Vincerx Pharma Presents Positive Preliminary Phase 1 Data for VIP236 and Updates on Pipeline Progress at the American Association for Cancer Research (AACR) Annual Meeting 2024

April 8, 2024

VIP236 demonstrated positive signs of clinical activity, including tumor reduction, and an improved safety profile in heavily pretreated patients with metastatic solid tumors

VIP943 pharmacokinetic (PK) data shows very little free payload in circulation, consistent with the favorable safety profile observed preclinically and clinically

In preclinical studies, Vincerx's next-generation effector chemistry improves the efficacy of two approved antibody-drug conjugates (ADCs), highlighting VersAptx™ platform's potential to advance cancer therapies

Management to host a virtual investor event today at 2:00 PM PDT / 5:00 PM EDT

PALO ALTO, Calif., April 08, 2024 (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 presented positive preliminary Phase 1 data for VIP236 and updates on pipeline progress at the American Association for Cancer Research (AACR) Annual Meeting 2024.

"The positive preliminary data we've reported for VIP236 and VIP943, coupled with preclinical findings leveraging our VersAptx platform to improve the efficacy of TRODELVY® and ENHERTU®, two marketed ADCs, underscore the power of our platform approach for hematologic malignancies and solid tumors," said Ahmed Hamdy, M.D., Chief Executive Officer of Vincerx. "The early VIP236 data demonstrated positive clinical activity, including tumor reductions. This represents significant promise for patients who have exhausted standard anticancer therapy options with many different tumor types, including tumors not usually responsive to camptothecin-derived therapies. Dose escalation continues in the VIP236 and VIP943 first-in-human studies. As we advance into higher dose levels, we look forward to sharing more clinical data for VIP236 later this summer and for VIP943 on or around the 2024 European Hematology Association annual meeting."

Raquel Izumi, Ph.D., President and Chief Operating Officer of Vincerx added, "The main objectives of a Phase 1 dose-escalation study are to assess safety and tolerability while establishing an optimal dose and schedule, so seeing dose-dependent clinical activity at this point in the development of VIP236 is exciting. We are still in dose escalation and are starting to see tumor reduction after only two doses. We expect to see responses deepen with more time on treatment and as we continue to escalate."

Vivek Subbiah, M.D., Chief of Early-Phase Drug Development at Sarah Cannon Research Institute commented, "In the oncology landscape, ADCs have emerged as a new and encouraging treatment option for people facing cancer. With a decade of invaluable insights in ADC drug development, we are transitioning from first to second to third generations, and the imperative now is for novel mechanisms of action. Innovations like VIP236's optimized camptothecin, which can potentially circumvent some of the known camptothecin liabilities and issues with drug resistance, deliver a potent payload from a clinically validated drug class. The goal is to deliver best-in-class therapies to meet the urgent needs of patients battling advanced cancers."

VIP236 Updates

- Study VNC-236-101 is an open-label, multicenter, Phase 1 dose-escalation study with monotherapy VIP236 for the treatment of patients with metastatic tumors who have exhausted all standard therapy options. The study's main objective is to determine a safe dose and schedule for VIP236 for further clinical development.
- Fifteen patients have been dosed to date on the once every three weeks (Q3W) schedule. Sequential dose-escalation cohorts with the Q3W schedule were 0.2 mg/kg (n=2), 0.4 mg/kg (n=5), 0.6 mg/kg (n=5), and 0.8 mg/kg (n=3). Results of the Q3W schedule (n=15) show:
    - The patient population is typical of a Phase 1 study with heavily pretreated patients and a wide range of tumor types.
    - The Q3W schedule is well tolerated with no dose-limiting toxicity (DLT) in any patients, and no patients have discontinued VIP236 due to an adverse event. Importantly, no severe or life-threatening diarrhea has been observed, validating the purposeful design of VIP236's optimized camptothecin payload.
    - First efficacy assessment was at the end of cycle 2 (i.e. after only two doses on the Q3W schedule). Seven patients have achieved objective stable disease, including tumor reduction. Four patients remain on study with the longest treated patient on study for 168 days.

- Dose escalation continues on the Q3W schedule. Vincerx anticipates presenting additional Phase 1 data for VIP236 later this summer.

