Vera Therapeutics Announces TRUTAKNA™ (atacicept-vymj) Stabilized eGFR and Prevented Kidney Disease Progression Through Two Years in ORIGIN 3 Final Efficacy Analysis in IgA Nephropathy

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- *TRUTAKNA, the first and only FDA-approved BAFF and APRIL inhibitor, met all prespecified endpoints, including unprecedented placebo-adjusted estimated glomerular filtration rate (eGFR) and composite kidney disease progression benefits.*
- *Favorable safety profile, and generally comparable to placebo.*
- *Strong commercial launch momentum with over 350 patient start forms generated in the first ten weeks.*
- *Plan to submit supplemental BLA to the U.S. Food and Drug Administration (FDA) for full approval in Q4 2026.*

BRISBANE, Calif., Sept. 15, 2026 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a commercial-stage biotechnology company, today announced that TRUTAKNA met all prespecified endpoints of the final efficacy analysis of the ORIGIN 3 trial in adults with primary IgA nephropathy (IgAN) at risk for disease progression. Topline results from the final analysis set of 428 patients are presented below.

	TRUTAKNA	Placebo	Treatment effect	p-value
Mean eGFR change from baseline at 52 weeks, mL/min/1.73m^2	**-0.1** (95% CI -1.4, 1.2)	**-5.7** (95% CI -7.0, -4.4)	**5.6** (95% CI 3.7, 7.5)	<0.0001
Annualized eGFR slope through 104 weeks, mL/min/1.73m^2/year	**-0.6** (95% CI -1.6, 0.4)	**-5.6** (95% CI -6.6, -4.6)	**5.0** (95% CI 3.6, 6.5)	<0.0001
Composite kidney disease progression event through 104 weeks, n	**11**	**38**	Hazard ratio **0.24** (95% CI 0.12, 0.48) **76%** risk reduction	<0.0001
Dialysis ≥30 days, transplant, or death through 104 weeks, n	**0**	**8**		

These eGFR results align with the KDIGO treatment goal to reduce the rate of kidney function decline to the physiologic rate (<1 mL/min/1.73m^2/year).[1] TRUTAKNA also achieved statistically significant reductions in the hierarchically tested endpoints of proteinuria, galactose-deficient IgA1 (Gd-IgA1), and hematuria. TRUTAKNA was well tolerated with a favorable safety profile generally comparable to placebo, consistent with previous results from the ORIGIN program.[2] Rates of overall adverse events and infections or infestations were similar between the TRUTAKNA and placebo groups, and there were no opportunistic infections or clinically relevant hypogammaglobulinemia. Detailed results from the final efficacy analysis will be shared at an upcoming scientific congress.

“The ORIGIN 3 final analysis, demonstrating a significant reduction in risk of composite kidney disease progression, true stabilization of eGFR, and a favorable safety profile through two years, marks a milestone in IgAN treatment,” said Richard Lafayette, M.D., F.A.C.P., Professor of Medicine, Nephrology and Director of the Glomerular Disease Center at Stanford University Medical Center, and a principal investigator for ORIGIN 3. “Prevention of kidney failure or kidney-related death is the ultimate goal. We now have evidence suggesting that TRUTAKNA may help patients avoid dialysis, transplantation, or kidney-related death over the long term.”

“We believe that upstream inhibition of BAFF and APRIL with TRUTAKNA achieves results that reflect the potential for comprehensive disease modification in IgAN. ORIGIN 3 is the first reported Phase 3 IgAN trial to reach alignment with the FDA on an earlier final efficacy analysis, offering patients randomized to placebo an earlier opportunity to transition to open-label TRUTAKNA. The final results support this alignment and we plan to submit the supplemental BLA in the fourth quarter of this year. We look forward to the potential full approval of TRUTAKNA in 2027,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “We reiterate our gratitude to the patients, investigators, employees, and collaborators who have helped us to deliver a transformative therapy to patients in need.”

“We are excited for the upcoming supplemental BLA submission based on the ORIGIN 3 final analysis. Since receiving

accelerated approval, we have seen significant interest from the IgAN community. In the first ten weeks, we have generated over 350 patient start forms. We are seeing paid claims and are pleased with initial payer policies. The early momentum of the TRUTAKNA launch is very encouraging," said Matt Skelton, Chief Commercial Officer of Vera Therapeutics.

About IgAN

IgAN is a serious, progressive, immune-mediated kidney disease and a leading cause of chronic kidney disease and kidney failure worldwide.[3,4] Approximately 2.5 adults per 100,000 worldwide are diagnosed with IgAN each year, most often between 30 and 40 years of age.[5,6] Over time, IgAN can lead to irreversible kidney damage and may ultimately require dialysis or kidney transplantation. At least 50% of patients may progress to kidney failure or death within 10 to 20 years of diagnosis.[4]

About TRUTAKNA (atacicept-vymj)

TRUTAKNA, a B-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL) inhibitor, is a soluble recombinant fusion protein containing the human transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines BAFF and APRIL.[7] BAFF and APRIL are key cytokines that activate B cells and drive IgAN pathophysiology. In IgAN, activated B cells produce both the antigen and associated antibodies that result in the production of damaging IgA immune complexes. The overlapping roles of BAFF and APRIL in activating B cells support the potential for TRUTAKNA as a disease-modifying therapy.[3] TRUTAKNA is self-administered as an at-home, small-volume (1 ml), 150 mg once-weekly autoinjector.

