

Vincerx Pharma Receives Orphan Drug Designation from European Commission for VIP152 for the Treatment of Diffuse Large B-Cell Lymphoma

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PALO ALTO, Calif., Dec. 07, 2021 (GLOBE NEWSWIRE) -- Vincerx Pharma, Inc. (Nasdaq: VINC), a biopharmaceutical company aspiring to address the unmet medical needs of patients with cancer through paradigm-shifting therapeutics, today announced that the European Commission has granted Orphan Drug Designation to VIP152, the Company's PTEFb/CDK9 inhibitor, for the treatment of diffuse large B-cell lymphoma (DLBCL).

"The granting of Orphan Drug Designation for VIP152 in DLBCL realizes another significant regulatory milestone for Vincerx," said Ahmed Hamdy M.D., Chief Executive Officer of Vincerx. "VIP152 has the potential to be an effective treatment for rare and highly refractory cancers, for which there is an unmet need in the current therapeutic landscape. We look forward to continued momentum with data presentations at the upcoming American Society of Hematology Annual Meeting, which include complete disease regression in DLBCL mouse models and modulation of key biomarkers in high-grade B-cell lymphoma cell lines and patients. In addition, we are presenting supportive preclinical mechanistic data in chronic lymphocytic leukemia."

The European Commission grants orphan drug designation for medicinal products intended to treat life-threatening or chronically debilitating conditions that affect fewer than five in 10,000 people in the European Union and when no satisfactory method of diagnosis, prevention or treatment of the condition can be authorized. The designation provides certain benefits and incentives in the EU, including protocol assistance, fee reductions, and ten years of market exclusivity once the medicine is on the market.

Vincerx is currently advancing Phase 1b studies of VIP152 in MYC-driven relapsed or refractory aggressive lymphomas and advanced solid tumors. The ongoing Phase 1b expansion, first-in-human (FIH) study is in patients with advanced cancer and consists of two expansion arms. Arm 1 will enroll up to 40 patients with relapsed/refractory aggressive lymphoma, including DLBCL, transformed follicular lymphoma, and mantle cell lymphoma. Arm 2 will enroll up to 40 patients with advanced solid tumors, including patients with ovarian cancer, triple negative breast cancer, castration-resistant neuroendocrine prostate cancer, and any other solid tumor with MYC aberration. All patients must have confirmed MYC overexpression or translocation.

About Vincerx Pharma, Inc.

Vincerx Pharma, Inc. (Vincerx) is a clinical-stage life sciences company focused on leveraging its extensive development and oncology expertise to advance new therapies intended to address unmet medical needs for the treatment of cancer. Vincerx has assembled a management team of biopharmaceutical experts with extensive experience in building and operating organizations that develop and deliver innovative medicines to patients. Vincerx's current pipeline is derived from an exclusive license agreement with Bayer and includes a clinical-stage and follow-on small molecule drug program and a preclinical stage bioconjugation platform, which includes next-generation antibody-drug conjugates and innovative small molecule drug conjugates. For more information, please visit www.vincerx.com.

Cautionary 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," "could," "could," "seek," "intend," "plan," "goal," "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, preclinical and clinical development and results and future capital requirements. 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 our 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 and changes in domestic and foreign markets; the potential effects of the COVID-19 pandemic; 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 milestones; changes in the assumptions underlying Vincerx's expectations regarding its future business or business model; Vincerx's ability to develop and commercialize product candidates; the availability and uses of capital; the effects of competition on Vincerx's future business; and the risks and uncertainties set forth in Forms 10-K, 10-Q and 8-K filed with or furnished to the SEC from time to time 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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