VIP943 Updates

- Study VNC-943-101 is an open-label, multicenter, Phase 1 dose-escalation study with monotherapy VIP943 for the treatment of patients with $CD123^+$ acute myeloid leukemia (AML), B-cell acute lymphocytic leukemia (B-ALL) or myelodysplastic syndromes (MDS) who have exhausted standard therapeutic options. The study's main objective is to determine a safe dose and schedule for VIP943 for further clinical development.
- VIP943 is administered once per week. Three patients were dosed in Cohort 1 (0.2 mg/kg) and four patients were dosed in Cohort 2 (0.4 mg/kg).
- Despite the initial low doses in the study, all seven sequentially enrolled patients completed the 28-day DLT evaluation period. Five out of seven received a cycle 2 dose and two of these patients started cycle 3. One patient with MDS is still on study on cycle 3.
- No DLTs occurred in Cohort 1 and 2. Four patients have been enrolled in Cohort 3 (0.7 mg/kg) and are undergoing DLT assessment.
- VIP943 PK data shows very little free payload in circulation, consistent with the favorable safety profile observed preclinically and clinically.
- As the study progresses through the dose escalation, Vincerx will present additional Phase 1 data for VIP943 on or around the 2024 European Hematology Association Annual Meeting in June 2024.

New In Vitro Solid Tumor Data

- Today Vincerx also reported preclinical experiments applying the next-generation effector chemistry of its VersAptx platform to the antibodies of approved ADCs, TRODELVY and ENHERTU, demonstrating the potential to improve tumor toxicity of ADCs by orders of magnitude.
- In in vitro tumor models, Vincerx's sacituzumab-legumain-KSPi ADC had a 20-fold improvement in tumor toxicity compared with TRODELVY (sacituzumab-govitecan). The company's trastuzumab-legumain-KSPi ADC demonstrated an 8-fold increase in tumor toxicity compared with ENHERTU (fam-trastuzumab-deruxtecan).
- These findings further support the versatility of VersAptx to address multiple cancer types, including solid tumors, and increase the efficacy and safety of ADCs. Further studies will be conducted in animal models.

Virtual Investor Event

Vincerx will host a virtual investor event featuring company management and key opinion leaders to review preliminary clinical data from its Phase 1 dose-escalation study of VIP236 and provide an update on pipeline progress today at 2:00 PM PDT/ 5:00 PM EDT. To register and view the live webcast, please visit: https://edge.media-server.com/mmc/p/xhv7kxf7/. An archived replay of the webcast will be available on the Vincerx Investor Page website following the conclusion of the live event.

About VIP236

VIP236, the first-in-class small molecule drug conjugate (SMDC) from the VersAptx Platform, consists of an $\alpha_V\beta_3$ integrin binder, a neutrophil elastase linker cleaved in the tumor microenvironment, and a camptothecin payload optimized for high permeability and low active efflux. VIP236 was designed to deliver its payload to advanced/metastatic tumors that express $\alpha_V\beta_3$. Preclinical data show enhanced efficacy, independent of HER2 status, in patient-derived and cell line-derived gastric cancer models compared with ENHERTU®, an approved ADC. VIP236 is being evaluated in a Phase 1 dose-escalation trial treating patients with advanced or metastatic solid tumors (NTC05371054).

About VIP943

VIP943, the first ADC from the VersAptx platform, consists of an anti-CD123 antibody, a unique linker cleaved intracellularly by legumain, and a novel kinesin spindle protein inhibitor (KSPi) payload enhanced with our CellTrapper® technology. The next-generation effector chemistry (linker + payload with CellTrapper) was designed to reduce non-specific release of the payload and ensure payload accumulation in cancer cells versus healthy cells. The increased therapeutic index has the potential to address challenges associated with many ADCs by improving efficacy and reducing severe toxicities. VIP943 is in a Phase 1 dose-escalation trial evaluating patients with relapsed/refractory AML, B-ALL, and MDS who have exhausted standard therapeutic options (NCT06034275).

About VersAptx Platform

VersAptx is a versatile and adaptable next-generation bioconjugation platform. The modular nature of this innovative platform allows for the combination of different targeting, linker, and payload technologies to develop bespoke bioconjugates to address different cancer biologies. With this platform, (i) antibodies and small molecules can be used to target different tumor antigens, (ii) linkers can be designed to reduce non-specific release of the payload, cleave intracellularly or extracellularly, and conjugate to single or multiple payloads, and (iii) payloads can be designed with reduced permeability using the CellTrapper technology to ensure accumulation in cancer cells or to be permeable for release in the tumor microenvironment. The VersAptx platform allows for the optimization of these technologies to a specific target and the development of bioconjugates designed to address

the safety and efficacy challenges of many ADCs and the needs of cancer patients.

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. Vincerx's diverse pipeline consists of the next-generation antibody-drug conjugate, VIP943, in Phase 1; small molecule-drug conjugate, VIP236, in Phase 1; preclinical antibody-drug conjugate, VIP924; CDK9 inhibitor, enitociclib, in an NIH-sponsored Phase 1; and VersAptx, its versatile and adaptable, next-generation 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 and follow Vincerx on LinkedIn.

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," "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, many of which are outside 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; 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 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, availability and uses of capital, and cash runway; and the risks and uncertainties set forth in Form 10-K for the year ended December 31, 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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