

# Vera Therapeutics Provides Business Update and Reports Third Quarter 2022 Financial Results

November 9, 2022

- Phase 2b ORIGIN clinical trial of atacicept in IgA nephropathy topline data planned to be presented in early Q1 2023
- Initiated pivotal Phase 3 COMPASS clinical trial of atacicept in lupus nephritis
- Strong balance sheet with \$114.4 million in cash, cash equivalents, and marketable securities as of September 30, 2022; together with credit facility, are expected to fund operations to Q2 2024

BRISBANE, Calif., Nov. 09, 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 quarter ended September 30, 2022.

"During the third quarter of 2022, we continued to make progress advancing our late-stage clinical pipeline of atacicept and MAU868," said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. "At the American Society of Nephrology (ASN) Kidney Week 2022 Annual Meeting, we were pleased to share new data supporting the disease modifying mechanism of action of atacicept. Atacicept targets B-cells, and we have now shown that it reduces the first three hits of IgA nephropathy (IgAN) pathogenesis – serum galactose-deficient IgA1 (Gd-IgA1), anti-Gd-IgA1, and now immune complex levels. Our ongoing Phase 2b ORIGIN clinical trial will demonstrate how atacicept has the potential to improve kidney function, as measured by proteinuria, and topline results are expected to be announced in early first quarter of 2023. Data from the ORIGIN trial are expected to support the initiation of a pivotal Phase 3 clinical trial of atacicept in 2023. IgAN is a common cause of kidney failure and there is a high unmet medical need for treatment of IgAN globally."

"We are also pleased to announce initiation of our pivotal Phase 3 COMPASS clinical trial of atacicept in lupus nephritis. This is a significant next step for the program, as we believe atacicept has the potential to be a best-in-disease treatment for lupus nephritis patients. There is an immense unmet medical need, with a high rate of morbidity and mortality, with many patients progressing to end-stage renal disease. We believe lupus nephritis represents a multi-billion-dollar aggregate annual market opportunity for novel therapeutics in the United States, Europe and Japan," he continued.

"We also recently announced positive safety and clinically meaningful results from the Phase 2 clinical trial of MAU868 to treat BK Virus (BKV) in kidney transplant patients in an oral presentation at ASN Kidney Week 2022. We believe these data support our plan to initiate a Phase 2b or Phase 3 clinical trial of MAU868 in kidney transplant patients with BK viremia in 2023," concluded Dr. Fordyce.

# Third Quarter and Recent Business Highlights

- Announced data from a new analysis of Phase 2a JANUS trial that showed atacicept reduced immune complex levels in patients with IgAN, which were presented during ASN Kidney Week 2022
- Initiated the COMPASS trial, a pivotal, randomized, double-blinded, placebo-controlled Phase 3 clinical trial of atacicept in lupus nephritis
- Presented positive final results from the Phase 2 trial of MAU868 versus placebo in kidney transplant recipients with reactivated BKV infection during ASN Kidney Week 2022, which showed MAU868 was well tolerated and demonstrated clinically meaningful BK antiviral activity through 36 weeks in kidney transplant patients with BK viremia
- Amended the MAU868 license agreement with Novartis which resulted in conversion of cash milestones into common stock issued at a 20% premium to previous close
- Extended Oxford credit facility through year-end 2023, offering additional financial flexibility
- Strong balance sheet with \$114.4 million in cash, cash equivalents, and marketable securities as of September 30, 2022; together with \$20.0 million drawn under credit facility in November 2022 and \$25.0 million available at Vera's option through 2023, are expected to fund operations to Q2 2024

# **Upcoming Milestones**

- Plan to announce topline data from the Phase 2b ORIGIN clinical trial of atacicept in IgAN in early first quarter of 2023
- Expect to initiate a Phase 2b or Phase 3 clinical trial of MAU868 in BK viremia in kidney transplant recipients in 2023

# Financial Results for the Quarter Ended September 30, 2022

For the three months ended September 30, 2022, the company reported a net loss of \$24.7 million, or a net loss per diluted share of \$0.91, compared to a net loss of \$7.6 million, or a net loss per diluted share of \$0.36, for the same period last year.

During the nine months ended September 30, 2022, net cash used in operating activities was \$46.4 million, compared to \$17.3 million for the same period last year.

Vera reported \$114.4 million in cash, cash equivalents, and marketable securities as of September 30, 2022.

# 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 showed a dose-dependent effect on key biomarkers and clinical markers in a Phase 2a 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 1,400 patients in clinical studies across different indications.

# About MAU868

MAU868, a first-in-class monoclonal antibody, has the potential to neutralize infection by blocking BK Virus (BKV) virions from binding to host cells. BK Virus 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.

#### 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 <u>www.veratx.com</u>.

#### **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 expectations regarding the strength and adequacy of its balance sheet, the timing and result of topline results from the Phase 2b ORIGIN clinical trial, Vera's expectations regarding the initiation of a Phase 2b or 3 clinical trial of MAU868 in BK viremia in kidney transplant recipients in 2023, 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," "plan," "expect," "believe" 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 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 geopolitical and macroeconomic events, including 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:

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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 September 30,			Nine Months Ended September 30,				
		2022	_	2021		2022		2021
		(unaudited)			(unaudited)			
Operating expenses:								
Research and development	\$	19,656	\$	3,564	\$	42,317	\$	9,731
General and administrative		5,588		3,688		15,005		8,086
Total operating expenses		25,244		7,252		57,322		17,817
Loss from operations		(25,244)		(7,252)		(57,322)		(17,817)
Total other income (expense), net		565	_	(359)		705		2,055
Net loss	\$	(24,679)	\$	(7,611)	\$	(56,617)	\$	(15,762)
Unrealized loss on available-for-sale securities		(127)		-		(279)		-
Total loss and comprehensive loss	\$	(24,806)	\$	(7,611)	\$	(56,896)	\$	(15,762)

Net loss per share attributable to common stockholders, basic and diluted

Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted

\$	(0.91)	\$ (0.36)	\$ (2.16)	\$ (1.46)
2	7,215,874	 21,265,519	 26,184,816	 10,793,436

# VERA THERAPEUTICS, INC. Condensed Balance Sheets (in thousands, except share amounts)

	Se	December 31, 2021		
Assets	(	unaudited)		
Current assets:				
Cash, cash equivalents, and short-term marketable securities	\$	114,420	\$	79,674
Prepaid expenses and other current assets		10,562		2,863
Total current assets		124,982		82,537
Operating lease right-of-use assets		5,768		-
Non-marketable equity securities		122		867
Other noncurrent assets		498		344
Total assets	\$	131,370	\$	83,748
Liabilities and stockholder's equity				
Current liabilities:				
Accounts payable	\$	7,012	\$	1,385
Operating lease liabilities		2,689		-
Restructuring liability		-		377
Accrued expenses and other current liabilities		6,219		5,928
Total current liabilities		15,920		7,690
Long-term debt		4,966		4,923
Operating lease liabilities, noncurrent		4,480		-
Restructuring liability, noncurrent		-		1,257
Accrued and other noncurrent liabilities		286		286
Total liabilities		25,652		14,156
Stockholders' equity				
Common stock		28		21
Additional paid-in-capital		286,642		193,627
Accumulated other comprehensive loss		(279)		-
Accumulated deficit		(180,673)		(124,056)
Total stockholders' equity		105,718		69,592
Total liabilities and stockholders' equity	\$	131,370	\$	83,748