Vincerx Pharma Reports Fourth Quarter and Full Year 2022 Financial Results and Provides a Corporate Update

March 28, 2023

First cohort dosed in Phase 1 first-in-human dose-escalation study of VIP236, an $\alpha_V\beta_3$ small molecule drug conjugate (SMDC) in advanced solid tumors

IND filing for antibody drug conjugate (ADC) VIP943 remains on track for mid-2023; expected to be in clinic in the second half 2023

Anticipate dosing first patient in Phase 1b combination study of enitociclib and approved Bruton tyrosine kinase (BTK) inhibitor in CLL in second quarter 2023

Expected cash runway into late 2024

PALO ALTO, Calif., March 28, 2023 (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 fourth quarter and full year ended December 31, 2022, and provided a corporate update.

“Vincerx made great progress in 2022, advancing multiple programs while moving closer towards achieving our mission of improving outcomes for patients with cancer,” said Ahmed Hamdy, M.D., Chief Executive Officer of Vincerx. “We are particularly excited with the advancements we have made with our bioconjugation platform. This quarter, we started dosing the first cohort in our Phase 1 dose-escalation study in advanced solid tumors for VIP236, our first-in-class, front-runner $\alpha_V\beta_3$ SMDC with a tailored design to efficiently target aggressive and metastatic cancers. To date, we have generated robust preclinical results demonstrating how VIP236 can deliver up to 40 times more drug to the cancer, while sparing the surrounding tissues and normal organs. We look forward to sharing preclinical data at the upcoming AACR meeting, highlighting how VIP236 showed monotherapy efficacy in non-small cell lung cancer (NSCLC), gastric cancer, triple negative breast cancer (TNBC), renal cell carcinoma (RCC), colorectal cancer (CRC), and metastatic TNBC in vivo cancer models. Additionally, we will share exciting preclinical data in gastric cancer, where VIP236 showed improved efficacy in vivo compared with ENHERTU®, an approved ADC.”

“There have been some exciting developments in the ADC space recently, and our team has done great work positioning Vincerx to be a key player through the development and advancement of our next-generation, modular bioconjugation platform. Our lead ADC is VIP943, a novel anti-CD123 antibody that combines a unique payload class of kinesin spindle protein inhibitors (KSPi), a proprietary legumain-cleavable linker, and our CellTrapper™ modification of the KSPi, which allows for intracellular accumulation. CD123 is a validated target in myeloid malignancies, including higher-risk myelodysplastic syndrome (MDS) and acute myeloid leukemia (AML), which are the first indications we are pursuing. MDS and AML are aggressive and heterogeneous in their genetic makeup, and current treatments are quite toxic with high rates of relapse. This past ASH, we presented exciting preclinical data where, for the first time, we showed that our KSPi payload, linker and CellTrapper technology had a significant improvement in safety over Mylotarg™, an approved ADC for the treatment of AML. We also showed that VIP943 did not cause cytokine release in human blood cells. This indicates a potential reduced risk in the clinic for cytokine release syndrome, which is a common side effect of other CD123 targeting dugs (eg, ADCs and bispecifics). We believe these preclinical results, especially the improved safety over Mylotarg, demonstrate the benefit of our technology, which was designed to address some of the well-known challenges of existing ADCs. We remain on track to file the IND for VIP943 by mid-2023 and expect to get VIP943 into the clinic in the second half of this year,” added Dr. Hamdy.

“We also remain excited about enitociclib, our CDK9 inhibitor, and anticipate dosing the first patient in our Phase 1b enitociclib combination study with an approved BTK inhibitor in CLL next quarter. While great progress has been made in the treatment of CLL, limiting patients’ exposures to toxicities, preventing resistance, and minimizing risk of relapse and death following prolonged BTK inhibition monotherapy remain unmet needs. Our objective in the Phase 1b study is to put patients on a time-limited treatment, thus reducing their exposure to toxicities and preventing resistance to the BTK inhibitor,” concluded Dr. Hamdy.

