Vincerx Pharma Reports Third Quarter 2023 Financial Results and Provides Corporate Update

November 14, 2023

Phase 1 dose escalation for VIP943 - first antibody-drug conjugate (ADC) from VersAptx™*, versatile and adaptable, next-generation bioconjugation platform - moves quickly into 2nd cohort*

Phase 1 dose escalation for VIP236 - first-in-class small molecule-drug conjugate (SMDC) for treatment of solid tumors - progressing well with optimized dosing schedule

Phase 1 dose escalation combination study for enitociclib in collaboration with NIH - partial response in first patient dosed in second cohort

Cash balance expected to support planned operations into late 2024

PALO ALTO, Calif., Nov. 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 financial results for the third quarter ended September 30, 2023 and provided a corporate update.

"This has been a standout quarter for Vincerx, with progress across all three clinical programs, including VIP943, our first ADC from the VersAptx Platform, our versatile and adaptable, next-generation bioconjugation platform, and VIP236, our first-in-class SMDC," said Ahmed Hamdy, M.D., Chief Executive Officer of Vincerx. "The Vincerx team has done an outstanding job delivering ahead of expectations. Not only were we able to dose our first VIP943 patient within a matter of weeks of FDA clearance, but we have quickly moved through our first cohort and are beginning enrollment in our second cohort. This momentum is a testament to the promising safety profile seen in the first cohort and the enthusiasm from investigators participating in the trial. We expect to report preliminary data from this study in mid-2024."

"We also continued to make excellent progress with our other clinical programs. VIP236, our first-in-class SMDC for advanced solid tumors, is dosing patients under an optimized dosing schedule of once every three weeks, and we are pleased with the early safety profile we are seeing. We expect to report preliminary data in early 2024. In addition, enitociclib, our CDK9 inhibitor, continues to show promise. The transformed follicular lymphoma patient in our monotherapy study remains on treatment and has achieved long-term stable disease for more than 16 months with a 51% reduction in target lesions. Furthermore, our collaboration with the National Institute of Health (NIH) on a Phase 1 dose-escalation study of enitociclib with venetoclax and prednisone continues to make progress, with four patients dosed and an overall favorable safety profile. Even more exciting, the first patient on the second dose level remains on study with a partial response with evidence of an 80% reduction in the pulmonary lesion and resolution of skin lesions from their peripheral T-cell lymphoma," added Dr. Hamdy.

"We continue to take a very disciplined approach to our portfolio, focusing our resources on our two lead programs, VIP943 and VIP236. Concurrently, we are exploring business development opportunities that can advance all of our clinical programs as well as leverage the power of our VersAptx Platform. The therapeutic and safety potential of ADCs and other conjugates is being widely recognized, as evidenced by the overall excitement and activity in the ADC space, including collaborations, acquisitions, and positive clinical results. We believe that our next-generation ADC technology represents a significant step forward in the treatment of cancer by potentially overcoming the safety and efficacy challenges associated with many ADCs. As a result, we feel we are well-positioned to capitalize on industry enthusiasm for bioconjugates," concluded Dr. Hamdy.

Third Quarter 2023 Corporate Highlights:

VIP943: CD123-KSPi ADC for leukemias and myelodysplastic syndrome

- VIP943, the first ADC from our 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. Our proprietary effector chemistry (linker + payload) 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 acute myeloid leukemia, myelodysplastic syndrome, and B-cell acute lymphoblastic leukemia who have exhausted standard therapeutic options (NCT06034275).
- The VIP943 IND was approved by the FDA within 30 days, and we dosed our first patient in less than three weeks of FDA clearance. In addition, enrollment has moved quickly (Cohort 1, n=3), and we are now enrolling our second cohort. We are pleased with the early safety profile.
- We will present new data on robust preclinical activity at the 65th American Society for Hematology Meeting (ASH 2023) in

December.

- We expect to report preliminary clinical trial data in mid-2024.

VIP236: SMDC with $\alpha_v\beta_3$ integrin binder linked to optimized CPT payload for solid tumors

- VIP236, the first-in-class SMDC from our VersAptx Platform, consists of an $\alpha_v\beta_3$ integrin binder, a neutrophil elastase linker cleaved in the tumor microenvironment, and a camptothecin (CPT) payload optimized for high permeability and low 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). As VIP236 is a first-in-class drug, the Phase 1 trial is evaluating various dosing schedules.
- To date, 10 patients with advanced or metastatic disease that has relapsed or is refractory to standard of care have received VIP236; the early safety profile of once every three weeks dosing is promising.
- We expect to report preliminary clinical trial data in early 2024.

VIP924: CXCR5-KSPi ADC for B-cell malignancies

- VIP924, the second ADC from our VersAptx Platform, consists of an anti-CXCR5 antibody, a unique linker cleaved intracellularly by legumain, and a novel KSPi payload enhanced with our CellTrapper technology. Our proprietary effector chemistry (linker + payload) 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.
- VIP924 preclinical data demonstrate significant tumor growth inhibition in a panel of lymphoma cell lines and cell line- and PDX-derived lymphoma models. VIP924 also induces sustained tumor regression in mantle cell lymphoma (MCL) and diffuse large B-cell lymphoma (DLBCL) models, including ibrutinib-refractory MCL models.
- At ASH 2023, preclinical data will be presented showing that our first-in-class anti-CXCR5 ADC compares favorably to the approved ADCs, Polivy® and Zynlonta®.
- Despite compelling preclinical data, we continue to judiciously pace our investment in VIP924 to focus resources on VIP236 and VIP943.

