UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 26, 2024

Vera Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40407**	**81-2744449**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

8000 Marina Boulevard, Suite 120 **Brisbane, California**	**94005**
(Address of principal executive offices)	**(Zip Code)**

(650) 770-0077
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Class A common stock, $0.001 par value per share	VERA	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On October 28, 2024, Vera Therapeutics, Inc. (the "Company") announced that its preliminary unaudited cash, cash equivalents and marketable securities as of September 30, 2024 were approximately $353.2 million.

The Company has not yet completed its quarter-end financial close process for the quarter ended September 30, 2024. This estimate of the Company's cash, cash equivalents and marketable securities as of September 30, 2024 is preliminary, has not been audited and is subject to change upon completion of the Company's financial statement closing procedures. Additional information and disclosure would be required for a more complete understanding of the Company's financial position and results of operations as of September 30, 2024. The Company's independent registered public accounting firm has not audited, reviewed or performed any procedures with respect to this preliminary result and, accordingly, does not express an opinion or any other form of assurance about it. The information presented herein should not be considered a substitute for the financial information the Company files with the U.S. Securities and Exchange Commission ("SEC") in its quarterly report on Form 10-Q for the quarter ended September 30, 2024. The Company has no intention or obligation to update preliminary estimates of its cash, cash equivalents and marketable securities set forth above.

The information contained in this Current Report on Form 8-K under Item 2.02 is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and will not be incorporated by reference into any filing by the Company under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, unless specifically identified as being incorporated therein by reference.

Item 7.01 Regulation FD Disclosure.

On October 26, 2024, the Company announced positive 96-week data from the Company's Phase 2b ORIGIN clinical trial of atacicept in patients with immunoglobulin A nephropathy ("IgAN"). A copy of the press release is furnished as Exhibit 99.1. In connection with the data release, the Company compiled a presentation entitled "Virtual Investor Event to Discuss Long-Term Results from the Phase 2b ORIGIN Study of Atacicept in IgAN Presented at ASN Kidney Week 2024" (the "Presentation") that includes the week 96 data from the Phase 2b ORIGIN clinical trial referenced above. A copy of the Presentation is furnished as Exhibit 99.2. For important information about forward-looking statements, see the slide titled "Forward-Looking Statements" in Exhibit 99.2 attached hereto.

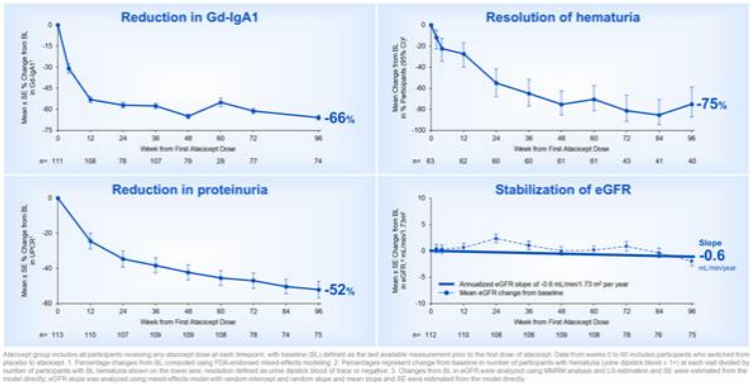
The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibits 99.1 and 99.2, shall not be deemed "filed" for purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act. The information contained in this Item 7.01, including Exhibits 99.1 and 99.2, shall not be incorporated by reference into any filing with the SEC made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 8.01 Other Events.

As noted in Item 7.01, on October 26, 2024, the Company announced positive 96-week data from the Company's Phase 2b ORIGIN clinical trial of atacicept in patients with IgAN. Atacicept is the Company's potential best-in-class, disease-modifying dual inhibitor of the cytokines B-cell activating factor and a proliferation-inducing ligand. ORIGIN is a multinational, randomized, double-blind, placebo-controlled clinical trial (n=116) evaluating the efficacy and safety of atacicept in patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite available ACE or ARB therapy.

Over 96 weeks, participants treated with atacicept demonstrated a -66% reduction in galactose-deficient IgA1 ("Gd-IgA1"), resolution of hematuria in 75% of participants, a -52% reduction in proteinuria, and a mean annualized estimated glomerular filtration rate ("eGFR") slope of -0.6 mL/min/1.73m^2/year. The cumulative generally favorable safety profile of atacicept remained consistent with that observed during the randomized period, with a 90% completion rate of atacicept treatment.

Phase 2b ORIGIN long-term 96-week results with atacicept was consistent with disease-modifying IgAN profile



The Company believes these data support the potential for atacicept to offer long-term, comprehensive IgAN disease modification and provide further confidence in the ongoing pivotal Phase 3 ORIGIN 3 trial of atacicept in IgAN.

Next Steps

The Company is continuing to advance the ongoing pivotal Phase 3 ORIGIN 3 clinical trial of atacicept 150 mg, with topline results expected in the second quarter of 2025. If such results are positive, the Company expects to submit a biologics license application ("BLA") for atacicept in IgAN to the U.S. Food and Drug Administration in the second half of 2025, with a projected commercial launch, if approved, in 2026.

Forward-Looking Statements

Statements contained in this Current Report on Form 8-K 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, estimates regarding the Company's preliminary unaudited cash, cash equivalents and marketable securities as of September 30, 2024, the Company'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, the Company's expectations regarding the potential for B cell modulation through BAFF/APRIL dual inhibition to transform the treatment landscape for certain autoimmune diseases, the Company's anticipated presentations of clinical trial data, the Company's product candidates, strategy and regulatory matters and the Company's expectations regarding submitting a BLA for atacicept in IgAN and projected commercial launch. 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 "believes," "expects," "plan," "potential," "will," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon the Company'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 the Company's business in general, the impact of macroeconomic and geopolitical events and the other risks described in the Company's filings with the SEC. All forward-looking statements contained in this Current Report on Form 8-K speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. The Company 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.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Press Release of Vera Therapeutics, Inc., dated October 26, 2024.
99.2	Slide presentation entitled "Virtual Investor Event to Discuss Long-Term Results from the Phase 2b ORIGIN Study of Atacicept in IgAN Presented at ASN Kidney Week 2024".
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Vera Therapeutics, Inc.

