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): January 30, 2023

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 7.01 Regulation FD Disclosure.

On January 30, 2023, Vera Therapeutics, Inc. (the "Company") announced an update to the topline results from the Company's Phase 2b ORIGIN clinical trial evaluating its product candidate atacicept in patients with immunoglobulin A nephropathy ("IgAN") previously released on January 3, 2023. In connection with the data release, the Company compiled a presentation entitled "Origin Phase 2b Clinical Trial Data Update", which includes atacicept clinical summary results to date, including both data from the intent-to-treat (ITT) analysis (previously released on January 3, 2023) and prespecified per-protocol (PP) analysis (as released on January 30, 2023), in each case, from the Phase 2b ORIGIN clinical trial referenced above.

A copy of the presentation is furnished as Exhibit 99.1. For important information about forward-looking statements, see the slide titled "Forward-Looking Statements" in Exhibit 99.1 attached hereto.

The information in this Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, 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 Exhibit 99.1, 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 8.01 Other Events.

As noted in Item 7.01, on January 30, 2023, the Company announced an update to the topline data from its Phase 2b ORIGIN clinical trial of atacicept in patients with IgAN previously released on January 3, 2023. The prior topline results reflected the ITT analysis of all randomized patients (n=116), which is a conservative assessment of efficacy. In the prespecified PP analysis, the population was defined as patients who had completed treatment according to protocol (n=102). 14 patients across treatment arms who had protocol violations were identified by a blinded third-party clinical research organization ("CRO") and excluded, for prespecified reasons as outlined in Figure 1.

Figure 1. Patients Identified by Blinded Third-Party CRO and Excluded from Prespecified PP Analysis

Number of Patients	Reason for Exclusion
6	Change in background RAASi post-randomization
3	Inadequate time of SGLT2i stability (initiated <8 weeks prior to screening)
3	Missing urine protein to creatinine ratio (UPCR) data at week 24
1	Received prohibited medication
1	Compliance <80%

Atacicept is the Company's potential best-in-class, disease-modifying dual inhibitor of the cytokines B lymphocyte stimulator and a proliferation-inducing ligand. ORIGIN is a multinational, randomized, double-blind, placebo-controlled clinical trial 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.

Prespecified Per-Protocol (PP) Analysis from the Phase 2b ORIGIN Clinical Trial

In the topline results published on January 3, 2023, all treated patients (n=116) were included in the results as the ITT population. In the prespecified PP analysis, the population was defined as patients who had completed treatment according to protocol (n=102), where 14 patients who had protocol violations identified by a blinded third-party CRO were excluded. These protocol violations are outlined above in Figure 1.

In the PP analysis, at Week 24, the atacicept 150 mg dose group achieved a 41% mean reduction in proteinuria versus baseline and a 34% delta versus placebo (p=0.025). With interim data at Week 36, the atacicept 150 mg dose group achieved a 47% mean reduction in proteinuria from baseline and a 48% delta versus placebo, as shown in Figure 2. Data for the atacicept 150 mg dose group versus placebo from both the PP and ITT analyses can be referenced in Figure 3.

Figure 2. Prespecified PP Analysis: UPCR % Change In Atacicept 75 and 150 mg Through Week 36

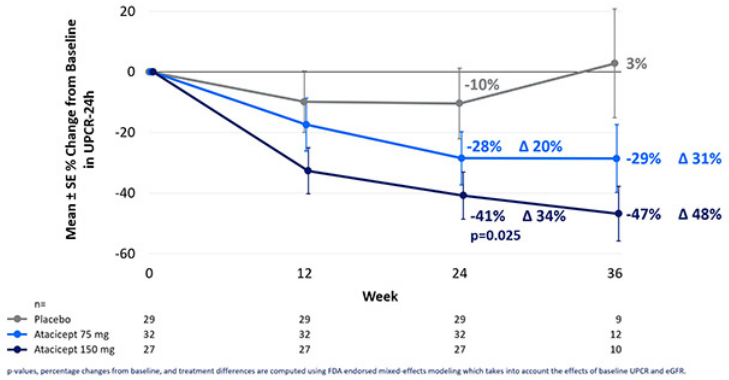


Figure 3. Summary of Positive Phase 2b Results (PP Analysis, ITT Analysis)