Enitociclib: CDK9 inhibitor for hematologic malignancies and solid tumors

- Enitociclib, a highly selective CDK9 inhibitor, prevents activation of RNA polymerase II, resulting in reduction of known oncogenes MYC and MCL1.
- Enitociclib is in a dose-escalation Phase 1 trial (NTC05371054) in collaboration with the NIH evaluating the combination of enitociclib, venetoclax and prednisone in DLBCL and peripheral T-cell lymphoma (PTCL). The first dose level completed enrollment with no drug-related safety signal (n=3; 1=DLBCL, 2=PTCL). The first patient on the second dose level (n=1; 1=PTCL) remains on study with a partial response due to an 80% reduction in the pulmonary lesion on computerized tomography (CT) scan and resolved skin lesions. Investigators are pleased with the safety profile of this novel combination and continue with enrollment.
- Additional combination studies will be determined based on financing/partnering support.
- Proof-of-concept monotherapy efficacy has been generated in early-stage clinical studies:
    - Hematologic malignancies: two patients with double-hit DLBCL achieved complete metabolic responses after 10 cycles of treatment and remain in remission, off treatment, for over four years; one patient with transformed follicular lymphoma remains on treatment, achieving long-term stable disease for over 16 months with a 51% reduction in target lesions.
    - Solid tumors: 13 responses of stable disease, including durable disease control, in patients with ovarian, pancreatic, and salivary gland cancer.
- Strong preclinical evidence for additional indications (eg, multiple myeloma) and pediatric indications.
- Collaborators from the University of Calgary will present a poster at ASH 2023 showing preclinical activity in pediatric leukemia.

Additional Corporate Highlights

- Our next-generation bioconjugation platform is now known as the VersAptx Platform. This name reflects the versatile and adaptable features and strengths of this innovative technology.
- We received a one-year extension of Small and Medium-Sized Enterprise (SME) status by the European Medicines Agency's (EMA) Micro, Small and Medium-Sized Enterprise, enabling us to become eligible for EMA fee reductions and waiver and other financial incentives.

Third Quarter 2023 Financial Results

- Vincerx had approximately $20.8 million in cash, cash equivalents and marketable securities as of September 30, 2023, as compared to approximately $52.5 million as of December 31, 2022. Based on its current business plans and assumptions, Vincerx believes its available capital will be sufficient to meet its planned operating requirements into late 2024.
- Research and development expenses for the three- and nine-months ended September 30, 2023 were approximately $6.8 million and $25.3 million, as compared to approximately $11.1 million and $40.8 million for the same periods in 2022. The decrease for the three months ended September 30, 2023 compared with the same period in 2022 is primarily the result of decreases in manufacturing services associated with our ADC program of approximately $4.1 million and clinical services of approximately $0.9 million, partially offset by the $1.0 million development milestone in connection with Vincerx's IND filing for VIP943. The decrease for the nine months ended September 30, 2023 compared with the same period in 2022 is primarily the result of decreases in manufacturing services associated with our ADC program of approximately $5.5 million, stock-based compensation expense of approximately $5.1 million, clinical services of approximately $2.7 million, and payroll related costs of approximately $1.7 million as a result of our headcount reduction in June 2022.
- General and administrative expenses for the three- and nine-months ended September 30, 2023 were approximately $3.5 million and $11.8 million, as compared to approximately $4.5 million and $14.9 million for the same periods in 2022. These decreases are primarily due to decreases in stock-based compensation expense of approximately $0.5 million and $2.3 million for the three- and nine-months ended September 30, 2023, respectively, as well as a decrease in professional services of $0.5 million and $0.8 million for the three and nine months ended September 30, 2023, respectively.
- For the quarter ended September 30, 2023, Vincerx reported a net loss of approximately $9.7 million, or $0.46 per share, compared to a net loss of approximately $16.9 million, or $0.80 per share, for the quarter ended September 30, 2022.

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, currently 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.

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, expected 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 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; 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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Vincerx Pharma, Inc.
Condensed Consolidated Balance Sheets
(in thousands)

	September 30, 2023 (unaudited)	December 31, 2022
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,078	$ 11,663
Short-term marketable securities	5,724	40,796
Prepaid expenses	322	134
Other current assets	1,694	3,371
Total current assets	22,818	55,964
Right-of-use assets	2,447	3,064
Property, plant and equipment, net	137	177
Other assets	874	81
Total assets	**$ 26,276**	**$ 59,286**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,062	$ 4,065
Accrued expenses	4,526	3,923
Lease liability	1,126	1,024
Common stock warrant liabilities	132	144
Total current liabilities	8,846	9,156
Lease liability, net of current portion	1,639	2,412
Other noncurrent liabilities	50	50
Total liabilities	10,535	11,618
Total stockholders' equity	15,741	47,668
Total liabilities and stockholders' equity	**$ 26,276**	**$ 59,286**

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

	For the three months ended September 30,		For the nine months ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
General and administrative	$ 3,517	$ 4,525	$ 11,816	$ 14,903
Research and development	6,800	11,066	25,260	40,779
Restructuring	-	1,310	-	2,469
Total operating expenses	10,317	16,901	37,076	58,151
Loss from operations	(10,317)	(16,901)	(37,076)	(58,151)
Other income (expense)				
Change in fair value of warrant liabilities	112	(79)	12	6,334
Interest income	260	204	1,053	204
Other income (expense)	230	(103)	804	(111)
Total other income (expense)	602	22	1,869	6,427
Net loss	**$ (9,715)**	**$ (16,879)**	**$ (35,207)**	**$ (51,724)**

Net loss per common share, basic and diluted	$ (0.46)	$ (0.80)	$ (1.66)	$ (2.46)
Weighted average common shares outstanding, basic and diluted	21,345	21,083	21,269	20,992

Source: Vincerx Pharma, Inc.