Dated: October 28, 2024

By: /s/ Marshall Fordyce, M.D.
Marshall Fordyce, M.D.
Chief Executive Officer

Vera Therapeutics Announces 96-week eGFR Stabilization in ORIGIN Phase 2b Study of Atacicept in IgAN in a Late-Breaking Oral Presentation at the American Society of Nephrology Kidney Week 2024

- Long-term improvements observed in the quartet of findings defining disease modification supports atacicept's potential to prevent kidney failure in patients with IgAN;
- Long-term results from the ORIGIN Phase 2b study were simultaneously published in the *Journal of the American Society of Nephrology;*
- Company will host an investor call and webcast on Monday October 28 at 8:00 AM ET

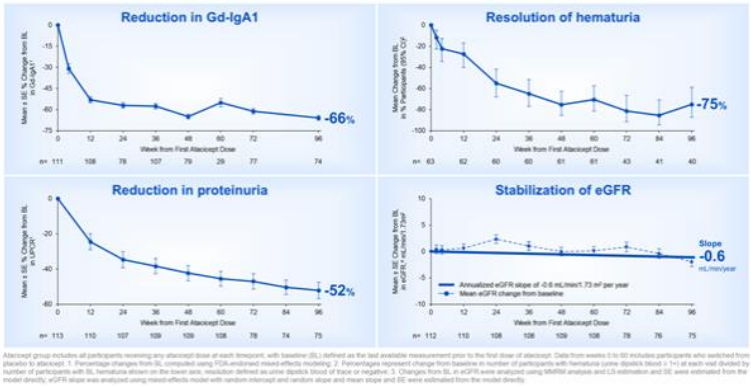
BRISBANE, Calif., October 26, 2024 (GLOBE NEWSWIRE) — Vera Therapeutics, Inc. (Nasdaq: VERA), a late clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today announced data from its ORIGIN Phase 2b trial of atacicept in immunoglobulin A nephropathy (IgAN) that show stabilized kidney function through 96 weeks of long-term follow-up. These data were presented in a late-breaking oral presentation at the American Society of Nephrology Kidney Week 2024 in San Diego, California, and simultaneously published in a manuscript in the *Journal of the American Society of Nephrology*.

"The 96-week results from the ORIGIN Phase 2b study demonstrated sustained and substantial reductions in Gd-IgA1, hematuria and proteinuria as measured by UPCR with long-term stabilization of eGFR," said Jonathan Barratt, MD, PhD, FRCP, Mayer Professor of Renal Medicine at the University of Leicester. "Converting patients with IgAN from an eGFR profile of unrelenting decline to a profile consistent with the general population without kidney disease is a differentiated and compelling finding. Collectively, the data support the potential of atacicept to modify the natural history of the disease and prevent kidney failure during the lifetime of patients with IgAN."

"We are excited to present these long-term efficacy and safety data from the ORIGIN Phase 2b study, which further demonstrate atacicept's potential to address the underlying pathogenesis of IgAN. The stabilization of kidney function through two years—the longest duration of data among B cell modulators to date—positions atacicept as a potential best- and first-in-class treatment option for patients with IgAN," said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. "We look forward to announcing expected topline results from the Phase 3 ORIGIN 3 trial in Q2 2025, with planned BLA submission to the U.S. FDA later in the year."

Over 96 weeks, participants treated with atacicept demonstrated a -66% reduction in galactose-deficient IgA1 (Gd-IgA1), resolution of hematuria in 75% of participants, a -52% reduction in proteinuria, and a mean annualized estimated glomerular filtration rate (eGFR) slope of -0.6 mL/min/1.73m^2/year. The cumulative generally favorable safety profile of atacicept remained consistent with that observed during the randomized period, with a 90% completion rate of atacicept treatment.

Figure 1. ORIGIN Phase 2b long-term 96-week results with atacicept was consistent with disease-modifying IgAN profile



The Company believes these data support the potential for atacicept to offer long-term, comprehensive IgAN disease modification and provide further confidence in the ongoing pivotal Phase 3 ORIGIN 3 trial of atacicept in IgAN.

The Company will host an investor call and webcast to discuss the data update on Monday, October 28, at 8:00 AM ET. The live webcast will be available on the Company's Investor Calendar at https://ir.veratx.com/news-events/investor-calendar, with the recording and presentation available immediately following the event.

The Kidney Week 2024 presentation and posters are available on the Company's website at https://ir.veratx.com/news-events/presentations.

Upcoming milestones:

- ORIGIN Extend – plan 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.
- Pivotal ORIGIN 3 trial on track to announce topline results in Q2 2025, with planned BLA submission to the U.S. FDA later in the year
- PIONEER Study – plan to initiate a study in 2025 that will evaluate 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, focal segmental glomerulosclerosis, and minimal change disease.

About the Phase 2b ORIGIN clinical trial

The Phase 2b ORIGIN clinical trial (NCT04716231) is a global, multicenter, randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of atacicept in 116 patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of a renin-angiotensin-aldosterone system inhibitor for at least 12 weeks that is the maximum labeled or tolerated dose. The Phase 2b ORIGIN clinical trial evaluated three dose strengths of atacicept versus placebo, administered weekly by prefilled syringe. Patients were randomized 2:2:1:2 to atacicept 150 mg, atacicept 75 mg, atacicept 25 mg or matching placebo. Upon completion of the 36-week blinded treatment period, all patients were offered open-label atacicept 150 mg for an additional 60 weeks.

The primary endpoint was the change in proteinuria as evaluated by urine protein to creatinine ratio (UPCR) at week 24, and the key secondary endpoint was the change in proteinuria as evaluated by UPCR at week 36. Additional exploratory endpoints include change in proteinuria as evaluated by UPCR at weeks 12, 48, and 96; change in eGFR; change in serum immunoglobulin levels, and change in serum Gd-IgA1 levels; safety and tolerability; and serum pharmacokinetics.

The trial met its primary and key secondary endpoints, with statistically significant and clinically meaningful proteinuria reductions and stabilization of eGFR versus placebo through week 36. The safety profile was comparable between atacicept and placebo.

For more information about the Phase 2b ORIGIN clinical trial, please visit www.clinicaltrials.gov.

About the Phase 3 ORIGIN 3 clinical trial

The ORIGIN 3 clinical trial (NCT04716231) is a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 trial evaluating the safety and efficacy of atacicept in patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of renin-angiotensin system inhibitors for at least 12 weeks that is the maximum labeled or tolerated dose. The objectives of the trial are to determine the effect of atacicept on proteinuria and preservation of kidney function compared to placebo.

For more information about the ORIGIN 3 clinical trial, please visit http://www.clinicaltrials.gov.

About Atacicept

Atacicept is an investigational recombinant fusion protein that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor 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.

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 BAFF and 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 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.