Indication

TRUTAKNA (atacicept-vymj) is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether TRUTAKNA slows kidney function decline over the long-term in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Important Safety Information

Contraindications: TRUTAKNA is contraindicated in patients with serious hypersensitivity to atacicept-vymj or any excipients of TRUTAKNA.

Warnings and Precautions

Immunosuppression and Increased Risk of Infections: TRUTAKNA suppresses the immune system by reducing antibody production, which may increase the risk of infections. Patients with chronic infection or recurring infections may have an increased risk of serious infection. In clinical trials, infections were reported in 32% of TRUTAKNA patients compared with 28% of placebo patients.

Before initiating TRUTAKNA, assess patients for active infections. Delay TRUTAKNA administration in patients with active infection until the infection resolves or is adequately treated. Monitor patients for signs and symptoms of infection during treatment with TRUTAKNA. If a serious infection develops, consider interrupting TRUTAKNA until the infection is controlled.

The concomitant use of TRUTAKNA and other immune-modulating therapies has not been evaluated. Concomitant use of TRUTAKNA with drugs that affect the immune system, including systemic corticosteroids, may increase the risk of infection.

Immunosuppression and Immunization Risk: TRUTAKNA may interfere with the immune response to vaccines and increase the risk of infection from live vaccines. Prior to initiating treatment with TRUTAKNA, complete all age-appropriate immunizations. Live vaccines are not recommended within 30 days prior to initiation or during treatment with TRUTAKNA as safety of coadministration has not been established.

Adverse Reactions: The most common adverse reactions (≥5%) in patients treated with TRUTAKNA and placebo, respectively, were infections (32% vs 28%) and local administration reactions (30% vs 5%). The most common infection was upper respiratory tract infection (12% vs 9%), and the most common local administration reactions were injection site reaction (19% vs 2%) and injection site erythema (6% vs 1%).

Use in Specific Populations

Pregnancy: Available data on TRUTAKNA used in pregnant women exposed during clinical trials are insufficient to evaluate for a drug-associated risk of major birth defects, miscarriage, or other adverse maternal or fetal outcomes.

Based on the mechanism of action, TRUTAKNA may cause immunosuppression in the in utero-exposed infant. Consider the potential clinical impact of TRUTAKNA exposure in infants exposed in utero. Pregnant women exposed to TRUTAKNA, or their healthcare provider, should report TRUTAKNA exposure by calling 1-833-633-8372.

Pediatric Use: The safety and effectiveness of TRUTAKNA in pediatric patients have not been established.

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Vera Therapeutics at 1-833-MED-VERA or medinfo@veratx.com.

Please see full Prescribing Information for additional Important Safety Information.

TRUTAKNA TRU SUPPORT™ Patient Support Program

We are dedicated to ensuring that eligible IgAN patients can access the first approved therapy that targets both BAFF and APRIL. TRUTAKNA TRU SUPPORT, our patient support program, offers insurance coverage assistance, financial assistance options for eligible patients, and educational resources designed to support patient access and care. Eligible commercially insured patients may pay as little as $0 out of pocket through our copay assistance program. More information will be available on www.veratx.com.

About Vera Therapeutics

Vera Therapeutics is a commercial-stage biotechnology company focused on the pursuit of truth in science to transform medicine in autoimmune disease, starting with the kidney. Vera Therapeutics' flagship commercial product is TRUTAKNA (atacicept-vymj), a BAFF and APRIL inhibitor indicated to reduce proteinuria in adults with primary IgA nephropathy at risk for disease progression. Beyond IgAN, Vera Therapeutics is evaluating additional diseases where the reduction of autoantibodies through inhibition of BAFF and APRIL may prove clinically meaningful. Vera Therapeutics was founded in 2016 and is based in Brisbane, California. To learn more, 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, the ability of TRUTAKNA to stabilize eGFR and prevent kidney disease progression; the strength of Vera Therapeutics' commercial launch momentum for TRUTAKNA; the plan to submit a supplemental BLA to the FDA in the fourth quarter of 2026 for full approval; the timing for the detailed results from the final efficacy analysis to be shared at an upcoming scientific congress; the ability of the ORIGIN 3 final analysis to mark a milestone in IgAN treatment; the ability for the upstream inhibition of BAFF and APRIL with TRUTAKNA to achieve results that reflect comprehensive disease modification in IgAN; the ability of TRUTAKNA to help patients avoid dialysis, transplantation, or kidney-related death over the long term; the potential for the FDA to grant full approval to TRUTAKNA and the timing of such approval; the interest the IgAN community has in TRUTAKNA; the potential success of the TRUTAKNA launch; and the plans, commitments, aspirations and goals under the caption "About Vera Therapeutics". Words such as "anticipate," "believe," "expect," "may," "plan," "potential," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Vera Therapeutics' 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, risks related to commercial launch, market acceptance, and payer coverage, 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 Therapeutics' business in general, the impact of macroeconomic and geopolitical events, and the other risks described in Vera Therapeutics' filings with the U.S. 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 Therapeutics 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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