

**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 2, 2024

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

Delaware <small>(State or other jurisdiction of incorporation)</small>	001-40407 <small>(Commission File Number)</small>	81-2744449 <small>(I.R.S. Employer Identification No.)</small>
8000 Marina Boulevard, Suite 120 Brisbane, California <small>(Address of principal executive offices)</small>		94005 <small>(Zip Code)</small>
	(650) 770-0077 <small>(Registrant's telephone number, including area code)</small>	
	Not Applicable <small>(Former name or former address, if changed since last report)</small>	

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 7.01 Regulation FD Disclosure.

On October 2, 2024, Vera Therapeutics, Inc. (the “Company”) announced an expanded atacept development program in multiple autoimmune kidney diseases through the initiation of two new studies – ORIGIN Extend and PIONEER. A copy of the press release is furnished as Exhibit 99.1. In connection with the press release, the Company compiled a presentation entitled “R&D Day” (the “R&D Day Presentation”) that includes a discussion of the study design and purpose of ORIGIN Extend and PIONEER. A copy of the R&D Day 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 Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section or Sections 11 and 12(a)(2) of the Securities Act of 1933, as amended. 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 U.S. Securities and Exchange Commission (“SEC”) made by the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release of Vera Therapeutics, Inc., dated October 2, 2024.
99.2	Slide presentation entitled “R&D Day”.
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 2, 2024

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

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

- 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., October 2, 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 m²), 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 event was held in advance of the anticipated 96-week data from the Phase 2b ORIGIN study of atacicept in immunoglobulin A nephropathy (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 Atacept

Atacept 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 atacept 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 atacept and placebo. Through 72 weeks, atacept 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.

Atacept 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, atacept may demonstrate substantial improvement on a clinically significant endpoint over available therapies for patients with IgAN. Vera believes atacept 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 atacept, atacept'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 atacept 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



R&D Day

October 2, 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 in this presentation that are not statements of historical fact are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include, without limitation, atacept'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 the presentation of anticipated 96-week data from the Phase 2b ORIGIN trial at ASN Kidney Week, 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, atacept's potential to be a transformational treatment for additional patient cohorts beyond those with IgAN, the Company's expectations regarding initiating clinical trials of atacept 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 atacept's projected launch. Words such as "believe," "anticipate," "plan," "expect," "intend," "will," "may," "goal," "project," "estimate," "on track," "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.

This presentation does not constitute an offer to sell or the solicitation of an offer to buy any securities, or a solicitation of any vote or approval, nor shall there be any sale of securities in any jurisdiction in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such jurisdiction. Investment in any securities described herein has not been approved or disapproved by the Securities and Exchange Commission or any other regulatory authority nor has any authority passed upon or endorsed the merits of the offering or the accuracy or adequacy of the information contained herein. Any representation to the contrary is a criminal offense.

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.

Agenda

Opening Remarks

Marshall Fordyce, MD
Founder and CEO, Vera Therapeutics

Vera Expansion Strategy

Robert Brenner, MD
Chief Medical Officer, Vera Therapeutics

Q&A Panel

Jonathan Barratt, MD, PhD, FRCP
Mayer Professor of Renal Medicine, University of Leicester

Richard Lafayette, MD, FACP
Professor of Medicine (Nephrology), Stanford University Medical Center
Director, Stanford Glomerular Disease Center

Brad Rovin, MD, FACP, FASN
Lee A. Herbert Professor of Nephrology
Ohio State University Wexner Medical Center

Closing Remarks

Marshall Fordyce, MD
Founder and CEO, Vera Therapeutics

Atacept 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 1.5 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
- Atacept 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 = IgA nephropathy; SC = subcutaneous.

Cumulative Atacicept data offers best-in-class potential

	 Atacicept	 Sibeprenlimab¹	 Povetacicept²	 Zigakibart³
Mechanism	BAFF/APRIL inhibition	APRIL inhibition only	BAFF/APRIL inhibition	APRIL inhibition only
Dosing & Administration	25/75/150 mg SC QW (Ph2) 150 mg SC QW (Ph3) 1x1 mL self-administered	2/4/8 mg/kg IV (Ph2) 400 mg SC QM (Ph3) 1x2 mL in-clinic injection	80/240 mg SC QM (Ph1b) 1xTBD mL injection	450 mg IV Q2W (Ph2) 600 mg SC Q2W (Ph3) 2x2 mL in-clinic injection
Development Stage	Ph3	Ph3	Ph3	Ph3
Randomized Controlled Trial Data	✓	✓	✗	✗
Gd-IgA1 Reduction	64% at W36 vs 7% placebo	~60% at W52 vs ~+20% placebo	No placebo controlled data	No placebo controlled data
Hematuria	80% resolution at W36	Reductions at W36 (nonquantifiable)	Not reported	Not reported
UPCR Reduction vs Placebo	Δ 43% (p=0.003) at W36	Δ 43% at W36	No placebo controlled data	No placebo controlled data
eGFR Duration Data	18 months, n=109 24 months coming soon*	12 months, n=145	12 months, n=1	12 months, n=35
Projected Commercial Launch	2026	2026	2027	2027

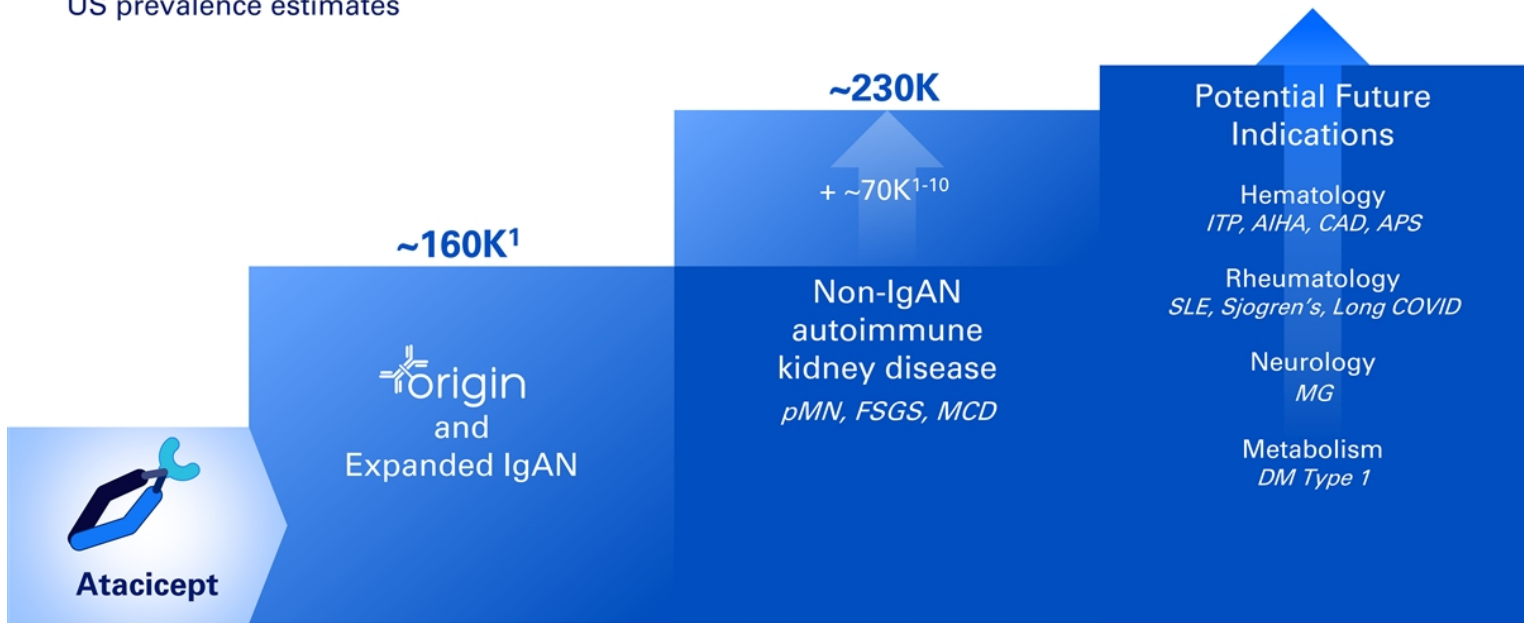
*To be presented at ASN Kidney Week 2024.