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 the ORIGIN Extend 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, including the announcement of topline results from the Phase 3 ORIGIN 3 trial in the second quarter of 2025, Vera's plans for a BLA filing for atacicept in 2025 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 "believes," "expects," "plan," "potential," "will," 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:

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LifeSci Communications
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Exhibit 99.2

vera therapeutics™

Virtual Investor Event to Discuss Long-Term Results from the Phase 2b ORIGIN Study of Atacicept in IgAN Presented at ASN Kidney Week 2024

October 28, 2024

Forward-looking statements

Disclaimer

This material has been made available to you with the consent of Vera Therapeutics, Inc. ("we", "us", "our", or the "Company"). Statements contained in this presentation 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, atacicept's potential to be a transformational treatment for patients with IgAN and a best-in-class and first-in-class therapy, the Company's expectations regarding completing the pivotal Phase 3 ORIGIN 3 trial and initiating a Phase 2 extension study in participants who complete the Phase 2b or Phase 3 ORIGIN trials, atacicept's potential to be a transformational treatment for additional patient cohorts beyond those with IgAN, the Company's expectations regarding initiating clinical trials of atacicept for additional indications, the design and management of the Company's clinical trials, expectations regarding reporting results from such clinical trials and regulatory matters, including the timing and likelihood of success in obtaining drug approvals and atacicept's projected launch. Words such as “anticipate,” “plan,” “expect,” “will,” “may,” “potential” and similar expressions are intended to identify forward-looking statements, though not all forward-looking statements necessarily contain these identifying words. These forward-looking statements are based on the beliefs of the Company’s management as well as assumptions made by and information currently available to the Company. Such statements reflect the current views of the Company with respect to future events and are subject to known and unknown risks, including business, regulatory, economic and competitive risks, uncertainties, contingencies and assumptions about the Company, including, without limitation, risks related to the regulatory approval process, the potential that results of earlier clinical trials may not be obtained in later clinical trials, risks and uncertainties associated with the Company's business in general, the impact of macroeconomic and geopolitical events, including the COVID-19 pandemic, and the other risks described in the Company's filings with the Securities and Exchange Commission. In light of these risks and uncertainties, the events or circumstances referred to in the forward-looking statements may not occur. The actual results may vary from the anticipated results and the variations may be material. These forward-looking statements should not be taken as forecasts or promises nor should they be taken as implying any indication, assurance or guarantee that the assumptions on which such forward-looking statements have been made are correct or exhaustive or, in the case of the assumptions, fully stated in this presentation. You are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this presentation, and are based on management's assumptions and estimates as of such date. The Company 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.

Certain data in this presentation are based on cross-study comparisons and are not based on any head-to-head clinical trials. Cross-study comparisons are inherently limited and may suggest misleading similarities or differences.

This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates are being studied.

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

Atacicept potentially *best* and *first-in-class* dual BAFF/APRIL B cell modulator in IgAN, with pipeline-in-a-product opportunity

IgAN Potential Best-in-Class

- eGFR normalization may suggest functional cure
- Only program with 2-yr data in Phase 2 → potential for commercial differentiation, if approved
- Only investigational drug with at home self administration of 1 mL QW and 90% patient retention at 2 yr
- Phase 3 read out on track for Q2 2025; if successful, anticipated PDUFA 2026

Indication Expansion

- B cell modulation represents a treatment paradigm shift for autoimmune diseases
- Atacicept clinical data to date supports potential for chronic administration
- Progressive expansion in addressable patients: initial autoimmune kidney disease opportunity >200K
- Additional potential upside in hematologic, rheumatologic, and other kidney indications

Resourced for Potential Launch

- Regulatory exclusivity expected through 2038 in US and 2037 in EU
- Currently ~$384M cash, cash equivalents and marketable securities as of June 30, 2024
- Management focused on potential for successful commercial launch

BAFF = B cell activating factor; APRIL = A proliferation inducing ligand; eGFR = estimated glomerular filtration rate; IgAN = immunoglobulin A nephropathy; PDUFA = Prescription Drug User Fee Act; QW = once weekly; SC = subcutaneous.

Strong financial position

~$384M

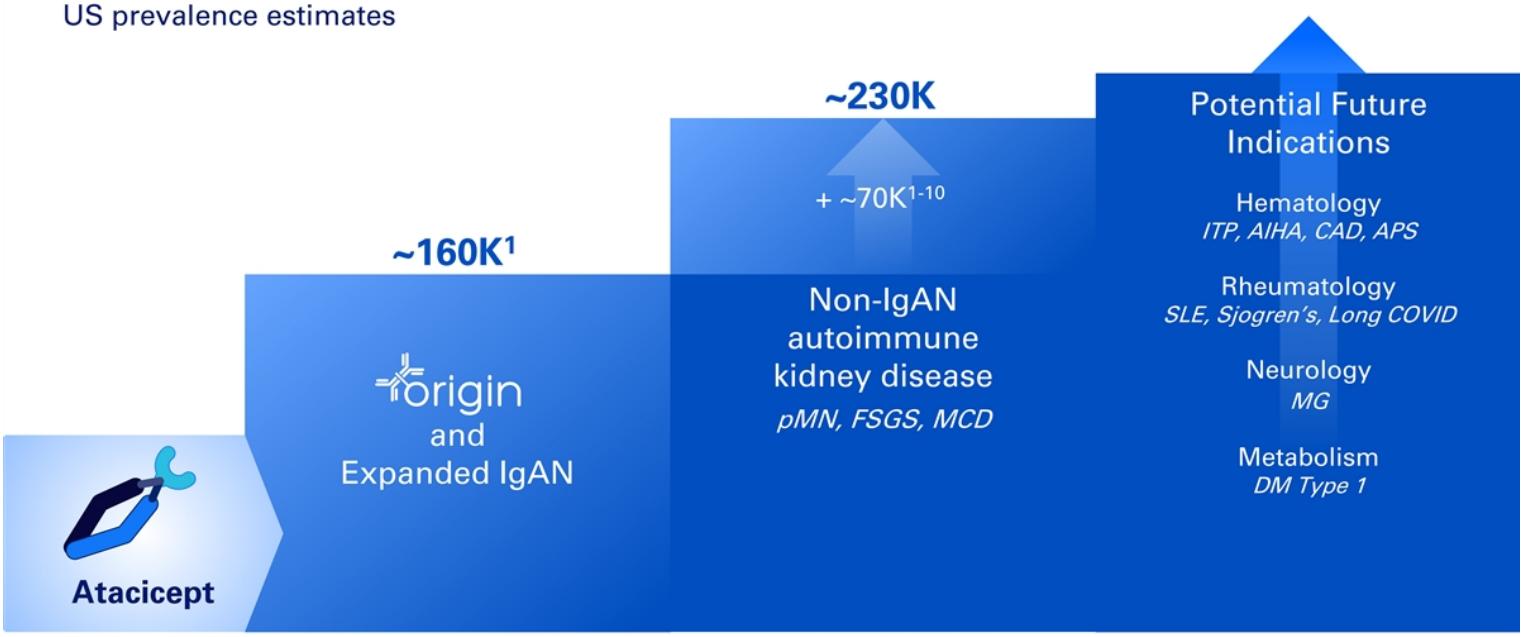
Cash, cash equivalents, and marketable securities
(as of 6.30.24)