	Week 24 full data			Week 36 interim data		
	Atacicept 150 mg	Placebo	Δ	Atacicept 150 mg	Placebo	Δ
PP analysis	**-41%**	**-10%**	**34%**	**-47%**	**+3%**	**48%**
ITT analysis	-33%	-7%	28%	-36%	-4%	33%

Safety results indicated that atacicept was generally well-tolerated and were consistent with the previously observed safety profile of atacicept, including a 1% discontinuation rate due to adverse events (“AEs”) and comparable rates of infection compared to placebo. Serious treatment-emergent AEs were observed in 2% of patients in all atacicept arms and in 9% of patients in the placebo arm. These results build upon the prior integrated analysis of atacicept in randomized, double-blind, placebo-controlled clinical trials in over 1,500 patients to date – in which atacicept was well-tolerated.

Next Steps

The Company is continuing to rapidly advance atacicept into pivotal Phase 3 development, which is anticipated in the first half of 2023, subject to and following discussions with the U.S. Food and Drug Administration. The full data sets from the ORIGIN clinical trial will be presented at upcoming medical congresses. The Company plans to prioritize and focus current resources on the advancement of atacicept in IgAN into a pivotal Phase 3 trial, extending cash runway to the fourth quarter of 2024. This updated cash runway guidance assumes a delay in enrollment in the pivotal Phase 3 trial for lupus nephritis, and a delay of commitment of resources to the MAU868 program until regulatory agreement is reached regarding the pivotal Phase 3 program for the treatment of BK viremia in kidney transplant recipients.

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, atacicept's potential to be a transformational treatment for patients with IgAN and a best-in-class therapy, the Company's plans to advance atacicept into pivotal Phase 3 development in the first half of 2023, and regulatory matters, including the timing and likelihood of success in obtaining drug approvals. 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 "anticipate," "will," "potential," "plan," 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, 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 SEC. 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. 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	Slide presentation entitled "Origin Phase 2b Clinical Trial Data Update".
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: January 30, 2023

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

Exhibit 99.1

vera therapeutics

origin

Phase 2b Clinical Trial Data Update

January 30, 2023

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 therapy, the Company's plans to advance atacicept into pivotal Phase 3 development in the first half of 2023, and regulatory matters, including the timing and likelihood of success in obtaining drug approvals. 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 “could,” “will,” “potential,” “plan,” 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, 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. All forward-looking statements contained in this presentation 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.

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.

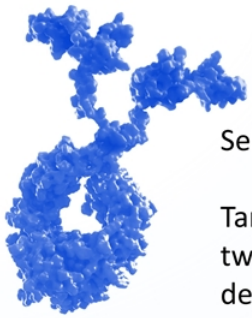
This presentation discusses product candidates that are under clinical study and which have not yet been approved for marketing by the U.S. Food and Drug Administration. No representation is made as to the safety or effectiveness of these product candidates for the use for which such product candidates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

Opening Remarks	Marshall Fordyce, MD	Founder and CEO, Vera Therapeutics
origin Phase 2b Results	Jonathan Barratt, PhD, FRCP	Professor, University of Leicester
Takeaways and Phase 3 Plans	Marshall Fordyce, MD	Founder and CEO, Vera Therapeutics
Q&A	Marshall Fordyce, MD Celia Lin, MD Jonathan Barratt, PhD, FRCP	Founder and CEO, Vera Therapeutics CMO, Vera Therapeutics Professor, University of Leicester

Atacicept for IgA Nephropathy



Self-administered subcutaneous biologic therapy in development for IgAN

Targets the source of IgAN disease, Gd-IgA1 and its immune complexes, by inhibiting two cytokines, BLyS (also known as BAFF) and APRIL, important in B cell and plasma cell development and maturation

origin

Currently being studied in a Phase 2b multinational, 36-week randomized, placebo-controlled, double-blind trial, with a 60-week open label extension

January 2023, reporting positive week 24 and 36 prespecified per-protocol (PP) and intent-to-treat (ITT) results

Gd-IgA1 = galactose-deficient IgA1; BLyS = B lymphocyte stimulator; BAFF = B cell activating factor; APRIL = a proliferation-inducing ligand.