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.

Atacicept 150 mg data shown for urine protein-creatinine ratio (UPCR), galactose-deficient immunoglobulin A1 (Gd-IgA1), and hematuria. 1. Ph2 4 mg/kg IV Gd-IgA1 data from Mathur M, et al. NEJM 2023, Ph2 4 mg/kg IV hematuria data from Barratt J, et al. WCN 2024, WCN24-AB-1799, Ph2 pooled sibeprenlimab UPCR data from Kooienga ASN 2022, TH-PO991, and estimated glomerular filtration rate (eGFR) data from Barratt J, et al. ASN 2023, abstr TH-PO1124; 2. Ph1b 80 mg data from Tumlin J, et al. ASN 2023, TH-PO1125, and Tumlin J, et al. WCN 2024, WCN24-AB-762. 3. Barratt J, et al. ERA 2024, late breaking abstract.

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; *MG* = myasthenia gravis; *COVID* = Coronavirus disease 2019; *DM* = diabetes mellitus.

Vera financial position is strong

~\$384M

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

~54.8M

Shares outstanding
(as of 8.5.24)

Atacept: previously shared projected catalysts

Catalyst	2024	2025	2026
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			●




Vera holds worldwide, exclusive rights to develop and commercialize atacept

Based on management's current assumptions.

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Atacept: additional projected catalysts

	Catalyst	2024	2025	2026
	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			●
New clinical trial	Initiation	●		
	Initial data available		●	
New clinical trial	Initiation		●	
	Initial data available		●	

Vera holds worldwide, exclusive rights to develop and commercialize atacept

Based on management's current assumptions.

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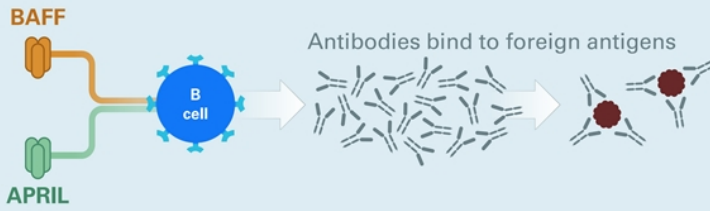
Brad Rovin, MD, FACP, FASN
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Closing Remarks

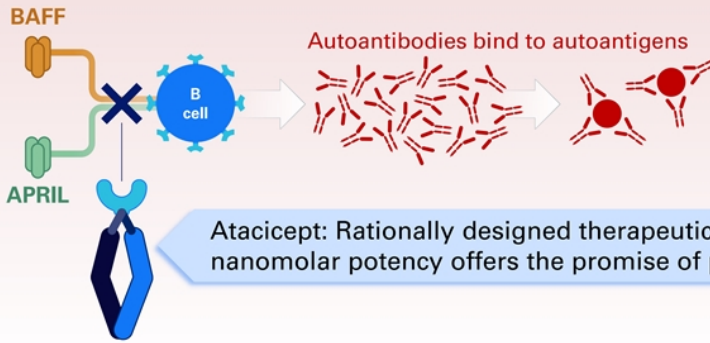
Marshall Fordyce, MD
Founder and CEO, Vera Therapeutics

Atacept has broad therapeutic potential in autoimmune disease

Immunity in health



Autoimmune disease



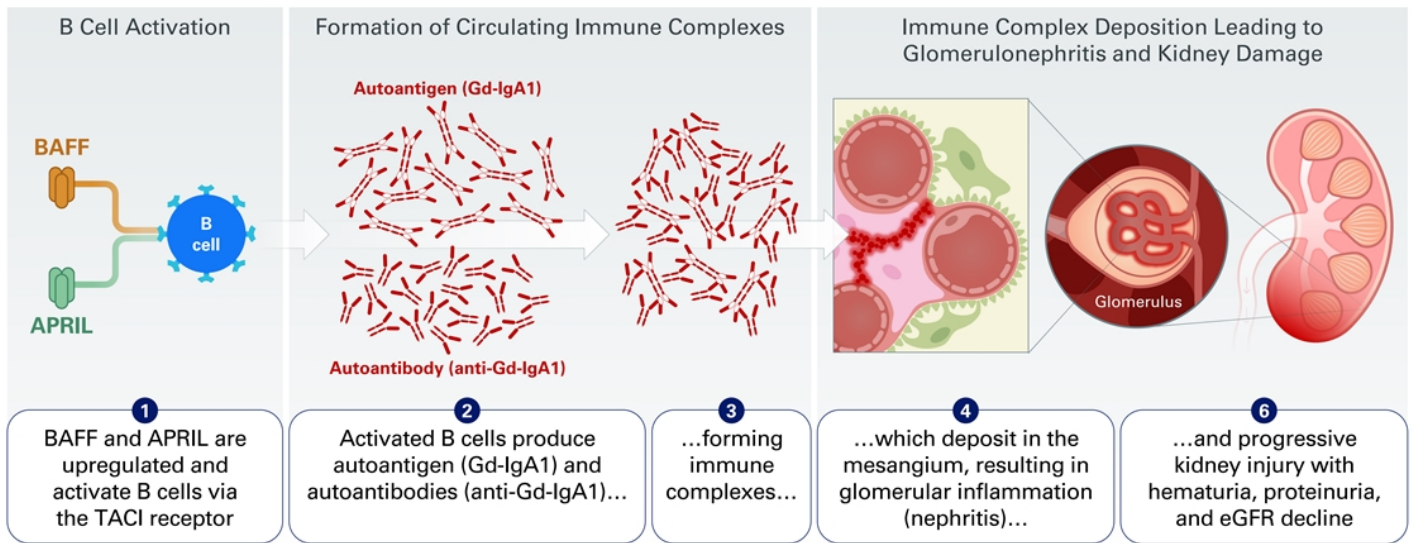
Autoantigens and autoantibodies mediate autoimmune disease

B cells are the source of autoantibodies → target cell of interest for therapeutic intervention

B cells are fueled by two (and only two) cytokines, BAFF and APRIL

Atacept: Rationally designed therapeutic of modern biotechnology that binds BAFF and APRIL with nanomolar potency offers the promise of precision modulation of B cells and autoantibodies