~54.8M

Shares outstanding
(as of 8.5.24)

Vera optionality to expand in autoimmune kidney disease & beyond

US prevalence estimates



Vera Therapeutics corporate estimates for peak year prevalence based on 1. ClearView Healthcare Partners Analysis; 2. US Census 2023; 3. McGrogan A. Nephrol Dial Transplant 2011; 4. Couser ASN 2017; 5. Beck LH. N Engl J Med 2009; 6. Filler G. Am J Kidney Dis 2003; 7. Troyanov S. J Am Soc Nephrol 2005. 8. Hommos MS. Mayo Clin Proc 2017; 9. Hengel FE. N Engl J Med 2024; 10. Vivarelli M. Clin J Am Soc Nephrol 2017.
pMN = primary membranous nephropathy; FSGS = focal segmental glomerulosclerosis; MCD = minimal change disease; ITP = immune thrombocytopenia; AIHA = autoimmune hemolytic anemia; CAD = cold agglutinin disease; APS = antiphospholipid syndrome; SLE = systemic lupus erythematosus; COVID = Coronavirus disease 2019; MG = myasthenia gravis; DM = diabetes mellitus.

Atacicept projected catalysts

	Catalyst	2024	2025	2026
origin (IgAN)	Phase 3 primary endpoint cohort full enrollment	✓ 3Q		
	Phase 2b 96-week results	✓ 4Q		
	Phase 3 top-line results		2Q	
	BLA submission		2H	
	Projected US launch[1]			
origin extend (IgAN)	Initiation			
	Initial data available			
pioneer (IgAN, PMN, FSGS, MCD)	Initiation			
	Initial data available			

Vera holds worldwide, exclusive rights to develop and commercialize atacicept

Based on management's current assumptions. 1. Subject to US approval.

Long-term Results From the ORIGIN Phase 2b Study of Atacicept for the Treatment of IgAN

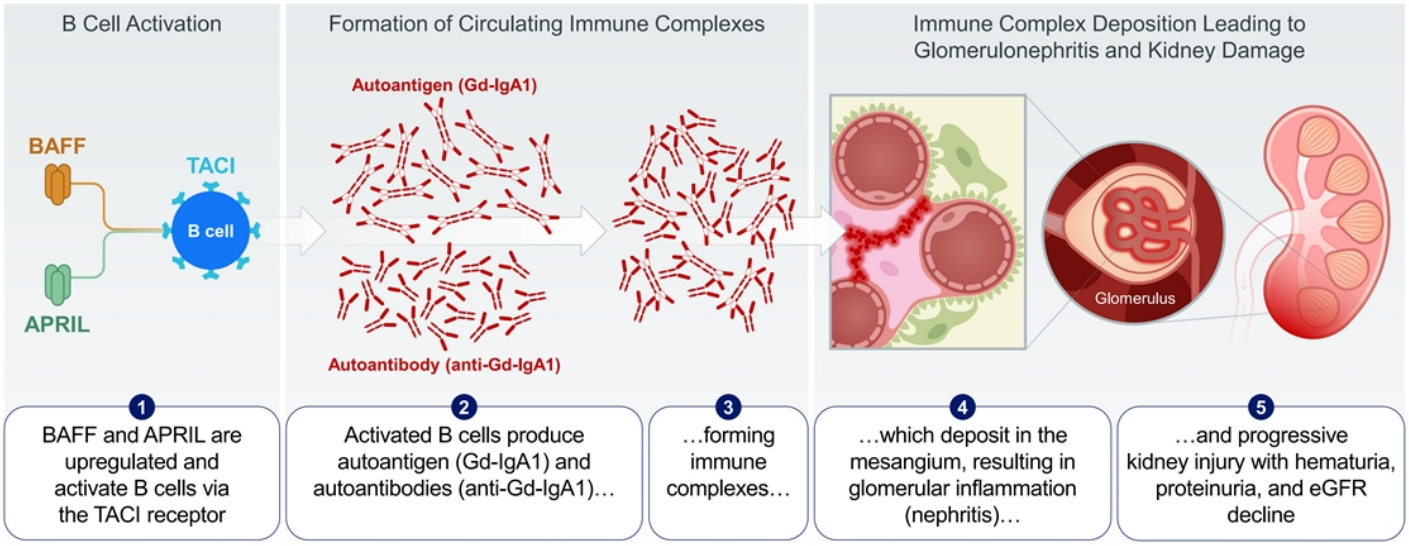
Jonathan Barratt,[1] Sean Barbour,[2] Robert Brenner,[3] Kerry Cooper,[3] Xuelian Wei,[3] Necmi Eren,[4] Jürgen Floege,[5] Vivekanand Jha,[6] Sung Gyun Kim,[7] Bart Maes,[8] Richard Phoon,[9] Harmeet Singh,[10] Vladimir Tesar,[11] Richard Lafayette[12]

[1]University of Leicester, Leicester, UK; [2]The University of British Columbia, Vancouver, BC, Canada; [3]Vera Therapeutics, Inc., Brisbane, CA, USA; [4]Kocaeli Universitesi, Kocaeli, Turkey; [5]Rheinisch-Westfälische Technische Hochschule Aachen, Aachen, Nordrhein-Westfalen, Germany; [6]The George Institute for Global Health India, New Delhi, Delhi, India; [7]Hallym University Sacred Heart Hospital, Anyang, Gyeonggi-do, Korea; [8]AZ Delta vzw, Roeselare, West-Vlaanderen, Belgium; [9]The University of Sydney, Sydney, NSW, Australia; [10]Western Nephrology, Arvada, CO, USA; [11]Univerzita Karlova, Praha, Czechia; [12]Stanford University, Stanford, CA, USA; on behalf of the ORIGIN Phase 2b Investigators

