Vera Therapeutics Reports Fourth Quarter and Full Year 2021 Financial Results

March 24, 2022

- *Phase 2b ORIGIN clinical trial of atacicept on track, topline data expected Q4 2022*
- *Acquired MAU868, a first-in-class monoclonal antibody to treat BK Virus infections, full results from interim analysis of Phase 2 study of MAU868 in kidney transplant recipients planned for mid-2022*
- *Initiation of Phase 3 pivotal clinical trial of atacicept in lupus nephritis planned for 2H-2022*
- *BK Virus and MAU868 key opinion leader webinar to be held Tuesday, March 29, 2022*
- *Management to host business update webcast today at 8:00 a.m. ET*

BRISBANE, Calif., March 24, 2022 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today reported its business highlights and financial results for the fourth quarter and full year ended December 31, 2021.

“2021 was a defining period for our company, as we executed against our business strategy and accomplished a number of key objectives. We have built a world class team, completed our initial public offering, and both advanced and expanded the Vera pipeline, with two programs currently in Phase 2 clinical trials. We believe this initial progress is being recognized by our investors, as Vera finished the year as the top performing biotech IPO in 2021,” said Marshall Fordyce, M.D., founder and CEO of Vera Therapeutics.

“At the start of 2022, we strengthened our balance sheet by completing an equity offering with net proceeds of approximately $80.2 million. Looking ahead, we expect to achieve several clinical milestones in 2022. At the forefront of our pipeline is atacicept for IgA nephropathy, currently in the Phase 2b ORIGIN study. This study is expected to complete enrollment in mid-2022 and announce topline results in the fourth quarter. We expect these data to support initiation of a pivotal Phase 3 clinical trial of atacicept in 2023. In addition, we recently announced a positive meeting with the FDA evaluating the development program for atacicept to treat lupus nephritis. As a result, we are planning to advance this program into a Phase 3 pivotal clinical trial later this year.

“At the end of 2021, we acquired a promising new clinical stage program, MAU868, to treat patients with BK Virus infections, a population that currently lacks an effective therapeutic option. MAU868 is being studied in an ongoing Phase 2 study in patients with BK Virus reactivation after kidney transplant, and we plan on presenting the full interim data from this study in mid-2022, and initiating a Phase 2b or Phase 3 clinical trial of MAU868 in kidney transplant patients with BK Virus reactivation in 2023. To help educate the market about the clinical importance of BK Virus reactivation and the opportunity for MAU868, we have scheduled an event that will include a presentation from world-renowned transplant nephrologist and pioneering kidney transplant researcher, Stanley C. Jordan, M.D., FASN, FAST,” concluded Dr. Fordyce.

Fourth Quarter and Recent Business Highlights

- Strengthened the balance sheet by completing an equity offering with net proceeds of approximately $80.2 million in February 2022. The offering included J.P. Morgan, Cowen, and Evercore ISI acting as joint book-running managers.
- Announced the acquisition of MAU868, a first-in-class monoclonal antibody to treat BK Virus (BKV) infections, from Amplyx Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer Inc. Vera believes MAU868 has the potential to neutralize infection by blocking BKV virions from binding to host cells.
- Secured a $50 million credit facility through Oxford Finance LLC (Oxford) with $45 million of remaining borrowing capacity.
- Hosted a key opinion leader (KOL) webinar that featured Richard Lafayette, M.D., FACP, Stanford University Medical Center and Jonathan Barratt, Ph.D., FRCP, University of Leicester, who discussed the rationale for targeting dual inhibition of a proliferation inducing ligand and B lymphocyte stimulator and the potential of atacicept as a disease-modifying treatment option.
- Presented positive clinical data from the Phase 2a JANUS trial that show the potential of atacicept to reduce Gd-IgA1 levels and therefore potentially mitigate the poor prognosis of patients with IgA nephropathy (IgAN) based on Gd-IgA1. These data showed that the 75mg atacicept dose lowered serum Gd-IgA1 levels by 60 percent compared to baseline – the largest reduction demonstrated in a randomized placebo-controlled study by an investigational compound in development for IgAN.
- Expanded the management team with several key new hires throughout 2021, including the appointment of Sean Grant, MBA, as chief financial officer, Celia Lin, M.D., as chief medical officer, Tad Thomas, Ph.D., as senior vice president and head of product development and manufacturing, and Joseph Young, MBA, as senior vice president of finance and chief accounting officer.
- Appointed Kimball Hall to the board of directors in December 2021. Ms. Hall is a pharmaceutical industry leader who brings more than 30 years of quality, regulatory, and manufacturing experience.

Upcoming Milestones

- The company is scheduled to host a KOL webinar about BKV and MAU868 on March 29, 2022, To register for the event, please click here.
- Plan to share the full results from the interim analysis of a Phase 2 study in BK viremia among kidney transplant recipients in mid-2022. MAU868 has been shown in an interim analysis of week 12 data from Cohort 1 and 2 of a Phase 2 study to be well tolerated and showed a greater proportion of subjects with decrease in BK plasma viral load versus placebo.
- Plan to initiate a Phase 3 clinical trial of atacicept in 2H-2022 in lupus nephritis following positive feedback from the U.S. Food and Drug Administration of the proposed study.

