CinCor Pharma Announces Topline Data for Phase 2 HALO Trial Evaluating Selective Aldosterone Synthase Inhibitor Baxdrostat in Uncontrolled Hypertension

November 28, 2022

Primary endpoint in Intention to Treat (ITT) was not met despite large absolute reductions in Systolic Blood Pressure (SBP)

12.6 mmHg placebo-adjusted reduction in SBP with 2 mg baxdrostat in a pre-specified subgroup that represents approximately 81-89% of the U.S. hypertension population (nominal p-value = 0.001)

Safety profile and tolerability consistent with BrigHtn Phase 2 data; no patient discontinued due to treatment-related adverse events; low hyperkalemia incidence

HALO in combination with BrigHtn informs the dose and study populations anticipated to be recruited into Phase 3 trials pending confirmation by FDA at planned end of Phase 2 meeting in January 2023; Phase 3 trials expected to begin first half of 2023

Baxdrostat's clinical program remains on track for a potential NDA submission in 2025

Conference call and live webcast today at 8:00 AM Eastern Time

WALTHAM, Mass., Nov. 28, 2022 (GLOBE NEWSWIRE) -- CinCor Pharma, Inc. ("CinCor") announced today the topline results and completion of its Phase 2 HALO trial evaluating the efficacy and safety of baxdrostat in patients with uncontrolled hypertension taking up to two blood pressure medications at the maximally tolerated doses. Baxdrostat is a once daily potentially first-in-class, highly selective aldosterone synthase inhibitor. While HALO did not achieve statistical significance on its primary endpoint evaluating change from baseline in mean seated systolic blood pressure (SBP) in the intention to treat (ITT) population (n = 249), a pre-specified subgroup analysis of non-Hispanic patients (47%, 116/249) representing approximately 81-89% of the hypertension population in the United States, demonstrated a placebo-adjusted reduction in SBP of 12.6 mmHg (nominal *p*-value = 0.001) at the 2 mg dose. The safety profile and tolerability of baxdrostat was consistent with previously reported Phase 2 BrigHtn data in resistant hypertension.

"We are pleased HALO has achieved our prospective goal of better understanding which patients respond best to baxdrostat, as well as further confirming baxdrostat's safety profile and tolerability," said Marc de Garidel, Chief Executive Officer at CinCor. "The results of the two Phase 2 trials, involving over 500 patients of diverse backgrounds, enable us to maintain our previously announced plans to meet with the FDA in January 2023 at an end of Phase 2 meeting to discuss our Phase 3 program plans. Following that meeting, we anticipate initiating our pivotal Phase 3 trials in the first half of 2023. We are very excited about developing a potentially well differentiated drug to address the unmet medical need of tens of millions of uncontrolled and resistant hypertension patients in the U.S. alone."

Mason Freeman, M.D., Chief Medical Officer at CinCor added, "While we still need to learn more about the factors driving different responses in our pre-specified sub-group analyses, it is clear that baxdrostat generated double-digit SBP reductions in study sub-groups, which include Black/African American patients, representative of approximately 81-89% of the hypertensive population of the U.S. The data also demonstrate a favorable safety profile and tolerability across the treated patient groups. Patients in HALO were not pre-selected for inclusion on the basis of aldosterone, renin, or other hormonal characteristics, suggesting baxdrostat's utility in the uncontrolled hypertensive population may be broader than expected. When combined with data from our BrigHtn study of treatment resistant patients, the HALO trial has provided key insights needed to select patient populations and dosing of baxdrostat that we plan to propose to the FDA for our Phase 3 program. We want to thank all the patients and healthcare providers who have contributed to a better understanding of this new mechanistic class."

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 reductions in systolic blood pressure levels among the patients from HALO who were adherent to study drug are consistent with the overall positive data from BrigHtn. HALO also reconfirms the safety profile of baxdrostat. The data from these two trials provides the necessary dosing, safety, and target population information CinCor needs to design and execute its Phase 3 programs in resistant and uncontrolled hypertension. I am excited to continue working with the Company to help them investigate the safety and effectiveness of baxdrostat in potentially providing improved treatment options for the large numbers of patients whose hypertension remains refractory to current therapies."