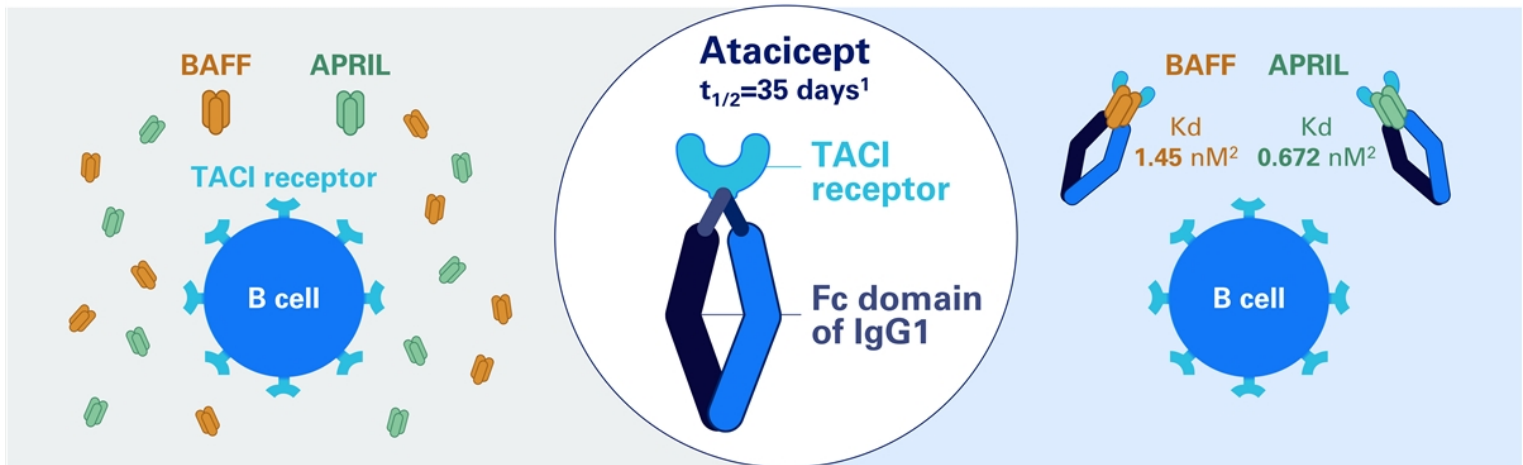
Lead indication: IgAN is a disease of B cell origin with kidney pathology



TACI = transmembrane activator and calcium-modulator and cyclophilin ligand.

Atacicept is an example of rational drug design

Native TACI-Fc fusion: Soluble protein binds both BAFF and APRIL with nanomolar potency

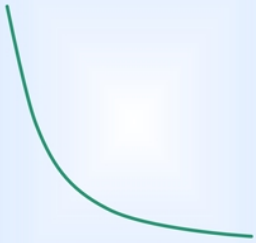


Fc = fragment crystallizable. 1. Willen D, et al. Eur J Drug Metab Pharmacokinet 2020;45(1):27-40; 2. Vera data on file.

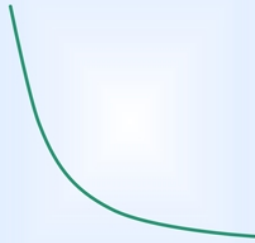
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An ideal IgAN disease modifying therapy would be expected to...

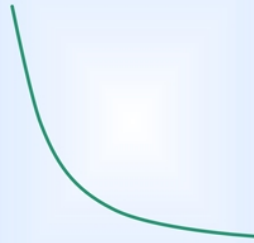
**Reduce
Gd-IgA1**



**Reduce
hematuria**



**Reduce
proteinuria**

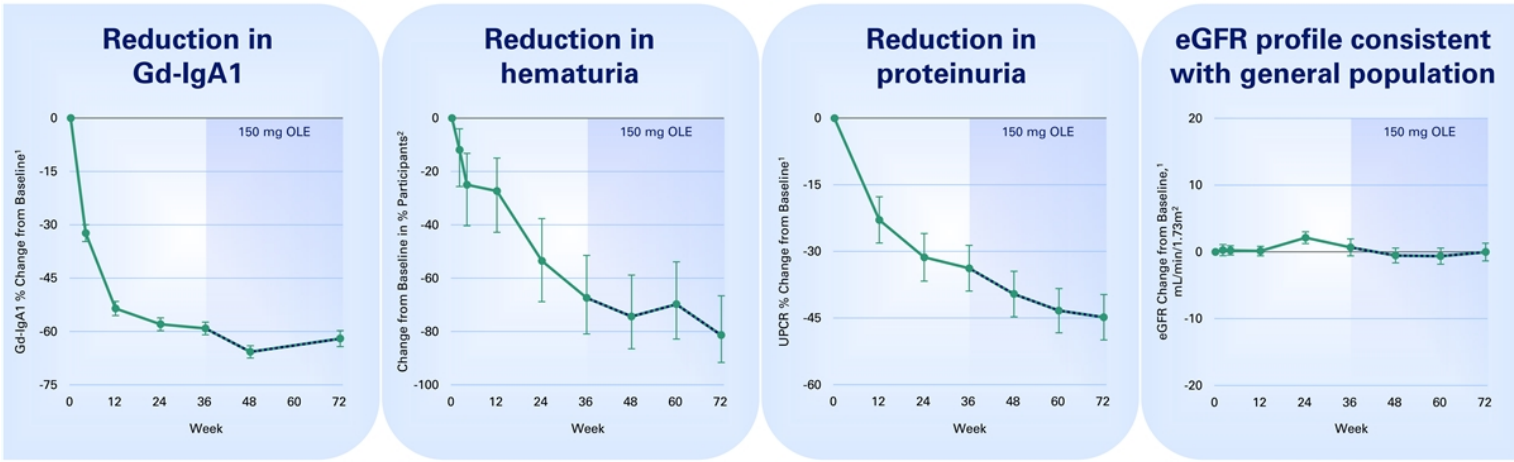


**Convert eGFR profile to
general population**



ORIGIN Phase 2b 72-week results consistent with IgAN disease modification

Including eGFR Profile consistent with the general population of -1 mL/min/year



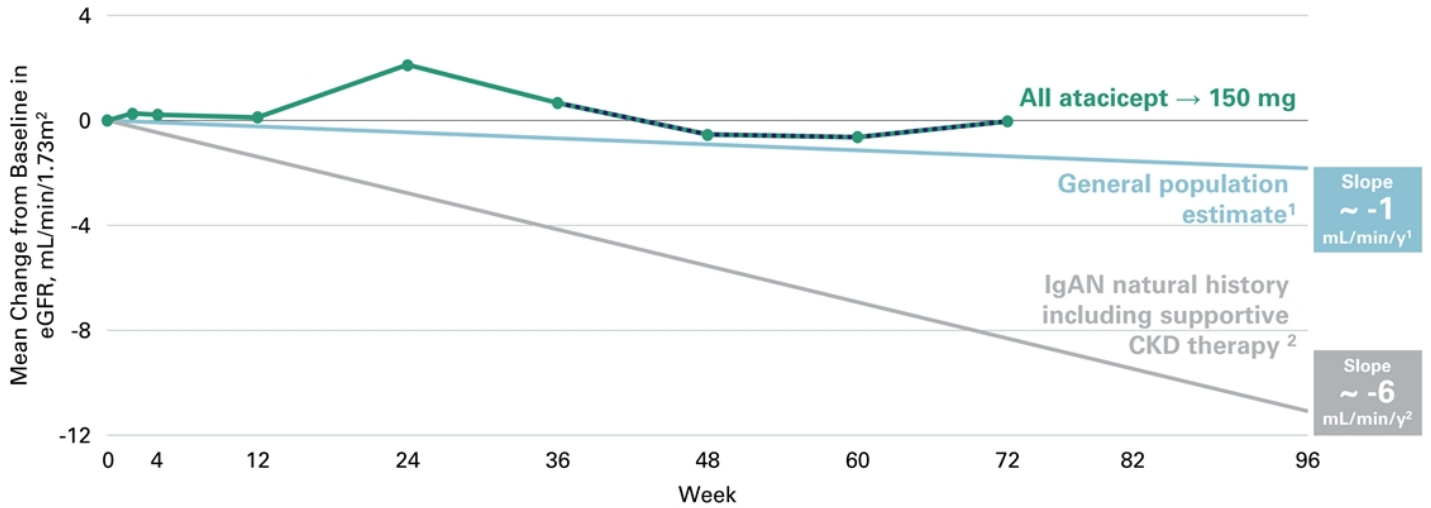
Set the standard in IgAN

Lafayette R, et al. ERA 2024, abstr 812.

