Vincerx Pharma Doses First Patient in the Phase 1 Clinical Trial Evaluating VIP943

September 14, 2023

Phase 1 trial enrolling patients with relapsed/refractory AML, MDS and B-cell ALL

PALO ALTO, Calif., Sept. 14, 2023 (GLOBE NEWSWIRE) -- Vincerx Pharma, Inc. (Nasdaq: VINC)("Vincerx"), a biopharmaceutical company aspiring to address the unmet medical needs of patients with cancer through paradigm-shifting therapeutics, today reported that the first patient has been dosed in the Phase 1 trial evaluating VIP943 in patients with relapsed/refractory acute myeloid leukemia (R/R AML), myelodysplastic syndrome (MDS), and B-cell acute lymphoblastic leukemia (B-cell ALL), NCT06034275.

"Dosing of the first patient is a major achievement for the VIP943 development program and our next-generation bioconjugation platform. This achievement occurred 17 business days from receiving our safe to proceed letter, underscoring the enthusiasm from our investigators and the strong execution capabilities of the Vincerx team," said Ahmed Hamdy, M.D., Chief Executive Officer of Vincerx. "VIP943 is the first ADC candidate from our pioneering bioconjugation platform, designed to address the challenges of current ADCs, by increasing the therapeutic index (ie, increasing efficacy and reducing toxicity). We are the first company to bring to the clinic a legumain-cleavable linker and the first to utilize a kinesin spindle protein inhibitor (KSPi) as an ADC payload. This innovative and proprietary combination has generated strong preclinical evidence of activity and safety and has the potential to shift the treatment paradigm for patients with CD123+ hematologic malignancies. We look forward to evaluating the potential of VIP943 and expect to report preliminary safety and pharmacology data from our Phase 1 study in 2024."

Stephen A. Strickland, Jr., M.D., MSCI, Director of Leukemia Research for the Sarah Cannon Research Institute (SCRI) and Principal Investigator on the Phase 1 trial for VIP943, said, "Despite there being new medicines for hematologic malignancies such as AML, MDS and B-cell ALL, outcomes for many patients have not improved and relapse rates remain high. The urgent need for more effective treatment options persists. Several factors influence the outlook for these cancers including increased frequency in older patients and poor response rates, especially in patients who relapse after initial therapy. Vincerx's preclinical data provides a strong rationale to support the evaluation of VIP943 in the setting of hematologic malignancies, with hopes of providing more effective and less toxic therapeutic options for patients."

Howard A. "Skip" Burris, III, M.D., President of SCRI and Scientific Advisory Board member for Vincerx, said, "There is growing hope for delivering targeted therapies through the use of ADCs. Targeting hematologic malignancies with an ADC that combines selective binding to CD123 and a potentially improved safety profile, compared to other ADCs and CD123-targeting therapies, could provide a much needed treatment option for patients. Our team is excited to collaborate with Vincerx and begin enrolling patients in this Phase 1 dose escalation study."

About VIP943

VIP943 is the lead program from our next-generation ADC platform. VIP943 binds to CD123, a validated target in myeloid malignancies. Once inside the cell, it is only cleaved by an intracellular protein called legumain, allowing specific release and activation of the KSPi payload within the cancer cell. KSPi provides a novel way to deliver a cell cycle arrest agent, leading to cell death, which is a clinically validated ADC payload class mechanism. Vincerx's novel legumain-specific linker substantially reduces non-specific release of the payload, thereby reducing unwanted side effects on healthy cells. In addition, Vincerx's CellTrapper™ technology ensures that the KSPi payload accumulates in the target cells, limiting uptake into non-target, non-dividing cells. The innovative and intentional combination of a validated CD123 antibody, an intracellular cleavable legumain linker, and a potent KSPi payload holds the potential to address prevalent challenges of many ADCs by increasing the therapeutic window, thus improving efficacy and reducing common, severe toxicities such as myelosuppression, infections, peripheral neuropathy, and hepatotoxicity.

VIP943 has demonstrated increased survival and reduced tumor burden in AML cell lines and patient-derived tumor models. Additionally, Vincerx presented preclinical data on VIP943 at ASH 2022, demonstrating superiority versus Mylotarg™, an approved ADC, with significantly improved safety in monkeys and better efficacy in a mouse model of acute leukemia. Preclinical data suggest that VIP943 does not induce significant cytokine release syndrome, common to other CD123-targeting agents, and demonstrated favorable safety in monkeys, with an optimal drug metabolism and pharmacokinetics profile.

The Phase 1 trial of VIP943 is intended to assess safety, pharmacokinetics/pharmacodynamics, and preliminary efficacy of VIP943 in patients with R/R AML, MDS and B-cell ALL. The study will be conducted in several prominent U.S. cancer centers.

About Vincerx Pharma, Inc.

Vincerx Pharma, Inc. is a clinical-stage biopharmaceutical company committed to developing differentiated and novel therapies to address the unmet medical needs of patients with cancer. Vincerx has assembled a seasoned management team with a proven track record of successful oncology drug development, approvals, and value creation. The company's diverse pipeline consists of the next-generation antibody conjugate, VIP943, in Phase 1; small molecule drug-conjugate, VIP236, in Phase 1; preclinical antibody drug conjugate, VIP924; CDK9 inhibitor, enitociclib, currently in an NIH-sponsored Phase 1; and its next-generation modular bioconjugation platform.

Vincerx is based in Palo Alto, California, and has a research facility in Monheim, Germany. For more information, please visit www.vincerx.com.

Forward-Looking Statement

This press release contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended, that are intended to be covered by the “safe harbor” created by those sections. Forward-looking statements, which are based on certain assumptions and describe future plans, strategies, expectations and events, can generally be identified by the use of forward-looking terms such as “believe,” “expect,” “may,” “will,” “should,” “would,” “could,” “suggest,” “seek,” “intend,” “plan,” “goal,” “potential,” “on-target,” “on track,” “project,” “estimate,” “anticipate,” or other comparable terms. All statements other than statements of historical facts included in this press release are forward-looking statements. Forward-looking statements include, but are not limited to: Vincerx’s business model, pipeline, strategy, timeline, product candidates and attributes, and preclinical and clinical development, timing, and results. Forward-looking statements are neither historical facts nor assurances of future performance or events. Instead, they are based only on current beliefs, expectations, and assumptions regarding future business developments, future plans and strategies, projections, anticipated events and trends, the economy, and other future conditions. Forward-looking statements are subject to inherent uncertainties, risks, and changes in circumstances that are difficult to predict and many of which are outside of Vincerx’s control.

Actual results, conditions, and events may differ materially from those indicated in the forward-looking statements. Therefore, you should not rely on any of these forward-looking statements. Important factors that could cause actual results, conditions, and events to differ materially from those indicated in the forward-looking statements include, but are not limited to: general economic, financial, legal, political, and business conditions; the potential effects of health epidemics and pandemics, including COVID-19; risks associated with preclinical or clinical development and trials, including those conducted prior to Vincerx’s in-licensing; failure to realize the benefits of Vincerx’s license agreement with Bayer; risks related to the rollout of Vincerx’s business and the timing of expected business and product development milestones; changes in the assumptions underlying Vincerx’s expectations regarding its future business or business model; Vincerx’s ability to successfully develop and commercialize product candidates; Vincerx’s capital requirements and availability and uses of capital; and the risks and uncertainties set forth in Form 10-Q for the quarter ended June 30, 2023 and other reports filed with the Securities and Exchange Commission by Vincerx. Forward-looking statements speak only as of the date hereof, and Vincerx disclaims any obligation to update any forward-looking statements.

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Source: Vincerx Pharma, Inc.