Vera Therapeutics Provides Business Update and Reports Second Quarter 2024 Financial Results

August 8, 2024

- *Received FDA Breakthrough Therapy Designation for atacicept in IgA Nephropathy (IgAN)*
- *Presented data from Phase 2b ORIGIN study at ERA24 Congress showing atacicept stabilized kidney function through 72 weeks and led to rapid reductions in hematuria*
- *Topline 96-week data from Phase 2b ORIGIN study expected in Q4 2024*
- *On track to complete enrollment in pivotal Phase 3 ORIGIN 3 trial for primary endpoint in Q3 2024; topline data expected in Q2 2025*

BRISBANE, Calif., Aug. 08, 2024 (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 and financial results for the second quarter ended June 30, 2024.

“We continue to strengthen the data package for atacicept, including our “Best Ranked Abstract”-winning presentation of Phase 2b data from the ORIGIN trial at ERA24 that shows atacicept stabilized kidney function through 72 weeks and led to rapid reductions in hematuria. These data have generated broad excitement about the potential for atacicept to advance the treatment of IgAN and led to the FDA granting Breakthrough Therapy Designation for atacicept in the treatment of IgAN,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “We look forward to presenting the long-term 96-week clinical data from our Phase 2b ORIGIN trial in the fourth quarter of 2024. In addition, we are on track to complete enrollment in our pivotal ORIGIN 3 Phase 3 trial in the third quarter of 2024, and expect to present topline data from this trial in Q2 2025. We expect these data to support our submission for regulatory approval, which if approved, given the anticipated timeline, would position atacicept as one of the first B-cell modulators to be approved in IgAN.”

Second Quarter and Recent Business Highlights

- Received U.S. Food and Drug Administration (FDA) Breakthrough Therapy Designation for atacicept in the treatment of IgAN
- Presented two oral presentations at the 61st European Renal Association Congress (ERA24), including Best-Ranked Abstract, on the Phase 2b ORIGIN trial of atacicept in immunoglobulin A nephropathy (IgAN) showing atacicept stabilized kidney function through 72 weeks and led to rapid reductions in hematuria
- Appointed industry veterans David L. Johnson as Chief Operating Officer and Amit Sharma, M.D. as Executive Vice President of Medical Affairs and Clinical Research
- Appointed Christy J. Oliger as independent director to the Company’s Board of Directors

Upcoming Milestones in 2024

- Plan to present topline 96-week data from ORIGIN Ph 2b clinical trial of atacicept in IgAN in the fourth quarter of 2024
- Pivotal Phase 3 ORIGIN 3 trial on track to complete enrollment in the third quarter of 2024; expect to announce topline data in Q2 2025

Financial Results for the Quarter Ended June 30, 2024
For the quarter ended June 30, 2024, the company reported a net loss of $33.7 million, or a net loss per diluted share of $0.62, compared to a net loss of $20.2 million, or a net loss per diluted share of $0.46, for the same period last year.

During the six months ended June 30, 2024, net cash used in operating activities was $58.6 million, compared to $44.1 million for the same period last year.

Vera reported $384.4 million in cash, cash equivalents, and marketable securities as of June 30, 2024, which the Company believes to be sufficient to fund operations through approval and US commercial launch of atacicept, if approved.

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 immunological 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-cell Activating Factor (BAFF) and A PRoliferation-Inducing Ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including 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 (BKV), a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. Vera retains all global developmental and commercial rights to atacicept and MAU868. For more information, please visit www.veratx.com.

About Atacicept
Atacicept is an investigational recombinant fusion protein that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines B-cell activating factor (BAFF) 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 IgAN and lupus nephritis.

The Phase 2b ORIGIN clinical trial of atacicept in IgAN met its primary and key secondary endpoints, with statistically significant and clinically meaningful proteinuria reductions and stabilization of eGFR versus placebo through 36 weeks. The safety profile during the randomized period was comparable between atacicept and placebo. Through 72 weeks, atacicept demonstrated further reductions in Gd-IgA1, hematuria, and proteinuria, as well as stabilization of eGFR reflecting a profile consistent with that of the general population without IgAN.

Atacicept has received FDA Breakthrough Therapy Designation for the treatment of IgAN, which reflects the FDA's determination that, based on an assessment of data from the Phase 2b ORIGIN clinical trial, atacicept may demonstrate substantial improvement on a clinically significant endpoint over available therapies for 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 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, Vera's product candidates, financial condition and resources, strategy, and regulatory matters, including timelines for enrollment and release of results from clinical trials and the sufficiency of Vera's cash position to fund operations through approval and US commercial launch of atacicept, if approved. 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," "will," "expect," "on track," "may," "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, preliminary results may not be predictive of topline results, risks and uncertainties associated with Vera's business in general, the impact of macroeconomic and geopolitical events, 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.

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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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
	(unaudited)		*(unaudited)*	
Operating expenses:				
Research and development	$ 29,311	$ 16,231	$ 52,511	$ 41,340
General and administrative	8,032	5,739	$ 15,944	11,887
Total operating expenses	37,343	21,970	68,455	53,227
Loss from operations	(37,343)	(21,970)	(68,455)	(53,227)
Other income, net	3,635	1,808	6,364	2,996
Net loss	$ (33,708)	$ (20,162)	$ (62,091)	$ (50,231)
Change in unrealized gain (loss) on marketable securities	$ (277)	$ (138)	$ (700)	$ 82
Comprehensive loss	$ (33,985)	$ (20,300)	$ (62,791)	$ (50,149)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.62)	$ (0.46)	$ (1.17)	$ (1.23)
Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted	54,728,552	44,269,772	52,850,242	40,986,907

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

	June 30, 2024	December 31, 2023
	(unaudited)	
Assets		
Current assets:		
Cash, cash equivalents and marketable securities	$ 384,387	$ 160,716
Prepaid expenses and other current assets	10,360	11,307
Total current assets	394,747	172,023
Operating lease right-of-use assets	1,929	2,949
Other noncurrent assets	615	574
Total assets	$ 397,291	$ 175,546
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 4,664	$ 11,118
Operating lease liabilities	2,116	2,436
Accrued expenses and other liabilities, current	11,638	8,749
Total current liabilities	18,418	22,303
Long-term debt	50,263	49,877
Operating lease liabilities, noncurrent	455	1,395
Accrued expenses and other liabilities, noncurrent	286	286
Total liabilities	69,422	73,861
Stockholders' equity		
Common stock	55	44
Additional paid-in-capital	699,457	410,492
Accumulated other comprehensive income (loss)	(450)	251
Accumulated deficit	(371,193)	(309,102)
Total stockholders' equity	327,869	101,685
Total liabilities and stockholders' equity	$ 397,291	$ 175,546