# Vera Therapeutics Provides Business Update and Reports First Quarter 2025 Financial Results

May 6, 2025

- *On track to announce the primary endpoint results from the atacicept pivotal Phase 3 ORIGIN trial in IgA Nephropathy (IgAN) in 2Q 2025; planning for Biologics License Application (BLA) submission for atacicept accelerated approval to the U.S. FDA in 4Q 2025*
- *Expanded atacicept development program across multiple autoimmune kidney diseases is underway*

BRISBANE, Calif., May 06, 2025 (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 first quarter ended March 31, 2025.

“We are rapidly approaching a significant Vera milestone with the upcoming primary endpoint results from the pivotal atacicept ORIGIN 3 trial, and if successful, we expect this to enable a BLA submission to the FDA in the second half of this year, which may allow approval and commercial launch in 2026. If approved, we believe that atacicept has the potential to advance the standard of care in IgA nephropathy,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “The Vera team is well-positioned to build on the success of the lead atacicept development program in IgAN, with the expansion into additional potential indications in other autoimmune kidney diseases and beyond.”

**First Quarter 2025 and Recent Business Highlights**

- Completed full enrollment in the pivotal ORIGIN Phase 3 trial of atacicept in IgAN
- Enrolling participants in the ORIGIN EXTEND study, which provides participants in the ORIGIN Phase 2b or Phase 3 trials with extended access to atacicept, and captures longer-term safety and efficacy data
- Acquired exclusive development and commercialization rights to VT-109, a novel, next generation fusion protein targeting BAFF and APRIL, with wide therapeutic potential across the spectrum of B cell mediated diseases
- Introduced an expanded development program for atacicept across multiple autoimmune kidney diseases, including primary membranous nephropathy (PMN), focal segmental glomerulosclerosis (FSGS), and minimal change disease (MCD)

**Major Upcoming Milestones**

- Anticipated announcement of the primary endpoint results from the pivotal ORIGIN 3 trial in 2Q 2025
- Plan to submit a Biologics License Application (BLA) for atacicept in IgAN to the U.S. FDA in 4Q 2025 for accelerated approval; potential PDUFA date and commercial launch in 2026

**Financial Results for the Quarter Ended March 31, 2025**
For the quarter ended March 31, 2025, the company reported a net loss of $51.7 million, or a net loss per share of $0.81**,** compared to a net loss of $28.4 million, or a net loss per diluted share of $0.56, for the quarter ended March 31, 2024.

During the quarter ended March 31, 2025, net cash used in operating activities was $54.4 million, compared to $33.8 million for the same period last year.

Vera reported $589.8 million in cash, cash equivalents, and marketable securities as of March 31, 2025, which the company believes to be sufficient to fund operations through potential approval and U.S. commercial launch of atacicept.

**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 96 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 to reduce autoantibodies and having been administered to more than 1,500 patients in clinical studies across different indications.

**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 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. Vera also holds an exclusive license agreement with Stanford University for a novel, next generation fusion protein targeting BAFF and APRIL, known as VT-109, with wide therapeutic potential across the spectrum of B cell mediated diseases. 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, Vera's plans to receive and report primary endpoint results in the Phase 3 ORIGIN 3 trial, to submit a BLA to the FDA, and to potentially receive a PDUFA date, receive FDA approval for atacicept in IgAN and launch it commercially, and, in each case, the timing thereof, the potential for atacicept to bring value for patients and to the change the standard of care in IgAN, if approved, and Vera's ability to fund its operations through potential approval and U.S. commercial launch of atacicept. Because such statements are subject to risk and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipate," "believe," "on track," "plan," "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, 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 March 31, | |
|---|---|---|
| | **2025** | **2024** |
| | *(unaudited)* | |
| Operating expenses: | | |
| Research and development | $ 41,278 | $ 23,200 |
| General and administrative | 15,916 | 7,912 |
| Total operating expenses | 57,194 | 31,112 |

| | | |
|---|---|---|
| Loss from operations | (57,194) | (31,112) |
| Other income, net | 5,500 | 2,729 |
| Net loss | $ (51,694) | $ (28,383) |
| Change in unrealized gain/loss on marketable securities | $ 261 | $ (424) |
| Comprehensive loss | $ (51,433) | $ (28,807) |
| Net loss per share attributable to common stockholders, basic and diluted | $ (0.81) | $ (0.56) |
| Weighted-average shares used in computing net loss per share attributable to common stockholders, basic and diluted | 63,671,558 | 50,971,933 |

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

| | March 31, 2025 | December 31, 2024 |
|---|---|---|
| | *(unaudited)* | |
| **Assets** | | |
| Current assets: | | |
| Cash, cash equivalents and marketable securities | $ 589,834 | $ 640,852 |
| Prepaid expenses and other current assets | 16,242 | 10,366 |
| Total current assets | 606,076 | 651,218 |
| Operating lease right-of-use assets | 2,915 | 3,372 |
| Other noncurrent assets | 1,176 | 1,091 |
| Total assets | $ 610,167 | $ 655,681 |
| **Liabilities and stockholders' equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 9,262 | $ 7,665 |
| Operating lease liabilities | 1,191 | 1,483 |
| Accrued expenses and other liabilities, current | 11,441 | 16,223 |
| Total current liabilities | 21,894 | 25,371 |
| Long-term debt | 50,908 | 50,687 |
| Operating lease liabilities, noncurrent | 2,366 | 2,468 |
| Total liabilities | 75,168 | 78,526 |
| Stockholders' equity | | |
| Common stock | 64 | 64 |
| Additional paid-in-capital | 1,047,225 | 1,037,948 |
| Accumulated other comprehensive income | 654 | 393 |
| Accumulated deficit | (512,944) | (461,250) |
| Total stockholders' equity | 534,999 | 577,155 |
| Total liabilities and stockholders' equity | $ 610,167 | $ 655,681 |