Abstract SA-OR102
October 26, 2024

KIDNEY WEEK 2024

IgAN is a B-cell mediated disease with kidney pathology

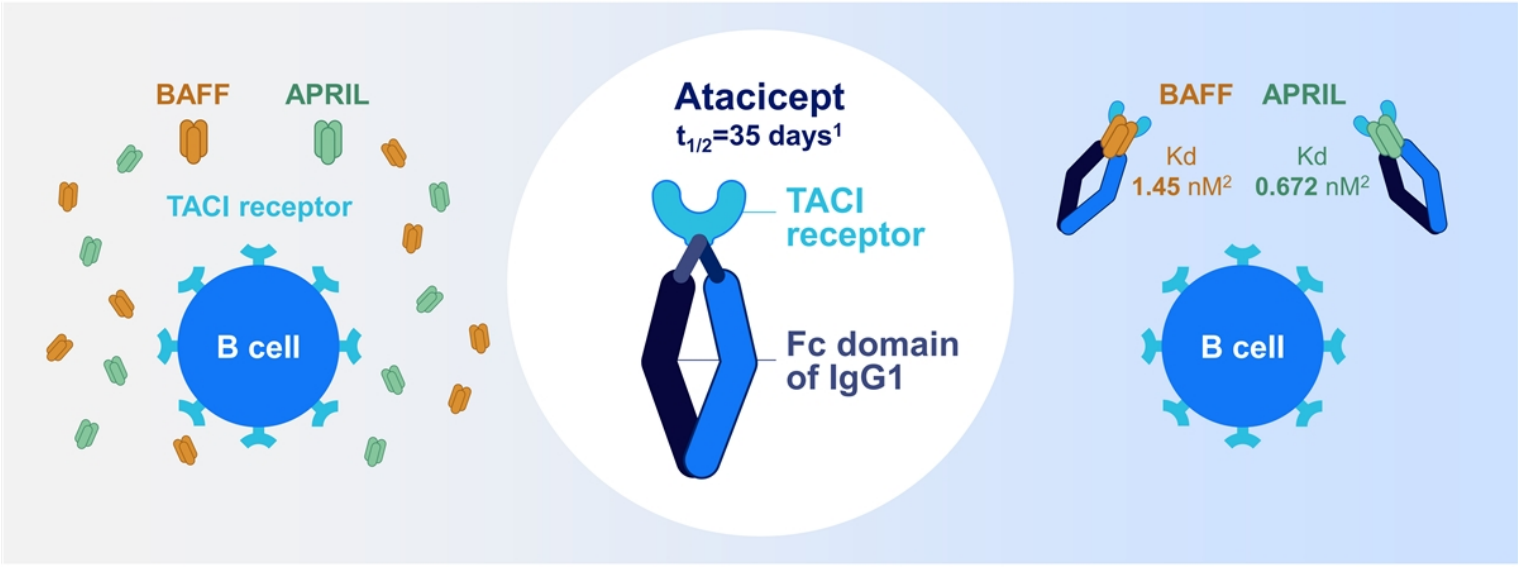


APRIL = a proliferation-inducing ligand; BAFF = B-cell activating factor; eGFR = estimated glomerular filtration rate; Gd-IgA1 = galactose-deficient immunoglobulin A1; IgAN = immunoglobulin A nephropathy; TACI = transmembrane activator and calcium-modulator and cyclophilin ligand interactor.

Cheung CK, et al. Front Nephrol. 2024;3:1346769.

Atacicept is a dual inhibitor of BAFF and APRIL

Rational drug design: native TACI receptor fused to Fc — fully humanized soluble fusion protein

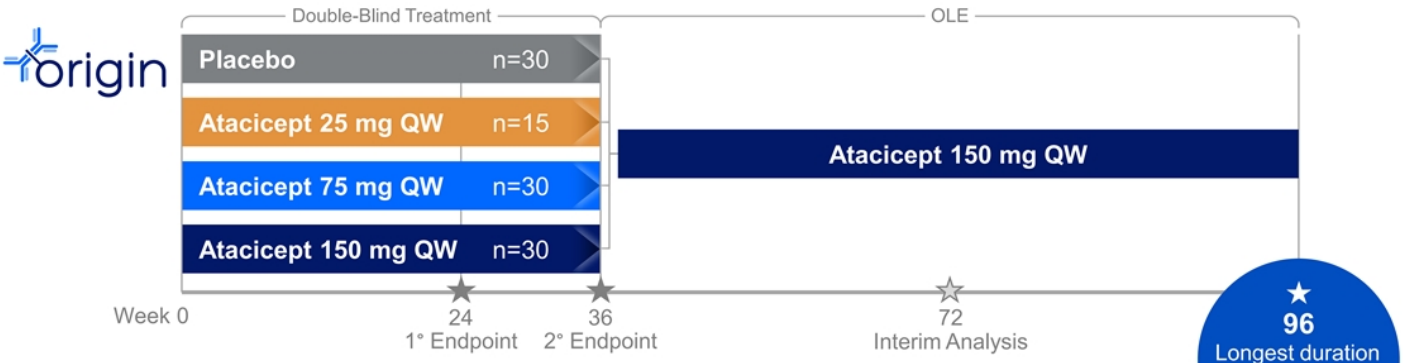


Fc = fragment crystallizable region; IgG1 = immunoglobulin G1; Kd = dissociation constant; $t_{1/2}$ = half-life.

1. Willen D, et al. Eur J Drug Metab Pharmacokinet. 2020;45(1):27-40; 2. Vera data on file.

ORIGIN Phase 2b IgAN trial: Study design and objectives

Multinational, randomized, placebo-controlled trial of atacicept self-administered at home via weekly 1-mL SC injection



Inclusion Criteria

- Participants ≥18 years old with biopsy-proven IgAN and high risk of disease progression
- UPCR-24h >0.75 g/g or UP >0.75 g per 24h
- eGFR ≥30 mL/min/1.73 m^2
- Stable and optimized RAASi for ≥12 weeks
- Use of SGLT2i allowed
- Blood pressure ≤150/90 mmHg

Endpoints

- Primary efficacy: UPCR-24h at week 24★
- Key secondary: UPCR-24h at week 36★
- eGFR change up to week 96☆
- Gd-IgA1 change
- Hematuria change
- Safety

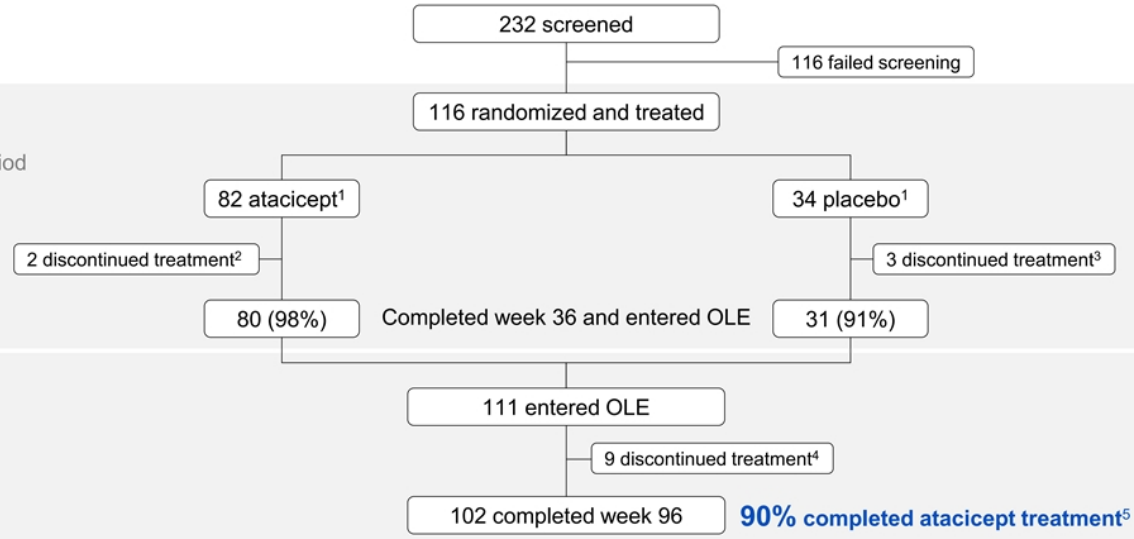
OLE = open-label extension; QW = once-weekly; RAASi = renin-angiotensin-aldosterone system inhibitors; SC = subcutaneous; SGLT2i, sodium-glucose cotransporter-2 inhibitor; UP(CR) = urine protein (to creatinine ratio).

