



Vincerx Pharma Presents Clinical Data on VIP512, its PTEFb/CDK9 Inhibitor, in Patients with Double-Hit Lymphoma at ASCO 2021

June 4, 2021

VIP152 shows favorable safety, on-target pharmacodynamics and signs of durable metabolic complete responses in monotherapy setting

Phase 1b study in MYC-Driven relapsed/refractory aggressive lymphomas and advanced solid tumors ongoing

PALO ALTO, Calif., June 04, 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 the presentation of safety and efficacy data from the Phase 1 study of VIP152, the Company's PTEFb/CDK9 inhibitor, in patients with double-hit lymphoma at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting being held virtually from June 4-8, 2021.

"The data generated in double-hit lymphoma are compelling, providing early evidence that on-target activity of VIP152 has the potential to provide durable responses in patients who have no standard of care therapy and poor prognoses," said Ahmed Hamdy M.D., Chief Executive Officer of Vincerx. "The achievement of durable metabolic complete responses with once weekly monotherapy lasting beyond two and three years is remarkable. These efficacy signals were also obtained with a favorable safety profile, with no patients stopping treatment due to adverse events, and the patients with metabolic complete responses stopping treatment only due to the COVID-19 pandemic. Our Phase 1 results, which also include durable disease control in solid tumors, provide a strong foundation of data, which support targeting MYC and MCL1-driven malignancies with our potent and selective PTEFb/CDK9 inhibitor. We look forward to further investigating the potential of VIP152 in challenging patient populations with our ongoing Phase 1b expansion study, which is currently enrolling patients with relapsed/refractory aggressive lymphoma and advanced solid tumors, and our soon to be launched Phase 1b dose-escalation in CLL relapsed/refractory to venetoclax and BTK inhibitors."

Key Presentation Highlights:

Poster presentation, titled, "Safety and efficacy of VIP152, a PTEFb / CDK9 inhibitor, in patients with double-hit lymphoma", include:

- CDK9 mediates the transcription of oncogenes such as MYC and MCL-1, which play a critical role in a variety of cancers.
- VIP152, a potent and selective inhibitor of CDK9, has completed dose escalation in patients with advanced malignancies (NCT02635672). Significant monotherapy clinical activity was observed with a favorable safety profile:
 - Seven patients with solid tumors had disease control during the dose escalation portion of the study, including a patient with pancreatic cancer (~14 cycles; dose 30 mg once weekly) and a patient with salivary gland cancer (~24 cycles; dose 22.5 mg once weekly).
 - One patient with double-hit DLBCL (DHL), who was treated with VIP152 30 mg once weekly, achieved metabolic complete remission. DHL is defined as a dual arrangement or overexpression of the MYC gene and either the B-cell lymphoma 2 (BCL2) or BCL6 genes.
 - No patients discontinued due to adverse events.
- An expansion cohort of 6 additional patients with DHL were dosed with VIP152 30 mg once weekly:
 - All patients with DHL (median [range] age 70 [58-84] years) had received front-line R-CHOP or R-EPOCH, with two patients having had prior stem cell transplant, and additional therapies include R-DHAP, R-GemOx, R-ICE and durvalumab. Four patients had 2 prior lines of therapy and 3 patients had ≥3 prior lines of therapy. Three patients had been refractory to their last treatment. Six patients had advanced disease (Ann Arbor Stage III or IV) at study entry.
 - VIP152 had a favorable safety profile, with most common adverse events (AEs) being Grade 1 and Grade 2 severity. Two patients had a serious AE (Grade 3 syncope and Grade 3 tumor pain). No patients withdrew from treatment due to any AEs.
 - Pharmacodynamic biomarker analysis showed significant reduction, lasting at least 4 hours, of MYC, PCNA and MCL-1 mRNA in all patients.
 - Anti-tumor activity consisted of 2 metabolic complete responses (CRs) in 7 patients (29%), based on investigator-assessed FDG-PET scans.
 - Both metabolic CRs were durable, with patients remaining on treatment for 3.7 and 2.3 years until study withdrawal due to the COVID pandemic. Both patients had metabolic CRs at the time of study exit.
 - The results from this expansion cohort of 7 patients with DHL, a cancer known to have MYC translocations, suggests that reduction of MYC expression for at least 4 hours can provide durable complete remissions lasting

several years. The favorable safety profile of VIP152 allowed for long-term dosing in elderly patients with advanced disease.

- A Phase 1b expansion study in MYC-driven advanced cancers is ongoing, evaluating up to 30 patients with relapsed/refractory aggressive lymphoma, and up to 40 patients with advanced solid tumors.

The poster can be accessed on the [presentations section](#) of the Vincerx website.

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," "would," "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 and preclinical and clinical development 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 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 conducted prior to Vincerx's in-licensing; failure to realize the anticipated benefits of the business combination with LifeSci Acquisition Corp.; 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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