Vera Therapeutics Announces Expanded Atacicept Development Program In Multiple Autoimmune Kidney Diseases

Oct 2, 2024

- PIONEER study expands the investigation of atacicept into a broad definition of IgA nephropathy and into multiple autoimmune glomerular diseases, supported by the disease-modifying potential of BAFF/APRIL dual inhibition;
- Multiple regulatory and clinical milestones expected over the next 18 months;
- Announcements made at Vera's R&D Day in New York, where the company's management team was joined by academic leaders Jonathan Barratt, Richard Lafayette, and Brad Rovin

BRISBANE, Calif., Oct. 02, 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 announced expansion of its development pipeline for its lead asset, atacicept. This program is expected to build on the positive data reported to date from the ongoing ORIGIN Phase 2b and 3 clinical program developing atacicept to treat patients with IgAN, by extending into a broader population of IgAN and other autoimmune kidney indications.

"Based on the positive clinical data announced over the past year, we have a greater understanding of atacicept's disease-modifying mechanism of action and potential to be a best-in-class treatment option for patients with IgAN. We're committed to providing long-term access to atacicept for all ORIGIN participants, and the PIONEER study will expand that opportunity to a significantly greater number of patients with IgAN," said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. "We believe that B cell modulation through BAFF/APRIL dual inhibition has the potential to transform the treatment landscape for other autoimmune diseases, including autoimmune forms of primary membranous nephropathy, focal segmental glomerulosclerosis, and minimal change disease."

"We view this expansion of our pipeline as highly complementary to our lead program in IgAN. As such, we remain focused on completing the pivotal clinical program for atacicept in IgAN. We look forward to keeping everyone apprised of our progress, as we have a number of significant milestones planned across our pipeline," concluded Dr. Fordyce.

- **ORIGIN Extend** – The company plans to initiate a study in Q4 2024 that will provide ORIGIN participants with extended access to atacicept prior to commercial availability in their region, as well as an opportunity to capture longer-term data.
- **PIONEER Study** – In 2025, the company plans to initiate a study evaluating the efficacy and safety of atacicept in:
    - **Expanded IgAN populations** – The first set of cohorts will include adults with low kidney function (eGFR 20 to <30 mL/min/1.73 m^2), low (UPCR <1.0 g/g) or high proteinuria (UPCR ≥5.0 g/g), or IgAN recurrence after kidney transplant; adolescents at high risk of progression (UPCR ≥0.3 g/g); as well as adolescents and adults with IgA vasculitis nephritis.
    - **Anti-PLA2R and anti-nephrin podocytopathies** – The PIONEER study will expand to additional autoimmune glomerular diseases characterized by the presence of antibodies to glomerular antigens, including primary membranous nephropathy (pMN), focal segmental glomerulosclerosis (FSGS), and minimal change disease (MCD).

These new indications represent a significant potential opportunity for atacicept, with the combined peak prevalence of IgAN and autoimmune-driven PMN, FSGS, and MCD in the US estimated at ~230,000. The company believes atacicept may have therapeutic potential in additional rheumatologic and hematologic indications.

Vera's management team was joined by Jonathan Barratt, MD, PhD, FRCP (University of Leicester), Richard Lafayette, MD, FACP (Stanford University Medical Center), and Brad Rovin, MD, FACP, FASN (Ohio State University Wexner Medical Center). A replay of the event is available on the Investor Calendar of the company's website at https://ir.veratx.com or (click here).

The R&D Day event was held in advance of the anticipated 96-week data from the Phase 2b ORIGIN study of atacicept in IgAN, which will be presented as a late-breaking oral presentation at the American Society of Nephrology Kidney Week 2024.

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.

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 expansion of its development pipeline for atacicept, atacicept's potential to be a best-in-class treatment for patients with IgAN, Vera's expectations regarding the potential for B cell modulation through BAFF/APRIL dual inhibition to transform the treatment landscape for certain autoimmune diseases, Vera's plans to initiate a study in the fourth quarter of 2024 providing extended access to atacicept to ORIGIN participants, Vera's plans to initiate the PIONEER study in 2025, Vera's anticipated presentations of clinical trial data, 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 "expanded," "substantial," 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.

For more information, please contact:

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

Media Contact:
Madelin Hawtin
LifeSci Communications
MHawtin@lifescicomms.com