Demographics and baseline characteristics[1]

	Atacicept treated participants[2] n=113
Age, median (range), y	37 (18, 67)
Male sex, n (%)	67 (59)
Race, n (%)	
White	59 (52)
Asian	51 (45)
Native Hawaiian or Other Pacific Islander	1 (1)
Other/not reported	2 (2)
eGFR, mean ± SD, mL/min/1.73 m^2	62 ± 28
UPCR by 24h urine, mean ± SD, g/g	1.8 ± 1.3

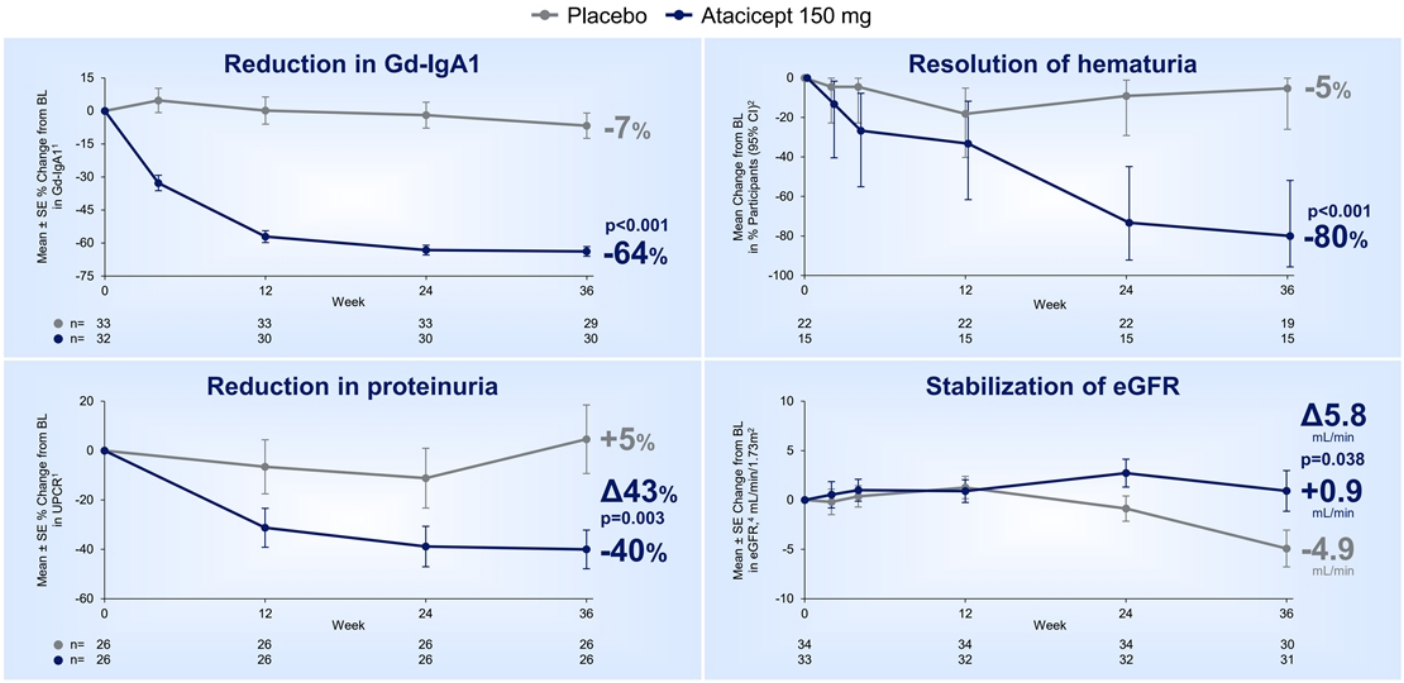
SD = standard deviation.
1. Baseline is defined as the last available measurement prior to the first dose of atacicept.
2. Atacicept group includes all participants receiving any atacicept dose at any timepoint.

Participant disposition through 96 weeks



1. Full analysis set and safety population
2. Discontinued to pursue elective surgery (n=1) and discontinued due to positive hepatitis B DNA and adverse event (n=1).
3. Initiated prohibited medication for concomitant disease (n=1), discontinued due to plan to start prohibited medication for concomitant disease (n=1) and adverse event (n=1).
4. Discontinued due to investigator decision (n=1), pregnancy (n=2), participant withdrawal (n=2), surgery (n=1), serious adverse event of pneumonia in a heavy smoker, resolved (n=1), adverse event of worsening alanine aminotransferase and aspartate aminotransferase (n=1), and medical monitor criteria (n=1).
5. 90% = 102/113 (out of the 116 randomized and treated participants, 3 discontinued placebo prior to week 36).

