Vera Therapeutics Provides Business Update and Reports Fourth Quarter and Full Year 2022 Financial Results

March 28, 2023

- *Announced positive interim data from the Phase 2b ORIGIN clinical trial of atacicept in IgAN, which showed a 41% mean reduction in proteinuria versus baseline in the 150mg dose group at 24 weeks*
- *36-week data from the Phase 2b ORIGIN clinical trial of atacicept in IgAN on track for the second quarter of 2023*
- *Management prioritizing advancement of atacicept in IgAN, plans to initiate Phase 3 clinical trial in second quarter of 2023*
- *Strong balance sheet expected to fund IgAN-focused operations to early 2026*

BRISBANE, Calif., March 28, 2023 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today reported its business highlights for the fourth quarter and financial results for the full year ended December 31, 2022.

“Over the past year, we have made significant progress executing our clinical development program for our lead product candidate, atacicept, for the treatment of IgA Nephropathy (IgAN),” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “We believe the recently announced positive efficacy and safety data from the ORIGIN study have further de-risked the atacicept program and position it as a potential best-in-disease therapy. We expect to announce 36-week results from the ORIGIN study in the second quarter of this year and initiate a pivotal Phase 3 trial for atacicept in IgAN during the second quarter of this year.”

“Given the significant market opportunity and unmet need of IgAN patients, we made the strategic decision to prioritize and focus both our financial and organizational resources at this time on the advancement of atacicept into a Phase 3 pivotal trial for IgAN,” continued Dr. Fordyce.

Full Year 2022 and Recent Business Highlights

- Released positive interim data from the Phase 2b ORIGIN clinical trial of atacicept in IgAN, which showed a 41% mean reduction in proteinuria versus baseline in the 150mg dose group at 24 weeks
- Announced data in oral presentation at the 59th European Renal Association – European Dialysis and Transplant Association (ERA-EDTA) Congress showing the effect of atacicept on serum anti-Gd-IgA1 in IgAN patients
- Presented final results from the Phase 2a clinical trial of MAU868 in patients with reactivated BK Virus Infection at the American Society of Nephrology (ASN) Kidney Week Annual Meeting
- Appointed Michael M. Morrissey, Ph.D., President and CEO of Exelixis, Inc., as Chairman of Vera’s Board of Directors
- Strengthened balance sheet with approximately $188 million in net proceeds from follow-on public offerings of Class A common stock since January 2022

Upcoming Milestones

- 36-week data from the Phase 2b ORIGIN clinical trial of atacicept in IgAN on track for the second quarter of 2023
- Expect to initiate Phase 3 clinical trial of atacicept in IgAN in second quarter of 2023
- Plan to present data from the ongoing ORIGIN trial in 2023

Financial Results for the Year Ended December 31, 2022
For the year ended December 31, 2022, the company reported a net loss of $89.1 million, or a net loss per diluted share of $3.35, compared to a net loss of $32.6 million, or a net loss per diluted share of $2.43, for the same period last year.

During the year ended December 31, 2022, net cash used in operating activities was $67.6 million, compared to $23.7 million for the same period last year.

Vera reported $114.7 million in cash, cash equivalents, and marketable securities as of December 31, 2022. Subsequent to December 31, 2022, the company raised approximately $107.6 million in net proceeds, after deducting underwriting discounts and commissions and offering expenses, from a public offering of its Class A common stock that was completed in February 2023.

About Vera
Vera Therapeutics is a late clinical-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.

About Atacicept

Atacicept is an investigational recombinant fusion protein self-administered as a subcutaneous injection once weekly that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines B lymphocyte stimulator (BlyS) and a proliferation-inducing ligand (APRIL). These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with certain autoimmune diseases, including IgA nephropathy (IgAN) and lupus nephritis. Atacicept has shown a clinically and statistically significant effect on key biomarkers and clinical markers in a Phase 2b clinical study in patients with IgAN. Vera believes atacicept is positioned for best-in-class potential, targeting B cells and plasma cells to reduce autoantibodies and having been administered to more than 1,500 patients in clinical studies across different indications.

About MAU868
MAU868, a potential first-in-class monoclonal antibody, has the potential to neutralize infection by blocking BK Virus (BKV) virions from binding to host cells. BKV is a polyoma virus that can be reactivated in settings of immunosuppression, such as in kidney transplant. It is a leading cause of kidney transplant loss and transplant-associated morbidity; there are currently no approved treatments for BKV. Vera holds an exclusive worldwide license from Amplyx Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer Inc., for the development and commercialization of MAU868 in all indications.

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, atacicept's potential to be a transformational treatment for patients with IgAN and a best-in-disease therapy, Vera's plans to advance atacicept into pivotal Phase 3 development in the second quarter of 2023, expectations regarding reporting Phase 3 topline data at Week 36 and ongoing data from the ORIGIN trial in 2023, Vera's plans to prioritize and focus current resources on the advancement of atacicept in IgAN into a pivotal Phase 3 trial,, and Vera's product candidates, strategy, and regulatory matters. 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 "potential," "expect," "plan," 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. 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.

For more information, please contact:

Investor Contact:
Joyce Allaire
LifeSci Advisors
212-915-2569
jallaire@lifesciadvisors.com

Media Contact:
Minyan Weiss
Uncapped Communications, Inc.
Minyan.Weiss@uncappedcommunications.com

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

	For the Year Ended December 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 68,993	$ 22,484
General and administrative	21,910	11,918
Total operating expenses	90,903	34,402
Loss from operations	(90,903)	(34,402)
Other income, net	1,848	1,794
Provision for income taxes	(1)	(1)
Net loss	$ (89,056)	$ (32,609)
Change in unrealized loss on marketable securities	(224)	-
Comprehensive loss	$ (89,280)	$ (32,609)
Net loss per share attributable to common stockholders, basic and diluted	$ (3.35)	$ (2.43)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	26,570,676	13,435,706

VERA THERAPEUTICS, INC.

Condensed Balance Sheets
(in thousands)

	December 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 114,653	$ 79,674
Prepaid expenses and other current assets	11,045	2,863
Total current assets	125,698	82,537
Operating lease right-of-use assets	5,173	-
Non-marketable equity securities	58	867
Other noncurrent assets	506	344
Total assets	$ 131,435	$ 83,748
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 11,991	$ 1,385
Operating lease liabilities	2,645	-
Restructuring liability	-	377
Accrued expenses and other current liabilities	10,964	5,928
Total current liabilities	25,600	7,690
Long-term debt	24,810	4,923
Operating lease liabilities, noncurrent	3,831	-
Restructuring liability, noncurrent	-	1,257
Accrued and other noncurrent liabilities	286	286
Total liabilities	54,527	14,156
Stockholders' equity		
Common stock	28	21
Additional paid-in-capital	290,216	193,627
Accumulated other comprehensive loss	(224)	-
Accumulated deficit	(213,112)	(124,056)
Total stockholders' equity	76,908	69,592
Total liabilities and stockholders' equity	$ 131,435	$ 83,748