 12 weeks of treatment
- Treatment-Emergent SAEs (TESAEs) were reported in 10 patients and deemed by investigators to be unrelated to baxdrostat. These TESAEs included hyponatremia, hyperkalemia, cellulitis, urinary tract infection, dehydration,

hyperglycemia, arthralgia, dizziness, syncope, acute kidney injury, nephrolithiasis, acute respiratory failure, and respiratory failure, with one patient in the 2mg dose cohort experiencing six of these SAEs
- One subject experienced an isolated instance of elevated potassium above 6mEq/L, which was deemed drug related, although upon retesting, the potassium level for this patient dropped sufficiently to allow resumption of baxdrostat, and the patient completed the trial with normal potassium levels. Overall, observed hyperkalemia rates in the trial were low, and resulted in no clinical safety concerns
- Low discontinuation rate of less than 1% (2 patients) due to treatment-related adverse events, which included hyperkalemia and hypotension

Deepak L. Bhatt, M.D., M.P.H., Executive Director of Interventional Cardiovascular Programs at Brigham and Women's Hospital and Professor of Medicine at Harvard Medical School, further added, "The low rates of hyperkalemia are encouraging since more than 90% of BrigHtn participants were on background antihypertensives that are challenging to combine with aldosterone blocking agents due to concerns over hyperkalemic off-target side effects. Overall, the double-digit placebo corrected reduction in systolic blood pressure, well-tolerated safety profile, and titratable dose response with once-daily baxdrostat has the potential to address multiple unmet needs in the treatment of treatment-resistant hypertension patients."

The BrigHtn trial was a Phase 2 randomized, double-blind, placebo-controlled dose-ranging study designed to assess the safety and efficacy of baxdrostat in subjects who have not achieved their target blood pressure despite receiving three or more antihypertensive agents at their maximally tolerated doses, one of which must be a diuretic. The trial evaluated three active doses of baxdrostat (0.5 mg, 1.0 mg, and 2.0 mg) compared to placebo control in 275 patients randomized across all four dosing cohorts, with 248 patients completing. The primary endpoint of BrigHtn was the change in SBP from randomization to study end after 12 weeks of treatment.

As recently announced, in July 2022 CinCor completed enrollment in the Phase 2 HALO trial with 249 patients randomized. HALO is studying the efficacy and safety of baxdrostat in patients whose blood pressure is not controlled despite treatment with up to two antihypertensive agents and remains on track to be completed in the second half of 2022. We also announced the initiation of a Phase 2 Open Label Extension trial to evaluate the safety and tolerability of baxdrostat in patients for up to 52 weeks.

Conference Call and Webcast Information
CinCor management will hold a conference call and webcast today at 8:30 AM Eastern Time to provide an update on the BrigHtn Phase 2 trial. The dial-in number for the conference call is 877-407-9039 (U.S./Canada) or 201-689-8470 (international). The conference ID for all callers is 13731977. The live webcast and replay may be accessed by visiting the CinCor website at https://www.cincor.com/events-presentations. The replay will be available for 30 days following the call.

About CinCor
CinCor, founded in 2018, is a clinical-stage biopharmaceutical company with a mission to bring innovation to the pharmaceutical treatment of 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 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 its HALO trial; the anticipated timing of disclosure of results of clinical trials, including for HALO; the progress of CinCor's research and development programs and clinical trials and studies, including enrollment and retention in clinical trials; 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 treatment-resistant hypertension, uncontrolled hypertension and CKD, and the ability of baxdrostat to address multiple unmet needs in patients; the potential of baxdrostat to emerge as a new mechanism of action in the hypertension treatment paradigm and to potentially be the first meaningful innovation in the treatment of blood pressure in decades; 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" 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, geopolitical events, including the ongoing military conflict between Russia and Ukraine and related sanctions against Russia, and macroeconomic conditions, including rising inflation and uncertain credit and financial markets, 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, quarterly report on Form 10-Q for the three months

ended March 31, 2022 filed with the SEC on May 10, 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 June 30, 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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