Vera Therapeutics Partners with University of Michigan on the NEPTUNE Match Project and PIONEER Study

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- Participants with nephrotic syndrome in NEPTUNE Match will receive information about the PIONEER study and other clinical trials based on their individual disease characteristics;
- PIONEER study expands the investigation of atacicept into multiple autoimmune glomerular diseases, supported by the disease-modifying potential of BAFF/APRIL dual inhibition;

BRISBANE, Calif., Nov. 11, 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, is partnering with the University of Michigan on the Nephrotic Syndrome Study Network (NEPTUNE) Match project.

NEPTUNE is a multicenter consortium of more than 30 North American academic centers that conducts clinical and translational research on kidney diseases that present as nephrotic syndrome (NS), including primary membranous nephropathy (pMN), focal segmental glomerulosclerosis (FSGS), and minimal change disease (MCD). Through NEPTUNE Match, participants and their nephrologists receive information about clinical trials targeting mechanisms that match the participant's molecular disease characteristics. This evidence-based approach to selecting clinical trials is aimed at improving treatment response and more successful outcomes across trials.

In partnership with Vera Therapeutics, NEPTUNE Match will inform potential participants about the PIONEER study. PIONEER represents the expansion of the atacicept development program into multiple autoimmune kidney indications based on the presence of antibodies to glomerular antigens. In addition to a broader population of IgAN, the PIONEER study will evaluate the efficacy and safety of atacicept in anti-PLA2R podocytopathies (pMN) and anti-nephrin podocytopathies (FSGS and MCD). NEPTUNE Match will help participants with anti-PLA2R and anti-nephrin antibodies learn about the PIONEER study and support an informed decision about clinical trial participation.

"Based on the positive long-term data from the ORIGIN Phase 2b study presented at ASN Kidney Week, we're excited to offer a clinical trial with atacicept to patients with nephrotic syndrome who have biomarkers that may predict a positive response to B cell modulation," said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. "In addition to providing patients with crucial resources and education about their individual disease biology, NEPTUNE Match will support the enrollment of eligible participants for the PIONEER study. We look forward to announcing initial data from PIONEER in 2025."

"We are thrilled to partner with Vera Therapeutics in NEPTUNE Match. With the new, disruptive insights into pathobiology of NS gleaned in NEPTUNE, we can now target specific antibody-mediated glomerular damage. Testing the efficacy of atacicept among patients identified with active, antibody-mediated disease will truly bring the latest science meaningfully back to our study participants and patients who are in urgent need of new therapies," stated Matthias Kretzler, M.D., Warner Lambert-Parke Davis Professor of Medicine, University of Michigan and principal investigator of NEPTUNE.

About NEPTUNE
The Nephrotic Syndrome Study Network (NEPTUNE) is a multi-site collaborative study that conducts clinical and translational research on FSGS, MCD, and MN that present as NS, pediatric incident NS without a diagnostic kidney biopsy and Alport syndrome. With the NEPTUNE Match precision medicine research platform, NEPTUNE connects patients' individual disease mechanisms to ongoing drug trials to ensure the right patients participate in the right trial at the right time. For more information, visit NEPTUNE-STUDY.org.

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. 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 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.

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, 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 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 "substantial," "will," "may," "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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