1. Mean ± SE; 2. Change from baseline in percentage of participants with hematuria at each visit out of those with baseline hematuria.

Data from participants originally randomized to any atacept group in the double-blind period in the intent-to-treat analysis for Gd-IgA1, hematuria, UPCR and eGFR. OLE = open-label extension.

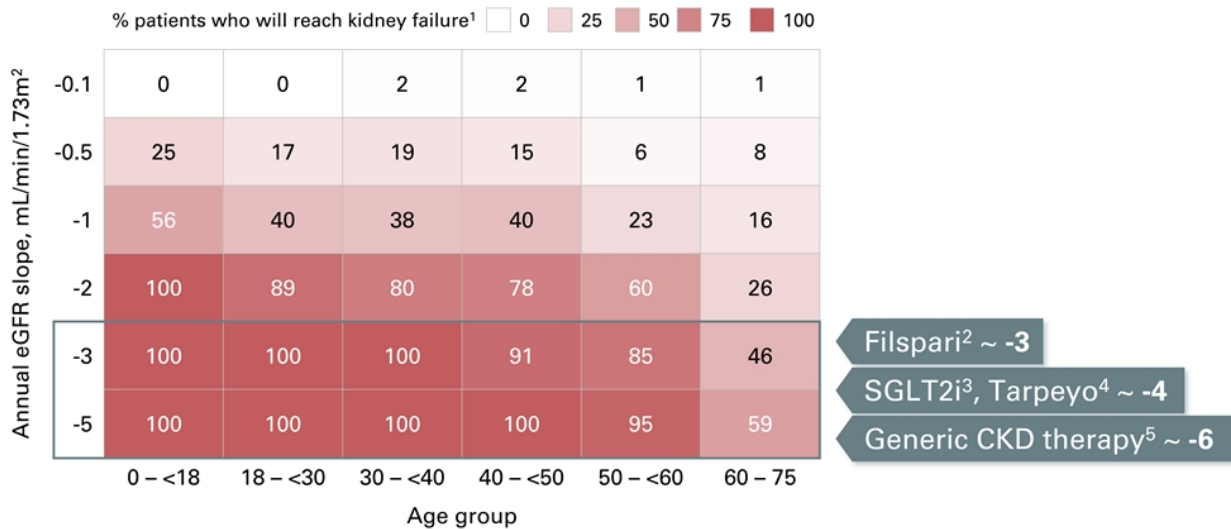
Atacept treated participants have an eGFR slope profile consistent with general population without kidney disease



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-PD1123; 11. Mathur M, et al. N Engl J Med 2023.

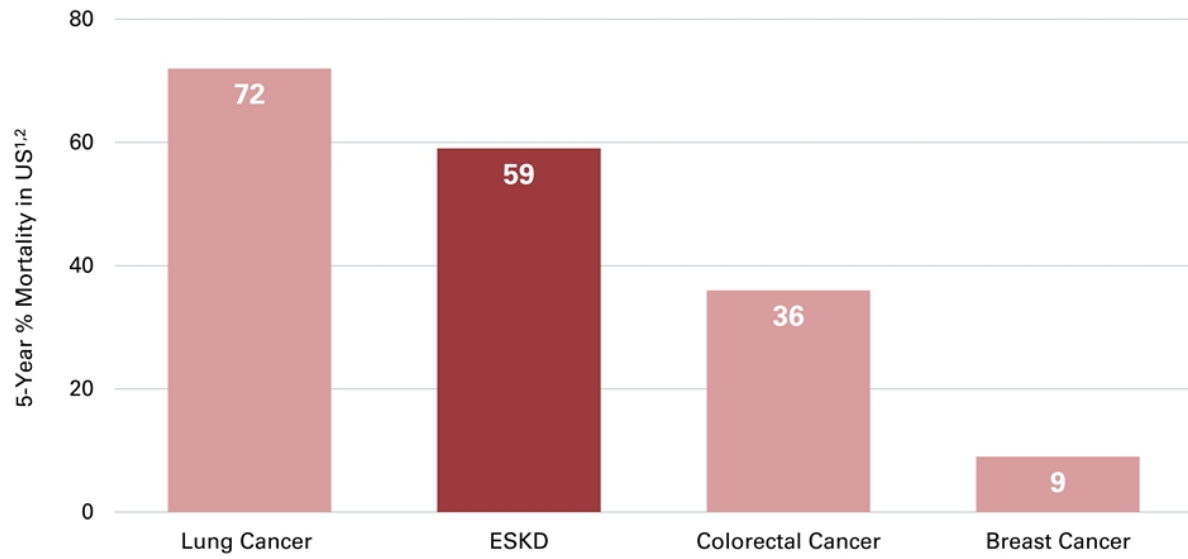
2024 Draft KDIGO IgAN guidelines call for target eGFR slope ≤ -1 mL/min/1.73m²



SGLT2i = sodium-glucose cotransporter-2 inhibitor.
 1. Adapted from Pitcher D, et al. CJASN 2023; 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.

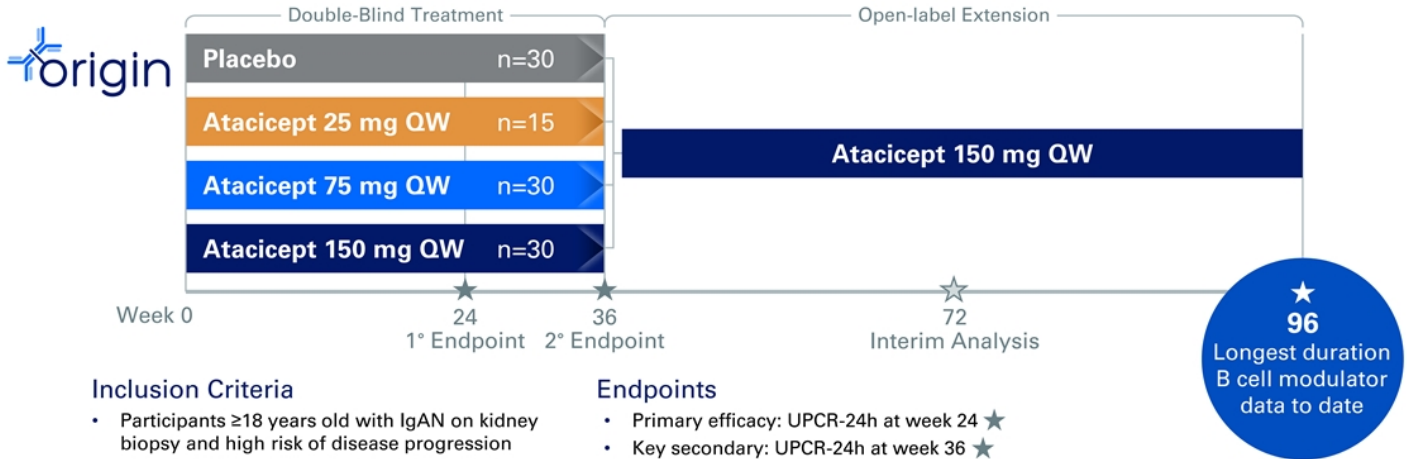


5-year mean mortality in ESKD comparable to cancer in US



ESKD = end-stage kidney disease. 1. US CDC Cancer Statistics; 2. Thurlow JS, et al. Am J Nephrol 2021.