Expect to announce topline data in the fourth quarter of 2022 for the Phase 2b ORIGIN clinical trial, a dose-ranging study evaluating the safety and efficacy of atacicept in patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression.

Financial Results for the Year Ended December 31, 2021
For the three months ended December 31, 2021, the company reported a net loss of $16.8 million, or a net loss per diluted share of $0.79, compared to a net loss of $42.9 million, or a net loss per diluted share of $137.63, for the same period last year. Outstanding shares of redeemable convertible preferred stock were excluded from the computation of net loss per diluted share for periods prior to the conversion of those shares to common stock in May 2021.

During the year ended December 31, 2021, net cash used in operating activities was $23.7 million, compared to $34.8 million for the same period last year.

Vera reported approximately $79.7 million in cash and cash equivalents as of December 31, 2021. Subsequent to the end of the quarter, the company raised approximately $80.2 million in net proceeds from a public offering of Class A Common Stock that was completed in February 2022. In addition, the company has secured a credit facility through Oxford with a remaining borrowing capacity of up to $45 million.

Conference Call and Webcast
Vera's management team will host a webcast today at 8:00 AM ET to discuss a financial results and recent corporate developments. The dial-in number for the webcast is 1-877-423-9813 for domestic participants and 1-201-689-8573 for international participants, with Conference ID #13727899. A live webcast of the conference call can be accessed at (click here) or through the Investors section of the Vera website at https://ir.veratx.com/news-events/investor-calendar. A replay will be available on this website shortly after conclusion of the event for approximately 90 days.

About Vera
Vera Therapeutics is a late-stage biotechnology company focused on developing treatments for serious immunological diseases. Vera's mission is to advance treatments that target the source of immunologic diseases in order to change the standard of care for patients. Vera's lead product candidate is atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including IgA nephropathy (IgAN), also known as Berger's disease and lupus nephritis. In addition, Vera is evaluating additional diseases where the reduction of autoantibodies by atacicept may prove medically useful. Vera is also developing MAU868, a monoclonal antibody designed to neutralize infection with BK Virus, a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. For more information, please visit www.veratx.com.

Forward-Looking Statements
Statements contained in this press release regarding matters, events or results that may occur in the future are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the continued tolerability of Vera's product candidates, research and clinical development plans and timing, the scope, progress, and results of developing Vera's product candidates, strategy, and regulatory matters, including the timing and likelihood of success of obtaining drug approvals. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "plans," "will," "expects," "potential," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Vera's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks related to the regulatory approval process, results of earlier clinical trials may not be obtained in later clinical trials, risks and uncertainties associated with Vera's business in general, the impact of the COVID-19 pandemic, and the other risks described in Vera's filings with the Securities and Exchange Commission, including in its Annual Report on Form 10-K expected to be filed with the Securities and Exchange Commission on March 25, 2022, particularly under the caption "Risk Factors." All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Vera undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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VERA THERAPEUTICS, INC.
Condensed Statements of Operations and Comprehensive Loss
(in thousands, except share and per share amounts)

	Three Months Ended December 31,		For the Year Ended December 31,	
	2021	2020	2021	2020
	(unaudited)			
Operating expenses:				
Research and development	$ 12,753	$ 39,844	$ 22,484	$ 45,206
General and administrative	3,832	1,136	11,918	4,039
Restructuring Costs	-	1,580	-	2,996
Total operating expenses	16,585	42,560	34,402	52,241
Loss from operations	(16,585)	(42,560)	(34,402)	(52,241)
Total other income (expense), net	(261)	(314)	1,794	(1,171)
Provision for income taxes	(1)	(1)	(1)	(1)
Net loss and comprehensive loss	$ (16,847)	$ (42,875)	$ (32,609)	$ (53,413)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.79)	$ (137.63)	$ (2.43)	$ (166.93)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	21,276,355	311,522	13,435,706	319,963

VERA THERAPEUTICS, INC.
Condensed Balance Sheets
(in thousands)

	December 31, 2021	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 79,674	$ 53,654
Restricted cash, current	-	50
Prepaid expenses and other current assets	2,863	557
Total current assets	82,537	54,261
Restricted cash, noncurrent	293	293
Prepaid expenses and other current assets, noncurrent	51	-
Non-marketable equity securities	867	-
Total assets	$ 83,748	$ 54,554
Liabilities, redeemable convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	$ 1,385	$ 909
Restructuring liability, current	377	962
Accrued expenses and other current liabilities	5,928	535
Total current liabilities	7,690	2,406
Long term debt	4,923	-
Restructuring liability, noncurrent	1,257	1,634
Accrued and other noncurrent liabilities	286	286
Total liabilities	14,156	4,326
Redeemable convertible preferred stock	-	139,576
Stockholders' equity (deficit)		
Common stock	21	-
Additional paid-in-capital	193,627	2,099
Accumulated deficit	(124,056)	(91,447)
Total stockholders' equity (deficit)	69,592	(89,348)
Total liabilities, redeemable convertible preferred stock and stockholders' equity	$ 83,748	$ 54,554