Vera Therapeutics Receives FDA Accelerated Approval for TRUTAKNA™ for Adult Patients with Primary IgA Nephropathy

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- *TRUTAKNA is the first and only available therapy that binds both B-cell activating factor (BAFF) and A PRoliferation-Inducing Ligand (APRIL), addressing the immunological drivers at the source of IgA nephropathy (IgAN).*[1,2]
- *The TRUTAKNA dose is 150 mg injected subcutaneously once weekly, self-administered via an autoinjector by patients at home.*[1]
- *Investor webcast is scheduled for July 7 at 4:30 pm EDT.*

A Media Snippet accompanying this announcement is available by clicking on this link.

BRISBANE, Calif., July 07, 2026 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a commercial-stage biotechnology company, today announced that the U.S. Food and Drug Administration (FDA) has granted TRUTAKNA (atacicept-vymj) accelerated approval to reduce proteinuria in adults with primary IgAN at risk for disease progression. In a prespecified interim analysis of the ongoing ORIGIN 3 trial, participants treated with TRUTAKNA achieved a 46% reduction from baseline in proteinuria, with a statistically significant and clinically meaningful 42% reduction compared to placebo ($p<0.0001$) at 36 weeks. In this registrational program, TRUTAKNA was generally well tolerated. The most common adverse reactions were infections and local administration reactions.[1]

IgAN is a serious, progressive, immune-mediated kidney disease and a leading cause of chronic kidney disease and kidney failure worldwide.[2,3] Approximately 160,000 patients are estimated to be impacted by IgAN in the U.S. Globally, approximately 2.5 adults per 100,000 are diagnosed with IgAN each year, most often between 30 and 40 years of age.[4,5]

“The approval of TRUTAKNA as the first and only BAFF and APRIL inhibitor for IgAN marks an important milestone and we believe it has the potential to meaningfully transform the treatment landscape. We believe TRUTAKNA offers a novel approach to addressing this serious disease and has the potential to advance care for patients with this significant unmet medical need,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “We are grateful to the patients, investigators, study teams and regulators whose efforts made this achievement possible.”

“I frequently hear from IgAN patients who are uncertain about what this disease may mean for their future, reflecting the historic high risk of poor outcomes with standard therapies,” 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 in the ORIGIN clinical program. “TRUTAKNA offers patients and their nephrologists an exciting new treatment advancement that inhibits both BAFF and APRIL, the two key cytokines that act on B cells, which are at the source of IgAN pathophysiology.”

“We started the IgAN Foundation 22 years ago to create a community and encourage the development of innovative therapies. People and families living with this disease know how urgently we need more treatment options,” said Bonnie Schneider, Director and Co-Founder of the IgAN Foundation. “We value our long-standing relationship with Vera Therapeutics and our shared commitment to making the patient experience central to clinical research. The approval of TRUTAKNA provides great hope for patients and the IgAN community.”

This accelerated approval is 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 the ongoing ORIGIN 3 trial, which continues in a placebo-controlled, blinded manner to evaluate change in kidney function as measured by estimated glomerular filtration rate (eGFR), with results anticipated in Q3 2026.

Investor Webcast on July 7 at 4:30 pm EDT

The investor webcast discussing the accelerated approval of TRUTAKNA will be on July 6 at 4:30 pm EDT. To register for the webcast, click here.

A replay of the webcast will be available on the Investors & Media page of the Company’s website following the event.

Data Supporting Approval

ORIGIN 3 (NCT04716231) is an ongoing global, multicenter, randomized, double-blind, placebo-controlled Phase 3 trial of adults with IgA nephropathy. Participants were randomized 1:1 to TRUTAKNA 150 mg, self-administered at home via once weekly subcutaneous injection, or placebo. The primary efficacy endpoint of the prespecified 36-week interim analysis was the change in 24-hour urine-protein-to-creatinine-ratio (UPCR) compared to placebo in the first 203 participants who had received at least 1 dose of TRUTAKNA or placebo. Participants treated with TRUTAKNA achieved a 46% reduction from baseline in UPCR, with a statistically significant and clinically meaningful 42% reduction compared to placebo ($p<0.0001$) at 36 weeks. Proteinuria efficacy was consistent across prespecified subgroups of age, sex, race, region, baseline proteinuria, baseline eGFR, and baseline SGLT2i use. Participants who received TRUTAKNA also experienced a 68% reduction in galactose-deficient IgA1 (Gd-IgA1), a secondary endpoint with observational results due to the absence of multiplicity adjustment.[1]

In ORIGIN 3, the safety of TRUTAKNA was assessed in 428 patients who had received at least 1 dose of TRUTAKNA or placebo. TRUTAKNA was generally well tolerated. 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%).[1] No serious, severe or opportunistic infections, or hypogammaglobulinemia, were observed in TRUTAKNA-treated patients.[6] Most adverse reactions observed in the TRUTAKNA group were mild or moderate in severity and resolved without treatment interruption or discontinuation. There were no clinically significant effects of anti-drug antibodies on the pharmacokinetics, pharmacodynamics, safety or effectiveness of TRUTAKNA over the 36-week treatment period.[1] Please see below for Important Safety Information.

About IgAN

IgAN is a serious, progressive, immune-mediated kidney disease and a leading cause of chronic kidney disease and kidney failure worldwide.[2,3] Approximately 2.5 adults per 100,000 worldwide are diagnosed with IgAN each year, most often between 30 and 40 years of age.[4,5] 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.[3] Current clinical guidelines recommend reducing the rate of kidney function decline to the physiological state (<1 mL/min/year for most adults) as a central treatment goal in IgAN, and proteinuria reduction is recognized as a surrogate marker of reduced risk of kidney function decline.[7]

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 TRUTAKNA (atacicept-vymj) injection

TRUTAKNA, a BAFF and 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.[1] These cytokines activate B cells to produce the autoantigen Gd-IgA1 and its autoantibodies, forming immune complexes that deposit in the kidneys and cause inflammation and progressive damage.[2] TRUTAKNA is a self-administered autoinjector dosed 150 mg once weekly.[1]

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.

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 number of patients impacted by IgAN in the U.S. and globally; the potential for continued approval of atacicept in IgAN; the potential for TRUTAKNA to meaningfully transform the treatment landscape; the ability of TRUTAKNA to offer a novel approach to addressing IgAN and its potential to advance care for IgAN patients; the potential for TRUTAKNA to provide hope for patients and the IgAN community; the expected results and timing of the results of the ORIGIN 3 eGFR analysis; 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, 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.

References

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For more information, please contact:

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

Media Contact:
Debra Charlesworth
Vera Therapeutics
415-854-8051
corporatecommunications@veratx.com