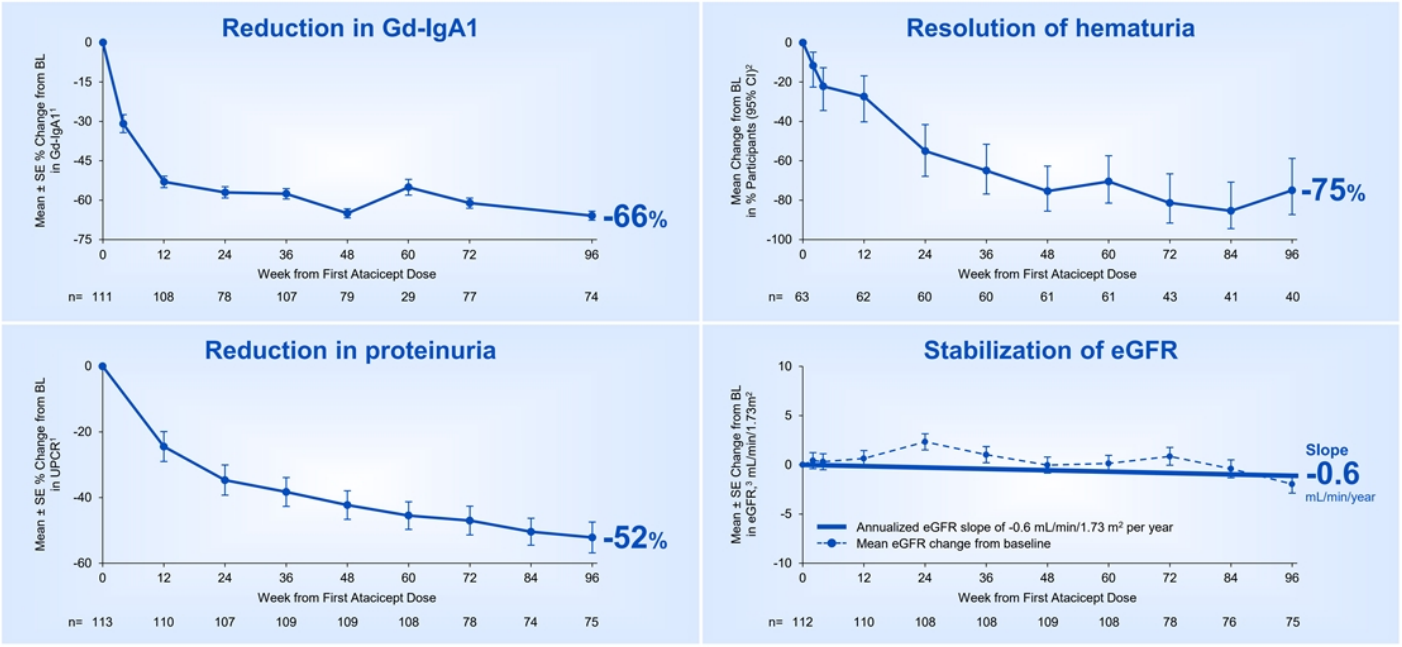
ORIGIN Phase 2b 36-week results consistent with disease modifying IgAN profile



1. p-values, percentage changes from baseline, and treatment differences were computed using FDA-endorsed mixed-effects modeling; 2. Percentages represent change from baseline in number of participants with hematuria (urine dipstick blood ≥ 1+) at each visit divided by number of participants with BL hematuria shown on the lower axis; resolution defined as urine dipstick blood of trace or negative; 3. Changes from BL in eGFR were analyzed using mixed-model repeated measures (MMRM) analysis and geometric least squares (LS) means, ratio of geometric LS means, and standard errors (SE), were transformed back into the original scale from model estimates. Lafayette R, et al. Kidney Int. 2024;S0085-2538(24)00236-9.

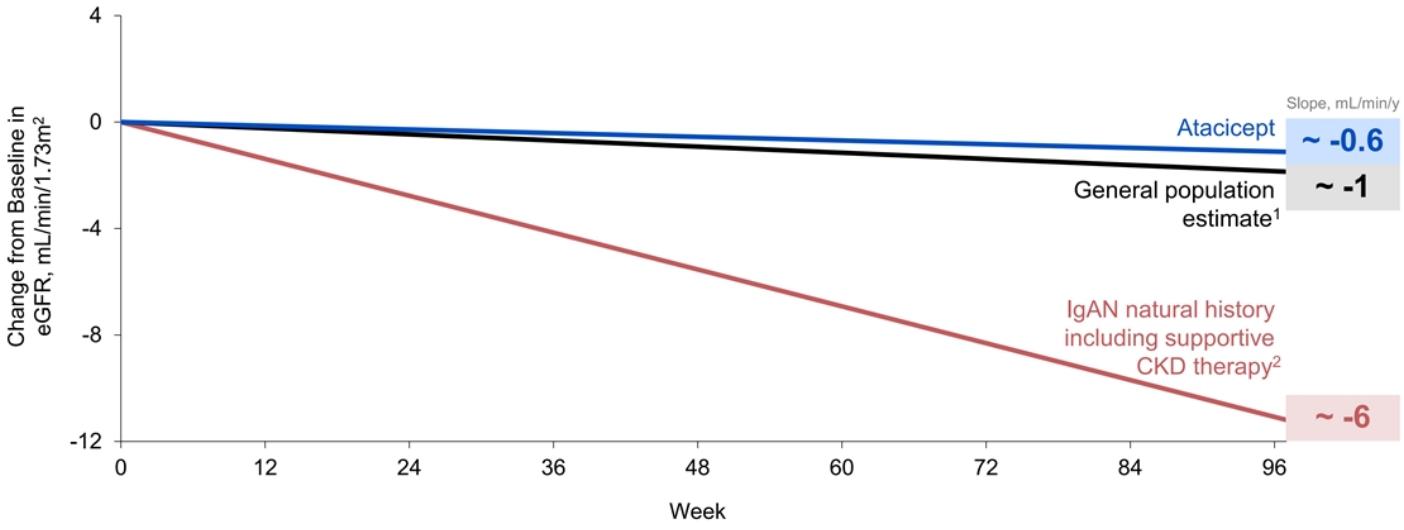
ORIGIN Phase 2b long-term results consistent with disease modifying IgAN profile

Data from first dose of atacicept through 96 weeks



Atacicept group includes all participants receiving any atacicept dose at each timepoint, with baseline (BL) defined as the last available measurement prior to the first dose of atacicept. Data from weeks 0 to 60 includes participants who switched from placebo to atacicept. 1. Percentage changes from BL computed using FDA-endorsed mixed-effects modeling; 2. Percentages represent change from baseline in number of participants with hematuria (urine dipstick blood ≥ 1+) at each visit divided by number of participants with BL hematuria shown on the lower axis; resolution defined as urine dipstick blood of trace or negative; 3. Changes from BL in eGFR were analyzed using MMRM analysis and LS estimation and SE were estimated from the model directly; eGFR slope was analyzed using mixed-effects model with random intercept and random slope and mean slope and SE were estimated from the model directly.

