Vincerx Pharma Reports First Quarter 2024 Financial Results and Provides Corporate Update

May 14, 2024

Vincerx continued to progress Phase 1 dose-escalation studies for VIP943, a potentially best-in-class anti-CD123 antibody-drug conjugate (ADC), and VIP236, a first-in-class small molecule-drug conjugate (SMDC)

The National Institutes of Health (NIH) and Vincerx announced positive results from enitociclib Phase 1 combination study, reporting a fourth partial response (PR) in a patient with peripheral T-cell lymphoma (PTCL)

Vincerx reported the first PR in a patient with transformed follicular lymphoma (tFL) in its Phase 1 dose-escalation study of enitociclib as a monotherapy

Recent financing provides expected cash runway through 2024

PALO ALTO, Calif., May 14, 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 reported financial results for the first quarter of 2024 and provided a corporate update.

“During the first quarter, we maintained momentum across our highly differentiated pipeline and our VersAptx™ platform,” said Ahmed Hamdy, M.D., Chief Executive Officer. “Our recent financing provides capital to support the dose-escalation studies for our potentially best-in-class ADC, VIP943, and first-in-class SMDC, VIP236. We look forward to sharing an update on VIP236 by the end of Q3 and on VIP943 by the end of Q4. This timing will enable us to present more advanced dose-escalation data for both programs.”

“We also continue to be excited by the clinical progress of enitociclib,” continued Dr. Hamdy. “We have one patient with tFL who has achieved a metabolic PR and continues on enitociclib monotherapy therapy after 33 cycles. In addition, in the NIH study of enitociclib in combination with venetoclax and prednisone, two-thirds of patients have achieved a PR. We believe these clinical results show enitociclib is a best-in-class CDK9 inhibitor and has the potential to be a preferred partner for innovative combination therapies for hard-to-treat cancers.”

FIRST QUARTER 2024 CLINICAL PROGRAM HIGHLIGHTS

VIP236

- VIP236 is an $\alpha_V\beta_3$ SMDC conjugated to an optimized camptothecin (CPT) payload, created from Vincerx’s VersAptx platform. VIP236 is a first-in-class drug designed to deliver its optimized CPT payload directly to tumor tissues to overcome chemotherapy-related side effects. Preclinical studies have shown 11 times more optimized CPT is delivered to the cancerous tissues than found circulating in the blood. In addition, the optimized CPT is designed to limit drug transporter liabilities, a common mechanism for cancer resistance to chemotherapy.
- At the 2024 American Association for Cancer Research (AACR) Annual Meeting, Vincerx reported positive preliminary monotherapy data on VIP236 from a Phase 1 dose-escalation study demonstrating signs of clinical activity, including tumor reduction, and an improved safety profile in heavily pretreated patients with metastatic solid tumors.
- As of March 25, 2024, the VIP236 open-label, multicenter, Phase 1 dose-escalation study (NTC05371054) had enrolled 20 patients with advanced or metastatic cancers unresponsive to standard therapies.
- Vincerx looks forward to sharing additional Phase 1 data by the end of Q3 2024.

VIP943

- VIP943, a novel CD123-targeted ADC created from Vincerx’s 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 Vincerx’s CellTrapper® technology. Its next-generation effector chemistry was designed to address challenges associated with many ADCs by improving efficacy and reducing severe toxicities.
- Enrollment has begun in the fourth cohort of the Phase 1 dose-escalation study of VIP943 in relapsed/refractory acute myeloid leukemia (AML), myelodysplastic syndrome (MDS), and B-cell acute lymphoblastic leukemia (B-ALL) (NCT06034275). Preliminary pharmacokinetic (PK) results on the first two cohorts were presented at the 2024 AACR Annual Meeting and as expected, showed very little payload circulating in the blood. In addition, no dose-limiting toxicities have occurred in the 11 patients who have received VIP943 so far. The preliminary PK and early observations of a

favorable safety profile are consistent with VIP943 preclinical data.
- Vincerx expects to present updated Phase 1 dose-escalation data for VIP943 by the end of Q4 2024.