ORIGIN Phase 2b long-term data will be revealed in late breaking oral presentation during ASN Kidney Week



Inclusion Criteria

- Participants ≥18 years old with IgAN on kidney biopsy and high risk of disease progression
- Stable and optimized RAASi for ≥12 weeks
- Use of SGLT2i allowed
- UPCR-24h >0.75 g/g or UP >0.75 g per 24h
- eGFR ≥30 mL/min/1.73 m²
- 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

ET = end of treatment; RAASi = renin-angiotensin-aldosterone system inhibitor; UPCR = urine protein:creatinine ratio.

Consistency with ORIGIN 2b instills great confidence in ORIGIN 3



Inclusion Criteria

- Patients ≥ 18 years old with IgAN on kidney biopsy and high risk of disease progression
- Stable and optimized RASi for ≥ 12 weeks, use of SGLT2i allowed
- UPCR-24h ≥ 1.0 g/g or UP ≥ 1.0 g per 24h
- eGFR ≥ 30 mL/min/1.73 m²
- Blood pressure $\leq 150/90$ mmHg

Endpoints

- Primary efficacy: UPCR-24h at week 36 ★
to support potential accelerated approval
– >90% power at week 36
- Key secondary: eGFR change up to week 104 ★
– 90% power for eGFR $\Delta 4$ mL/min at week 104
- Safety

- Operational efficiency leveraging similar study design and worldwide sites as ORIGIN 2b
- Same self-administered SC formulation and dose as used in ORIGIN 2b

Atacicept expansion roadmap

US prevalence estimates



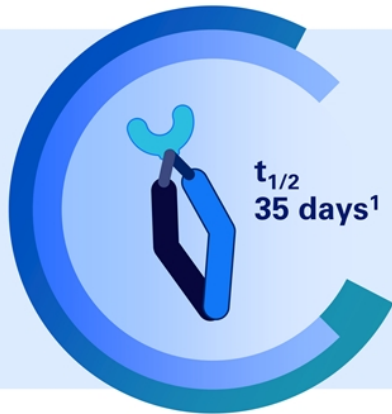
1. Vera Therapeutics corporate estimates for peak year prevalence based on ClearView Healthcare Partners Analysis.

ORIGIN Extend: Commitment to providing long-term access to atacept for all ORIGIN participants



- Phase 2 extension study in participants who complete ORIGIN 2b/3; initiating Q4 2024
- Objectives:
 1. Provide patients with extended access to atacept prior to commercial availability in their country/region
 2. Capture longer-term data for research purposes
 3. Document impact of withdrawal from therapy, followed by restart

Atacept at home, self-administered QW dosing highly attractive; QM program begins in 2025



- Biologic therapies utilizing at home, self-administered, SC 1 mL QW dosing widely used and accepted
- This dosing paradigm has the potential to support atacept as a foundational therapy for IgAN
- Atacept half life also supports evaluation of extended dosing
- QM dose finding study in 2025

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

PIONEER: Phase 2 basket study in expanded IgAN cohorts

Patients ineligible for ORIGIN 3 will have an opportunity to enroll in PIONEER at same clinical sites



Expanded IgAN populations, n ≤120

- 1 Adult IgAN with low kidney function¹, n ≤20
- 2 Adult IgAN with low proteinuria², n ≤50
- 3 Adult IgAN with high proteinuria³, n ≤20
- 4 Adolescent⁴ IgAN at high risk of progression⁵, n ≤10
- 5 Adult recurrent IgAN post kidney transplant, n ≤10
- 6 Adolescent⁴ and adult IgAVN, n ≤10

¹eGFR 20 to <30 mL/min/1.73 m²
²UPCR <1.0 g/g
³UPCR ≥5.0 g/g
⁴Age ≥15 years
⁵UPCR ≥0.3 g/g

Atacicept 150 mg qwk



Endpoints

- Primary: UPCR change at week 36
- Key secondary: eGFR change at weeks 36, 52
- Gd-IgA1 change at weeks 36, 52
- Change in percentage of participants with hematuria at weeks 36, 52
- Safety

IgAVN = immunoglobulin A vasculitis nephritis (purpura nephritis).

Atacicept expansion roadmap

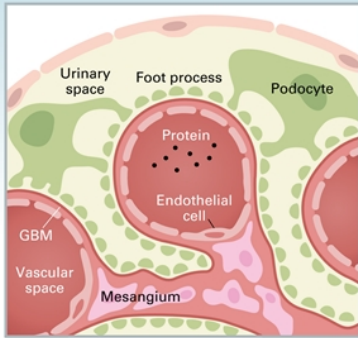
US prevalence estimates



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.

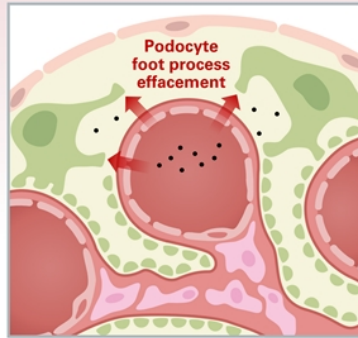
Autoimmune glomerular disease: podocyte injury and cytoskeletal derangement drives proteinuria and progressive disease

Healthy Podocyte Foot Processes



Podocytes play a key role in preventing large molecules (proteins) from being filtered into urine

Disrupted Podocyte Foot Processes

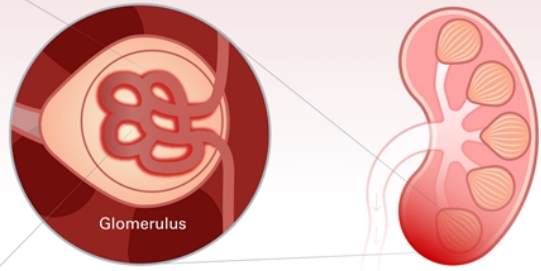


Causes of podocyte injury:

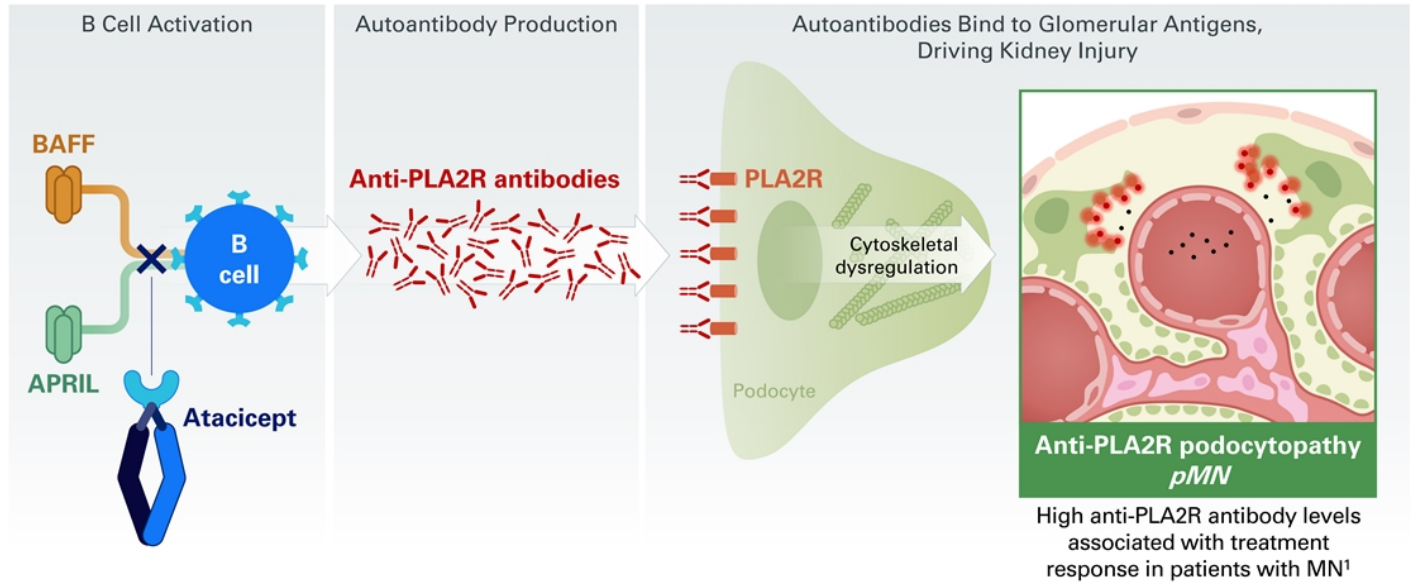
- Immune mediated injury
- Secondary causes
- Genetic predisposition
- Environmental factors

Resulting in clinically relevant alterations in the glomerular filtration barrier...

...leading to proteinuria including nephrotic syndrome and nephron loss



Atacicept mechanism of action has broad potential in autoimmune glomerular disease including membranous nephropathy



PLA2R = phospholipase A2 receptor.
1. Barbour SJ, et al. CJASN 2023.

Atacicept expansion roadmap

US prevalence estimates



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PIONEER: Operationally efficient Phase 2 basket study in expanded IgAN and anti-PLA2R podocytopathy (PMN)



Population 1, n ≤120
Expanded IgAN populations

Population 2, n ≤20
Anti-PLA2R podocytopathy
(Membranous Nephropathy)

Atacicept 150 mg qwk

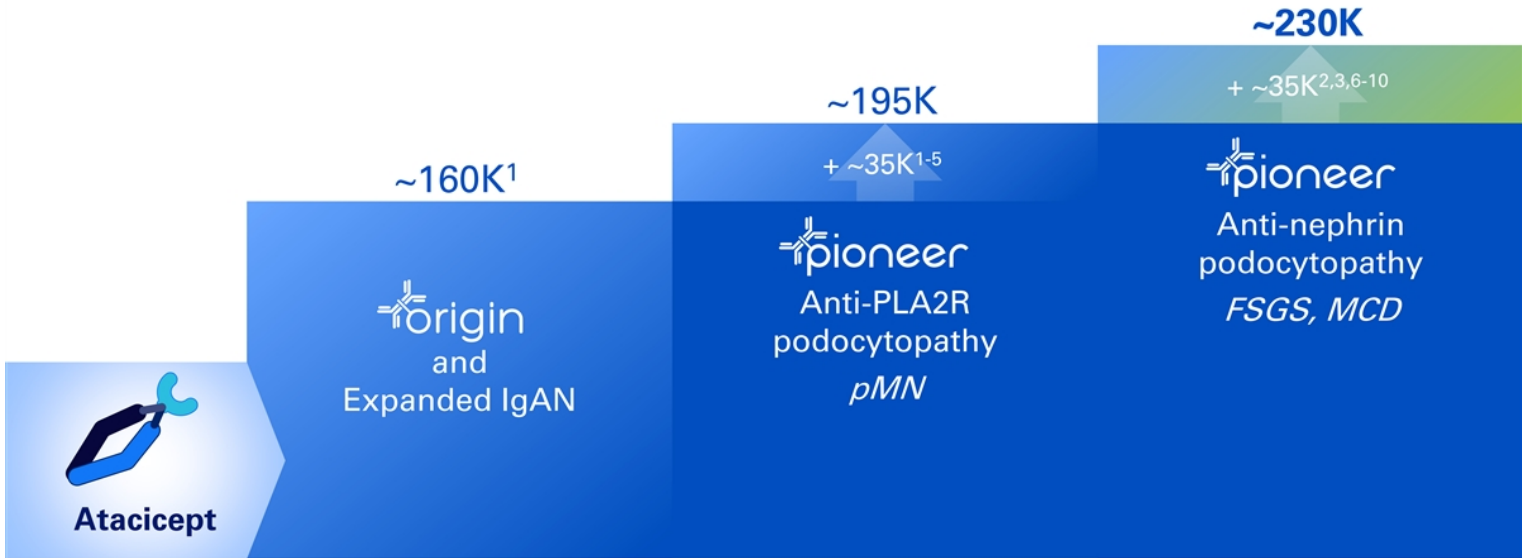


Endpoints

- Primary: UPCR change at week 36
- Key secondary: eGFR change at weeks 36, 52
- Exploratory:
 - Gd-IgA1 change at weeks 36, 52
 - Change in percentage of participants with hematuria at weeks 36, 52
 - Change in anti-PLA2R antibodies
- Safety