HALO informs target populations for planned Phase 3 trials:

- HALO did not achieve its primary endpoint of statistically significant change from baseline in mean seated SBP versus placebo in the ITT population; however, statistically significant reduction in SBP in the prespecified non-Hispanic subgroup analysis was demonstrated
- Hispanic or Latino patients represented 53% (133/249) of the ITT population of the study
- The non-Hispanic population of HALO represented 46% (116/249) of the ITT population in the study but represents approximately 81-89% of the hypertensive population of the U.S.

Change from baseline to Week 8, mean seated SBP	Dose of baxdrostat	Intent to Treat (ITT) N = 249	Hispanic Prespecified Subgroup	Non-Hispanic Prespecified Subgroup

			N = 133	N = 116
Total Placebo-adjusted *Nominal P-value* **Not significant (NS)*	2 mg	-20.0, -3.8 *NS**	-16.3, 1.9 *NS**	-26.8, **-12.6** ***0.001***
	1 mg	-16.1, 0.1 *NS**	-14.1, 4.0 *NS**	-18.0, -3.8 *NS**
	0.5 mg	-17.0, -0.8 *NS**	-17.1, 1.1 *NS**	-16.2, -2.0 *NS**

Total SBP change is the first number in the results column, Placebo-adjusted is the second number in the results column, and the third value is the nominal p-value for statistical significance of the placebo-adjusted change.

Safety and tolerability findings reinforce a consistent, and well-tolerated profile

- No drug related serious adverse events (SAEs) observed and no major safety concerns were reported across all three dose cohorts tested after 8 weeks of treatment
- No patient discontinued the study due to treatment-related adverse events
- Baxdrostat demonstrated a favorable safety and tolerability profile with 3 cases of moderate hyperkalemia (≥ 6 mEq/L) after 8 weeks of treatment none of which led to study discontinuation
- Treatment-emergent serious adverse events were reported in 2 patients after 8 weeks of treatment; no SAE was deemed related to baxdrostat
- 85% of patients that completed HALO enrolled in the ongoing open label extension (OLE) trial evaluating the safety and efficacy of baxdrostat over 52 weeks

The HALO trial was a 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 trial evaluated three active doses of baxdrostat (0.5 mg, 1.0 mg, and 2.0 mg) compared to placebo control in 249 patients randomized across all four dosing cohorts, with 249 patients completing. The primary endpoint of the trial was the change in SBP after eight weeks of treatment. Background antihypertensive therapy was to be discontinued after these eight weeks, and patients only took baxdrostat at the 2.0 mg dose for four additional weeks in Part 2 of the trial to characterize monotherapy responses and to enable long-term safety assessments of the drug in the ongoing 52-week open label extension study that follows the HALO trial, which is expected to be completed in the second half of 2023.

Conference Call and Webcast Information
CinCor management will hold a conference call and live webcast today at 8:00 AM Eastern Time to provide an update on the Phase 2 HALO 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 13734665. 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 hypertension and other cardio-renal diseases. Its lead asset, baxdrostat, a highly selective, oral small molecule inhibitor of aldosterone synthase, is in clinical development for the treatment of hypertension and primary aldosteronism.

About Baxdrostat
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 development and commercial potential of baxdrostat; expectations with respect to the planned end of Phase 2 meeting with the FDA and the anticipated timing thereof; expectations with respect to CinCor's ongoing open label extension trial and planned Phase 3 trials, including the timing, design and results thereof; the potential utility of baxdrostat in the uncontrolled hypertensive population to be broader than expected; the therapeutic potential of baxdrostat (CIN-107), including its potential to be an effective treatment for patients with treatment-resistant hypertension, uncontrolled hypertension, CKD and primary aldosteronism, and the ability of baxdrostat to address multiple unmet needs in patients; 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 interest rates 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, CinCor's Quarterly Report on Form 10-Q for the three months ended March 31, 2022 filed with the SEC on May 10, 2022, CinCor's Quarterly Report on Form 10-Q for the three months ended June 30, 2022 filed with the SEC on August 8, 2022, CinCor's Quarterly Report on Form 10-Q for the three months ended September 30, 2022 filed with the SEC on November 3, 2022, and other filings and reports that CinCor may file from time to time with the SEC. 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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