FOURTH QUARTER AND FULL YEAR 2022 CORPORATE HIGHLIGHTS

Bioconjugation Platform

- **VIP236, an $\alpha_V\beta_3$ integrin binder linked to an optCPT payload SMDC:**
  - Company published preclinical data in the Journal *Cancers:*
    - Compelling proof-of-concept data demonstrated that VIP236 can direct a potent cancer chemotherapy drug to tumors while sparing healthy tissues.
    - Compared with commonly used chemotherapeutics, VIP236 showed effective tumor targeting, better tumor regression, and better tolerability in mouse models of TNBC, SCLC, and CRC.
  - In December, the Company received U.S. Food and Drug Administration (FDA) safe-to-proceed letter for

Investigational New Drug (IND) application for VIP236 for the treatment of advanced solid tumors; initiated dosing the first cohort of the Phase 1 first-in-human dose-escalation study with VIP236 monotherapy in the first quarter 2023 (ClinicalTrials.gov NCT05712889).

- **VIP943, CD123-KSPi ADC:**
  - Company presented preclinical data on VIP943 in AML models at the 2022 American Society of Hematology (ASH) Annual Meeting demonstrating superiority with significantly improved safety in monkeys when compared with Mylotarg™ (gemtuzumab ozogamicin), AML ex vivo and in vivo monotherapy activity, no signs of cytokine release in human blood cells, and significant tumor regression in combination with venetoclax and azacytidine in a patient-derived AML model.
  - IND-enabling studies continue to advance, with IND filing expected mid-2023.
- **VIP924, CXCR5-KSPi ADC:**
  - IND-enabling studies continue to advance, with IND filing on track for mid-2024.

Enitociclib, Positive Transcription Elongation Factor b (P-TEFb)/CDK9 inhibitor

- Orphan Drug Designation was granted by the FDA for the treatment of high-grade B-cell lymphoma characterized by translocations of MYC and BCL2/BCL6 (double-hit lymphoma).
- Phase 1b study of enitociclib in combination with an approved BTK inhibitor in patients with high-risk CLL expected to start after assessing the safety of enitociclib monotherapy in patients with high-risk CLL (NCT04978779) at the once-weekly 30mg dose. Anticipate dosing first patient in Phase 1b study in second quarter 2023.
- Company presented preclinical and preliminary clinical data on enitociclib in gynecologic malignancies at the 2022 American Association for Cancer Research (AACR) Annual Meeting. In a preliminary monotherapy clinical study in patients refractory to multiple lines of prior therapy, treatment with enitociclib showed an early signal with stable disease in 3 out of 3 patients with gynecologic cancer as well as 1 out of 4 patients with ovarian cancer unselected for MYC.
- Company presented preclinical and clinical data on enitociclib in multiple tumor types at the 2022 ASH Annual Meeting. In a multiple myeloma (MM) preclinical study, potent monotherapy and combination antitumor efficacy was observed with enitociclib.
- National Institutes of Health collaboration Phase 1 combination study with venetoclax and prednisone (VVIP) in peripheral T-cell lymphoma (NTC05371054) ongoing.
- A recent publication from Dr. Steven Johnsen's lab at the Robert Bosch Center of Tumor Diseases, Germany, identified that epigenetic reprogramming and transcriptional changes in metastatic pancreatic ductal adenocarcinoma (PDAC) are factors in therapy resistance and can be targeted by enitociclib.
  - These data along with our phase 1 clinical data, where we observed 2 patients with pancreatic cancer treated for 3 and 14 cycles achieve stable disease, support a potential clinical trial in metastatic PDAC in combination with chemotherapy.

Additional Corporate Highlights:

- Company announced receipt of 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 Vincerx to become eligible for EMA fee reductions and waiver and other financial incentives.
- In June, Company announced key strategic update with realignment of resources to support key indications and programs, advancement of the bioconjugation platform, and extension of cash runway.
- Company invited to talk on "ADCs with KSP-Inhibitor Payloads and a Tailored Design of Linker and Metabolite Profile," at the Festival of Biologics meeting.
- In the first quarter 2023, Company announced upcoming poster presentations at the American Association for Cancer Research (AACR) Annual Meeting in April 2023.
  - VIP236: A small molecule drug conjugate with an optimized camptothecin payload has significant activity in patient-derived and metastatic cancer models.
  - Targeting CDK9 via the small-molecule inhibitor enitociclib as a therapeutic strategy to treat MYCN-amplified rhabdomyosarcoma and neuroblastoma in children.
  - Synthesis and characterization of novel small molecule drug conjugates with different payloads designed to be released in tumor microenvironment by neutrophil elastase.
  - CXCR5 is a very promising drug target for the development of antibody-drug conjugates to treat patients with lymphoma.
- Expected cash runway into late 2024.