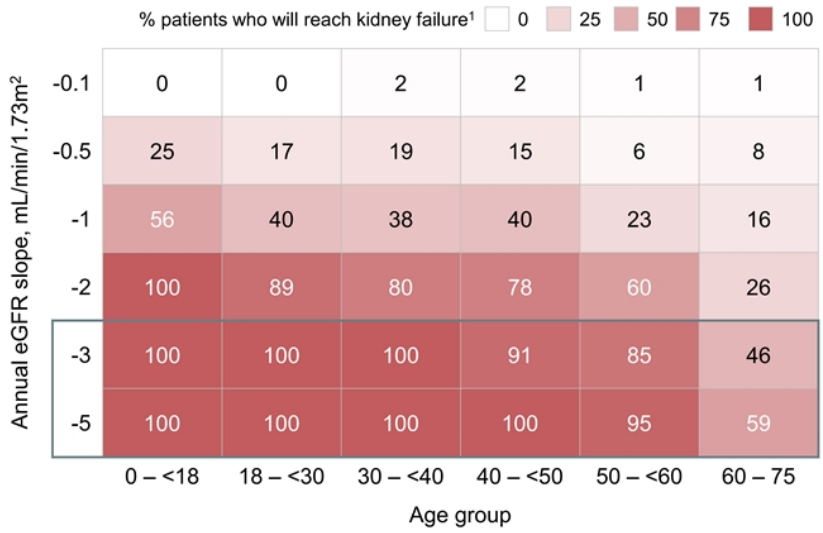
Atacicept treated participants have an eGFR slope profile consistent with the *general population without kidney disease*



This data is based on a cross-trial comparison and not a head-to-head clinical trial; such data may not be directly comparable due to differences in study protocols, conditions and patient populations.
Projected eGFR trajectories for general population and IgAN natural history do not represent clinical data and assume a constant eGFR slope over time. CKD = chronic kidney disease.

1. Slope estimate from Baba M, et al. PLOS ONE 2015; 2. Average historical placebo slope from 7 clinical trials3-11; 3. Lafayette R, et al. Lancet 2023; 4. Rovin BH, et al. Lancet 2023; 5. Li PK-T, et al. Am J Kidney Dis 2006; 6. Manno C, et al. Nephrol Dial Transplant 2009; 7. Lv J, et al. JAMA 2017; 8. Wheeler DC, et al. Kidney Int 2021; 9. Lv J, et al. JAMA 2022; 10. Zhang H, et al. ASN Kidney Week 2023, poster TH-PO1123; 11. Mathur M, et al. N Engl J Med 2023.

2024 Draft KDIGO IgAN guidelines call for target eGFR slope ≤ -1 mL/min/year



Endothelin receptor antagonist[2] ~ **-3**

SGLT2i[3], corticosteroid[4] ~ **-4**

Supportive CKD therapy[5] ~ **-6**

1. Adapted from Pitcher D, et al. CJASN 2023. eGFR slope data from approved therapies: 2. Rovin BH, et al. Lancet 2023; 3. Wheeler DC, et al. Kidney Int 2021; 4. Lafayette R, et al. Lancet 2023; 5. Average historical placebo (including chronic kidney disease standard of care) data from 7 clinical trials: Li PK-T, et al. Am J Kidney Dis 2006; Manno C, et al. Nephrol Dial Transplant 2009; Lv J, et al. JAMA 2017; Wheeler DC, et al. Kidney Int 2021; Lv J, et al. JAMA 2022; Zhang H, et al. ASN Kidney Week 2023, poster TH-PO1123; Mathur M, et al. N Engl J Med 2023; Lafayette R, et al. Lancet 2023, Rovin BH, et al. Lancet 2023.

Atacicept generally well tolerated through 96 weeks: OLE AE profile consistent with randomized period

	Double-Blind Baseline to Week 36		Open-Label Extension Week 36 to 96[1]
Participants, n (%)	**Placebo n=34**	**All Atacicept n=82**	**Atacicept 150 mg n=111**
TEAEs	28 (82)	60 (73)	85 (77)
Infections and infestations	11 (32)	35 (43)	43 (39)
Study drug-related TEAEs[2]	14 (41)	42 (51)	52 (47)
Serious TEAEs[3]	3 (9)	2 (2)	12 (11)
TEAEs leading to study drug discontinuation[4]	1 (3)	1 (1)	2 (2)
Deaths	0	0	0

- Total participant exposure: median 96 weeks (range 3, 99); mean 91 weeks

AE = adverse event; TEAE = treatment-emergent adverse event.

1. Week 96 cut-off includes all safety data as of June 03, 2024, including visits past Week 96. AEs were considered treatment-emergent during the open-label extension period if they started after the first dose of open-label atacicept 150 mg through the end of the study. n=111 represents 80 atacicept and 31 placebo who entered the open-label extension.
2. Mostly injection site reactions.
3. Serious TEAEs during double-blind period were previously reported (Lafayette R, et al. Kidney Int. 2024;S0085-2538(24)00236-9); serious TEAEs during the OLE: excess abdominal fat and left basal bronchopneumonia (n=1), acute kidney injury (n=1), angioedema (n=1), termination of pregnancy (n=1), post cricoid ulcer (n=1), pancreatitis, passed out common bile duct stone, and acute cholecystitis (n=1), tonsillitis (n=1), pneumonia (n=1), acute coronary syndrome required hospitalization (n=1), left 5th metatarsophalangeal joint gout (n=1), mild flare of IgA nephropathy (n=1), and urethral stricture worsening (n=1).
4. Reasons for discontinuation during double-blind period were previously reported; discontinuations during the OLE were due to: pneumonia in a heavy smoker, resolved (n=1); and worsening alanine aminotransferase and aspartate aminotransferase, resolved and unrelated to study treatment (n=1).

Conclusions

- Participants treated with atacicept for 96 weeks demonstrated sustained and substantial reductions in Gd-IgA1, hematuria and UPCR with long-term stabilization of eGFR
- The cumulative favorable safety profile remains consistent with that observed during the randomized 36 weeks of ORIGIN 2b
- The conversion of an eGFR profile in patients with IgAN from one of steady, unrelenting decline to one similar to that of the general population without kidney disease through 96 weeks is a unique and compelling finding
- Collectively, these data support the potential of B-cell modulation with atacicept to modify the natural history of the disease and the potential to prevent kidney failure during the lifetime of patients with IgAN

Acknowledgments

Thank you to all our ORIGIN Phase 2b study volunteers and their families
and the ORIGIN investigators, study staff, and collaborators

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Long-term Results From an Open-label Extension Study of Atacicept for the Treatment of IgA Nephropathy

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Atacicept projected catalysts

	Catalyst	2024	2025	2026
origin (IgAN)	Phase 3 primary endpoint cohort full enrollment	✓ 3Q		
	Phase 2b 96-week results	✓ 4Q		
	Phase 3 top-line results		2Q	
	BLA submission		2H	
	Projected US launch[1]			
origin extend (IgAN)	Initiation			
	Initial data available			
pioneer (IgAN, PMN, FSGS, MCD)	Initiation			
	Initial data available			

Vera holds worldwide, exclusive rights to develop and commercialize atacicept

Based on management's current assumptions. 1. Subject to US approval.


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