Enitociclib

- Enitociclib is a highly selective CDK9 inhibitor designed to block the activation of RNA polymerase II, leading to the reduction of oncogenes, including MYC and MCL1.
- Enitociclib is currently in a Phase 1 dose-escalation study (NTC05371054) evaluating the combination of enitociclib, venetoclax and prednisone in diffuse large B-cell lymphoma (DLBCL) and PTCL. This study is being conducted in collaboration with the NIH.
    - In January 2024, Vincerx and the NIH reported two PRs in patients with PTCL with tumor reductions ranging from 86% to 91%. Additionally, one PR was reported in a patient with double-hit diffuse large B-cell lymphoma (DH-DLBCL) with an 80% reduction in tumor burden. Most recently, an additional PR was announced in PTCL with a reduction in lymph node size and skin lesions, totaling four PRs observed to date. Notably, these results were obtained with enitociclib doses below the anticipated efficacious levels. Currently, the study is enrolling patients for the third dose level (30 mg), which is the recommended dose established in the enitociclib monotherapy study.
    - These data will be presented by the NIH at the upcoming AACR Advances in Malignant Lymphoma meeting in June 2024.
- In a Phase 1 dose-escalation study (NCT02635672) of enitociclib as a monotherapy, one newly confirmed metabolic PR was observed with 63% tumor reduction in a tFL patient who has been enrolled in the study for just under two years. This is particularly notable because outcomes of patients with tFL are historically poor.
    - In total, this study enrolled 63 patients in the dose-escalation and expansion cohorts.
    - Enitociclib showed a favorable safety profile, dose-proportional pharmacokinetics, and on-target pharmacodynamic activity.
    - Significant clinical benefit across various indications includes two patients with DH-DLBCL who experienced durable complete metabolic remissions (3.7 and 2.3 years), which continued more than two years after stopping treatment.
    - This long duration of treatment and response for patients with DH-DLBCL and tFL highlight enitociclib's favorable safety profile and monotherapy efficacy in hard-to-treat hematologic malignancies.
    - Additionally, 13 patients with solid tumors achieved stable disease as their best response to monotherapy treatment. Notably, of these, five were patients with ovarian cancer, providing a promising signal for future combination studies in this indication.
- Research collaborations continue with the University of Calgary and the Pediatric Oncology Experimental Therapeutics Investigators' Consortium (POETIC) to discover combination strategies for pediatric leukemia and central nervous system tumors. To date, these collaborations have shown that enitociclib has monotherapy and combination activity in preclinical models of rhabdomyosarcoma, neuroblastoma and KMT2A-rearranged pediatric leukemia.

VIP924

- VIP924 is a first-in-class CXCR5-targeted ADC created from Vincerx's VersAptx platform.
- VIP924 can be evaluated in B-cell malignancies, including MCL, FL, DLBCL, and CLL and monotherapy and in combination.
- IND application is anticipated in late 2025 or early 2026, pending funding.

VersAptx™ Platform

- VersAptx is Vincerx's versatile and adaptable, next-generation bioconjugation platform. The modular nature of this platform enables the combination of different targeting, linker and payload technologies to develop bespoke bioconjugates to address different cancer biologies.
- At the AACR Annual Meeting, Vincerx reported data from preclinical studies applying the next-generation effector chemistry of its VersAptx platform to TRODELVY® and ENHERTU®, two marketed ADCs, demonstrating the potential to improve tumor toxicity of ADCs by orders of magnitude, while improving on safety and tolerability. These findings further support the versatility of VersAptx to address multiple cancer types and increase the efficacy and safety of ADCs.

FIRST QUARTER 2024 FINANCIAL RESULTS

- Vincerx had approximately $5.1 million in cash and cash equivalents as of March 31, 2024, which does not include the proceeds from our recent financing in April, as compared to approximately $12.8 million as of December 31, 2023. Based on its current business plans and assumptions, Vincerx believes its available capital, including the recent financing proceeds of approximately $17.8 million, will be sufficient to meet its operating requirements through the end of 2024.
- Research and development expenses for the first quarter ended March 31, 2024 were approximately $4.6 million, as compared to approximately $10.9 million for the same period in 2023. This decrease is primarily the result of decreases in manufacturing services associated with our ADC programs of approximately $2.6 million, research services of

approximately $2.6 million, and personnel-related expenses of approximately $1.1 million.

- General and administrative expenses for the first quarter ended March 31, 2024 were approximately $2.9 million, as compared to approximately $4.5 million for the same period in 2023. This decrease is primarily driven by decreases in personnel-related expenses of approximately $0.6 million, professional services of $0.5 million and facilities and other corporate overhead expenses of $0.3 million.
- For the first quarter ended March 31, 2024, Vincerx reported a net loss of approximately $12.4 million, or $0.58 per share. For the first quarter ended March 31, 2023, Vincerx reported a net loss of approximately $14.6 million, or $0.69 per share.

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.

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, cash runway, 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 subsequent 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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Vincerx Pharma, Inc.
Condensed Consolidated Balance Sheets

(in thousands)

	March 31, 2024 (unaudited)	December 31, 2023
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,110	$ 12,782
Prepaid expenses	700	51
Grant receivable	1,025	1,044
Other current assets	842	856
Total current assets	7,677	14,733
Right-of-use assets	1,950	2,201
Property, plant and equipment, net	111	125
Other assets	1,345	1,158

Total assets	**$ 11,083**	**$ 18,217**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 2,314	$ 2,497
Accrued expenses	1,727	1,755
Lease liability	1,198	1,162
Common stock warrant liabilities	5,395	191
Total current liabilities	10,634	5,605
Lease liability, net of current portion	1,021	1,340
Other noncurrent liabilities	50	50
Total liabilities	11,705	6,995
Total stockholders' equity (deficit)	(622)	11,222
Total liabilities and stockholders' equity	**$ 11,083**	**$ 18,217**

Vincerx Pharma, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(in thousands, except per share amounts)

	For the three months ended March 31,	
	2024	**2023**
Operating expenses:		
General and administrative	$ 2,922	$ 4,497
Research and development	4,556	10,911
Total operating expenses	7,478	15,408
Loss from operations	(7,478)	(15,408)
Other income (expense)		
Change in fair value of warrant liabilities	(5,204)	18
Interest income	99	466
Other income	154	274
Total other income (expense)	(4,951)	758
Net loss	**$ (12,429)**	**$ (14,650)**
Net loss per common share, basic and diluted	$ (0.58)	$ (0.69)
Weighted average common shares outstanding, basic and diluted	21,400	21,188