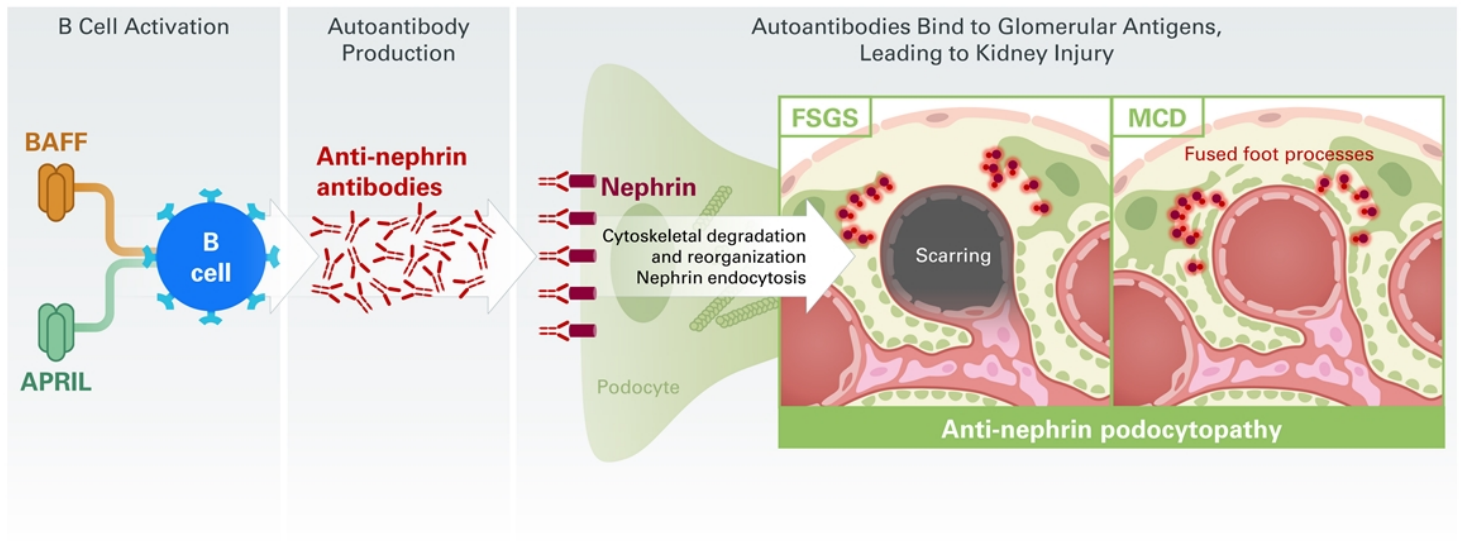
Atacicept expansion roadmap

US prevalence estimates



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FSGS and MCD are histologic diagnoses with heterogeneous etiology; Autoimmunity, including anti-nephrin antibodies, is one driver of disease



FSGS = focal segmental glomerulosclerosis; MCD = minimal change disease. Kopp JB, et al. Nat Rev Dis Primer 2021; Fogo AB. Nat Rev Nephrol 2015.

PIONEER: Operationally efficient Phase 2 basket study in expanded IgAN and anti-PLA2R & anti-nephrin podocytopathies



Population 1, n ≤120
Expanded IgAN populations

Population 2, n ≤20
Anti-PLA2R podocytopathy
(Membranous Nephropathy)

Population 3, n ≤20
Anti-nephrin podocytopathy
(Minimal Change Disease/FSGS)

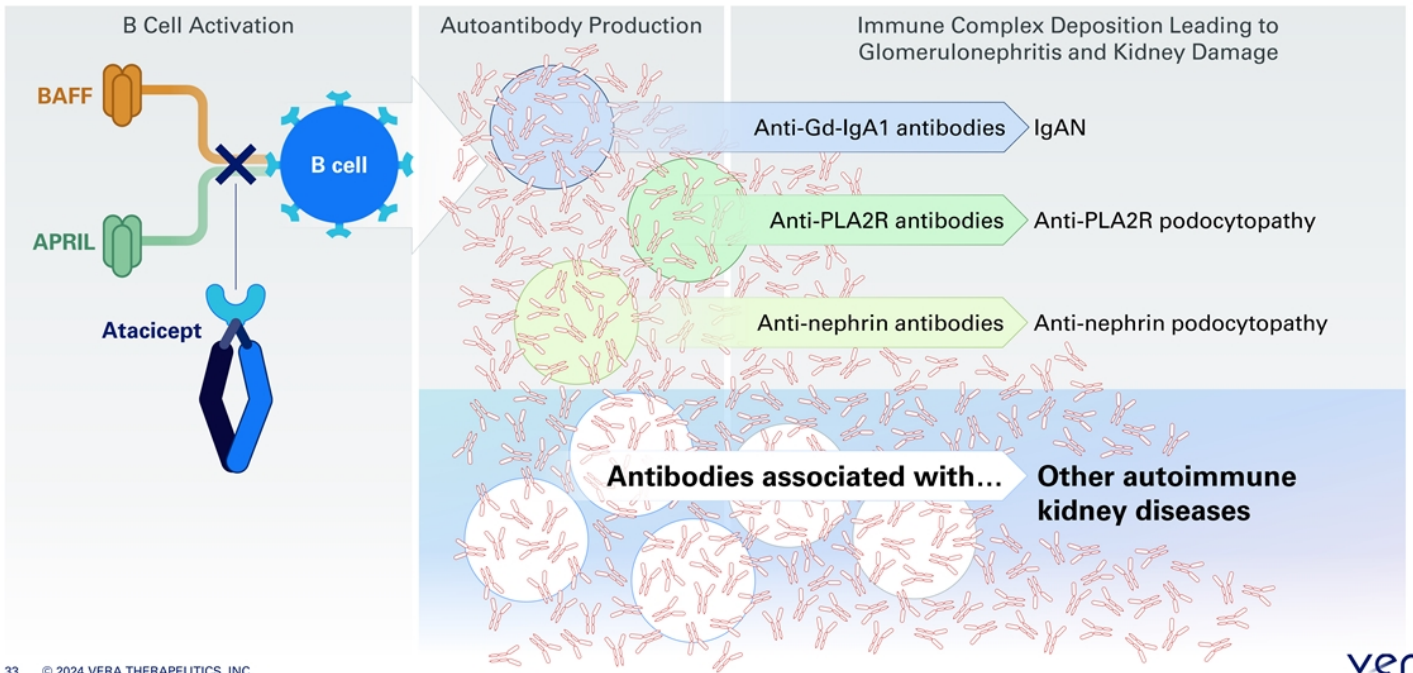
Atacicept 150 mg qwk



Endpoints

- Primary: UPCR change at week 36
- Key secondary: eGFR change at weeks 36, 52
- Exploratory:
 - Gd-IgA1 change at weeks 36, 52
 - Change in percentage of participants with hematuria at weeks 36, 52
 - Change in anti-PLA2R antibodies
 - Change in anti-nephrin antibodies
- Safety

Targeting B cell production of autoantibodies against glomerular antigens offers the promise of additional kidney indications



Vision for an evolved approach to autoimmune glomerular disease

Identification of autoantigen/autoantibody constructs that drive autoimmune glomerular diseases

Gd-IgA1 &
anti-Gd-IgA1



1999¹

PLA2R &
anti-PLA2R



2009²

Nephrin &
anti-nephrin



2022³

Today

Future
autoantigen/autoantibody
constructs identified

Importantly, atacicept represents both a **potential therapeutic agent** and also a **diagnostic tool**:

Characterize patients with proteinuric and nephritic conditions based on responsiveness to a diagnostic trial of atacicept

Patients demonstrating a response have a **B-cell modulatory responsive autoimmune glomerular disease**