FOURTH QUARTER AND FULL YEAR 2022 FINANCIAL RESULTS

- Vincerx had $52.5 million in cash, cash equivalents and marketable securities as of December 31, 2022, as compared to $111.5 million as of December 31, 2021. Based on its current business plans and assumptions, Vincerx believes its available capital will be sufficient to meet its operating requirements into late 2024.

- Research and development (R&D) expenses for the fourth quarter and full year 2022 were $11.4 million and $52.2 million, respectively, as compared to $12.3 million and $40.1 million, respectively, for each of the same periods in 2021. The annual increase was primarily driven by increases in manufacturing services, including the ongoing services associated with our ADC program, third party research and preclinical work, new employee salaries, and clinical services in connection with our preclinical studies and clinical trials, partially offset by a decline in stock-based compensation expense.

- General and administrative (G&A) expenses for the fourth quarter and full year 2022 were $4.1 million and $19.0 million, respectively, as compared to $5.4 million and $22.6 million for the same periods in 2021. The quarterly and annual decreases were primarily driven by decreases in stock-based compensation expense.

- For the fourth quarter and full year 2022, Vincerx reported a net loss of $13.6 million, or $0.65 per share, and a net loss of $65.4 million, or $3.11 per share, respectively. For the fourth quarter and full year 2021, Vincerx reported a net loss of $6.5 million, or $0.31 per share, and a net loss of $39.3 million, or $2.29 per share, respectively.

ABOUT VINCERX PHARMA, INC.

Vincerx Pharma, Inc. (Vincerx) 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. The company's diverse pipeline consists of enitociclib, currently in Phase 1, and a proprietary modular bioconjugation platform, which includes a small molecule drug-conjugate, VIP236, in Phase 1, and preclinical next-generation antibody drug conjugates, VIP943 and VIP924.

Vincerx is based in Palo Alto, Calif., and has a research facility in Monheim, Germany. 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," "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 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; the potential effects of health epidemics and pandemics, including COVID-19; 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, availability and uses of capital, and cash runway; and the risks and uncertainties set forth in Forms 10-K, 10-Q, and 8-K most recently filed with or furnished to the SEC 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)

	December 31, 2022	December 31, 2021
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,663	$ 111,459
Short-term marketable securities	40,796	-
Prepaid expenses	134	182
Other current assets	3,371	200
Total current assets	55,964	111,841
Right-of-use assets	3,064	3,949
Property, plant and equipment, net	177	233
Other assets	81	1,653
Total assets	**$ 59,286**	**$ 117,676**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 3,065	$ 2,019
Accrued expenses	4,923	4,715
Lease liability	1,024	738
Common stock warrant liabilities	144	6,447
Total current liabilities	9,156	13,919
Lease liability, net of current portion	2,412	3,436
Other noncurrent liabilities	50	-
Total liabilities	11,618	17,355
Total stockholders' equity	47,668	100,321
Total liabilities and stockholders' equity	**$ 59,286**	**$ 117,676**

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

	For the three months ended December 31,		For the years ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
General and administrative	$ 4,050	$ 5,369	$ 18,953	$ 22,575
Research and development	11,373	12,338	52,152	40,081
Restructuring	-	-	2,469	-
Total operating expenses	15,423	17,707	73,574	62,656
Loss from operations	(15,423)	(17,707)	(73,574)	(62,656)
Other income (expense)				
Change in fair value of warrant liabilities	(31)	11,256	6,303	23,358
Interest income	460	-	664	-
Other income (expense)	1,351	(21)	1,240	(8)
Total other income (expense)	1,780	11,235	8,207	23,350
Net loss	**$ (13,643)**	**$ (6,472)**	**$ (65,367)**	**$ (39,306)**
Net loss per common share, basic and diluted	$ (0.65)	$ (0.31)	$ (3.11)	$ (2.29)
Weighted average common shares outstanding, basic and diluted	21,138	20,841	21,029	17,176

Source: Vincerx Pharma, Inc.