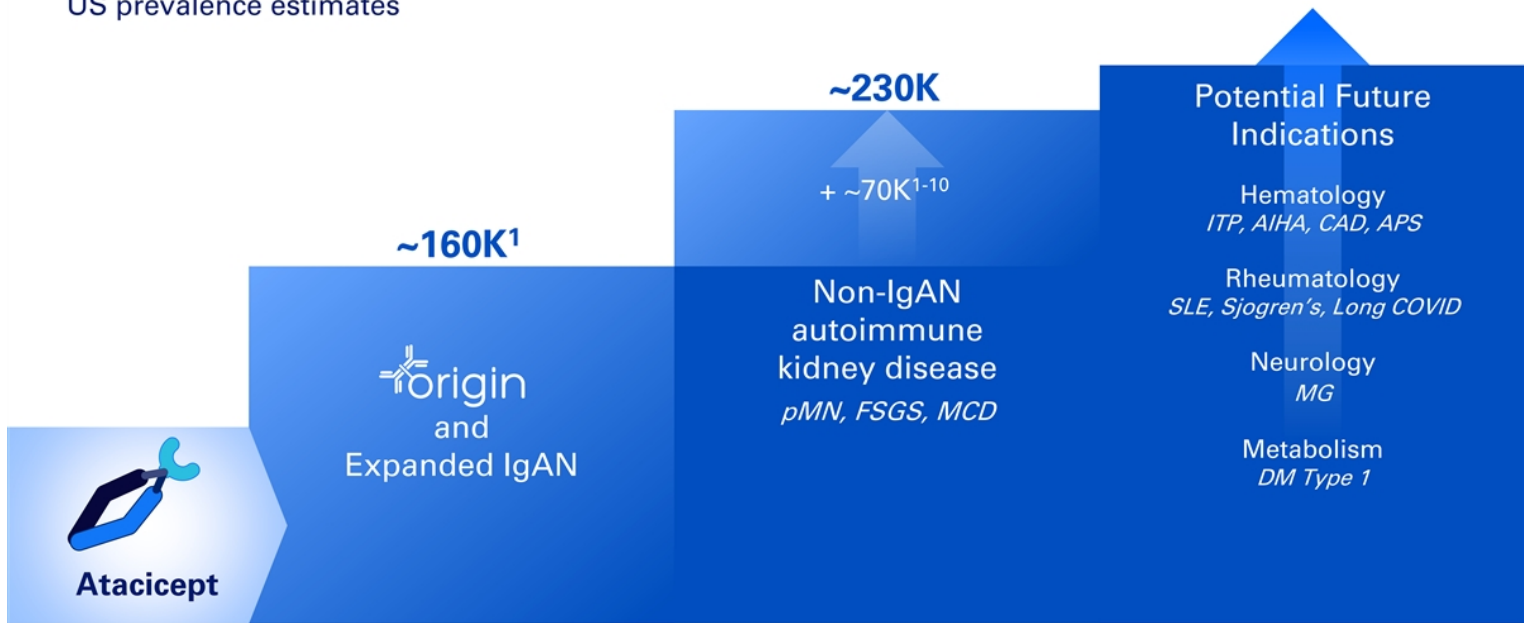
Does not require pre-existing elucidation of all autoantigen/autoantibody constructs

Provides an opportunity for both future clinical investigation and long-term treatment

1. Tomana M, et al. J Clin Invest 1999. 2. Beck LH, et al. N Engl J Med 2009. 3. Watts AJ, et al. JASN 2022.




Vera optionality to expand in autoimmune kidney disease & beyond

US prevalence estimates



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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; MG = myasthenia gravis; COVID = Coronavirus disease 2019; DM = diabetes mellitus.

Atacept projected catalysts

	Catalyst	2024	2025	2026
	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			●
	Initiation	●		
	Initial data available		●	
	Initiation		●	
	Initial data available		●	

Vera holds worldwide, exclusive rights to develop and commercialize atacept

Based on management's current assumptions.

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therapeutics

Agenda

Opening Remarks

Marshall Fordyce, MD
Founder and CEO, Vera Therapeutics

Vera Expansion Strategy

Robert Brenner, MD
Chief Medical Officer, Vera Therapeutics

Q&A Panel

Jonathan Barratt, MD, PhD, FRCP
Mayer Professor of Renal Medicine, University of Leicester

Richard Lafayette, MD, FACP
Professor of Medicine (Nephrology), Stanford University Medical Center
Director, Stanford Glomerular Disease Center

Brad Rovin, MD, FACP, FASN
Lee A. Herbert Professor of Nephrology
Ohio State University Wexner Medical Center

Closing Remarks

Marshall Fordyce, MD
Founder and CEO, Vera Therapeutics

Q&A Panel



Jonathan Barratt
MD, PhD, FRCP
 UNIVERSITY OF
LEICESTER

Dr. Barratt leads the Renal Research Group within the College of Life Sciences, University of Leicester. His research is focused on a bench-to-bedside approach to improving our understanding of the pathogenesis of IgAN, a common global cause of kidney failure. Dr. Barratt is the IgAN Rare Disease Group lead for the UK National Registry of Rare Kidney Diseases (RaDaR), and a member of the steering committee for the International IgAN Network. He works closely with pharmaceutical companies interested in new treatments for IgAN, is Chief Investigator for a number of international randomized controlled Phase 2 and 3 clinical trials in IgAN, and was a member of the U.S. Food and Drug Administration and American Society of Nephrology Kidney Health Initiative: Identifying Surrogate Endpoints for Clinical Trials in IgAN Workgroup.



Richard Lafayette
MD, FACP
 Stanford
MEDICINE

Dr. Lafayette is a Professor of Medicine (Nephrology) and Director of the Stanford Glomerular Disease Center at Stanford University Medical Center. Dr. Lafayette completed his medical education at New York Medical College and went on to complete his residency at the Long Island Jewish Medical Center, and his fellowship at Stanford University School of Medicine. Dr. Lafayette is board-certified in Internal Medicine and Nephrology. Dr. Lafayette served as the Associate Chair of the Stanford University Department of Medicine from 2002–2007, the Clinical Chief of Nephrology at Stanford University from 1999–2012, and currently serves as the Director of the Stanford Glomerular Disease Center since 2010. Dr. Lafayette was honored in America's Top Doctors, Best Doctors from 2004–2018, and received America's Top Doctors Award, Castle Connolly Medical Ltd. from 2014–2022. Dr. Lafayette has been part of the following boards and professional organizations: Editorial Board, Kidney News, American Society of Nephrology (2010–2021) Member, Glomerular Disease Advisory Committee, American Society of Nephrology (2013–2017) Member (ex-officio), Communications Committee, American Society of Nephrology (2015–Present).



Brad Rovin
MD, FACP, FASN
 THE OHIO STATE UNIVERSITY
WEXNER MEDICAL CENTER

Dr. Brad H. Rovin is the Lee A. Hebert Professor of Nephrology. Dr. Rovin received his BS in Chemical Engineering from Northwestern University and his MD from the University of Illinois Medical School. He completed a residency in Internal Medicine at Barnes Hospital in St. Louis, Missouri, and a Fellowship in Nephrology at Washington University School of Medicine, St. Louis. He joined the Ohio State University College of Medicine Faculty in 1990, became Director of the Division of Nephrology in 2004, and served as Vice Chairman of Medicine for Research from 2009–2019. In 2019 he became the Medical Director of the Ohio State University Center for Clinical Research Management. Dr. Rovin has had several leadership roles in the American Society of Nephrology, including running the Glomerular Diseases Pre-Course and Co-Editing NephSAP-Glomerular Diseases. Most recently, he was appointed Deputy Editor of *Kidney International*. He also is Co-Chair for glomerular disease guideline development for the Kidney Disease Improving Global Outcomes effort. Dr. Rovin's laboratory studies the immunopathogenesis of glomerular and autoimmune diseases. He is heavily involved in clinical trial development and design for investigator-initiated and industry-sponsored trials. He is a founding member of NephroNet, a grass-roots nephrology clinical trial organization, and the Lupus Nephritis Clinical Trials Network. He is and has been the Principal Investigator on several trials of novel therapeutics for glomerular diseases.

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Founder and CEO, Vera Therapeutics

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The logo for Vera Therapeutics features the word "vera" in a large, white, lowercase sans-serif font. The letter "v" is stylized with a horizontal line through its middle. Below "vera" is the word "therapeutics" in a smaller, white, lowercase sans-serif font. The background is a solid blue color with a pattern of lighter blue hexagons on the left side.

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