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Prespecified Per-Protocol Analysis of ORIGIN Results

Intent-to-treat (ITT)

- Jan 3 data disclosure of ORIGIN results reflected the ITT analysis of all randomized patients (n=116), which is a conservative assessment of efficacy
- ORIGIN benchmarked our primary endpoint to the Tarpeyo label to ensure a derisked Phase 3

Per-protocol (PP)

- In the prespecified PP analysis, the population was defined as patients who had completed treatment according to protocol (n=102); 14 patients across all treatment arms who had protocol violations were identified by a blinded third-party CRO and excluded:
  - 6 due to change in background RAASi post-randomization
  - 3 due to inadequate time of SGLT2i stability (<8 weeks prior to screening)
  - 3 due to missing UPCR data at week 24
  - 1 due to prohibited medication
  - 1 due to compliance <80%
- PP analysis was a planned and prespecified analysis, but not available at the time of our ITT data disclosure
- We believe the PP analysis represents a more accurate assessment of treatment efficacy when compared to the ITT analysis because it minimizes potential confounders for proteinuria measure

RAASi = renin-angiotensin-aldosterone system inhibitor; SGLT2 = sodium-glucose cotransporter-2; UPCR = urine protein:creatinine ratio.

Summary of Positive Phase 2b Results

Met primary endpoint, clinically & statistically significant UPCR reductions, deepening over time

	Week 24 full data			Week 36 interim data		
	Atacicept 150 mg	Placebo	Δ	Atacicept 150 mg	Placebo	Δ
PP analysis	**-41%**	**-10%**	**34%**	**-47%**	**+3%**	**48%**
ITT analysis	-33%	-7%	28%	-36%	-4%	33%

Stable eGFR through week 24 for patients on atacicept

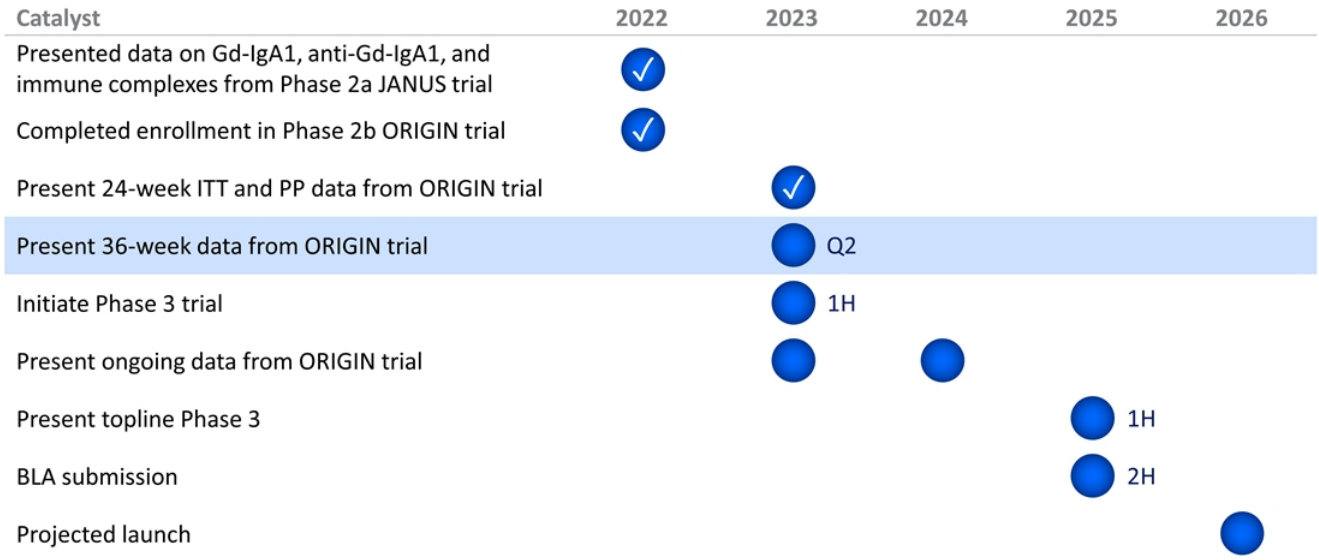
Gd-IgA1 reduction of 60% at week 24 with atacicept 150 mg

Atacicept safety profile in IgAN patients similar to placebo

Atacicept 150 mg dose selected for Phase 3 clinical trial, expected to initiate in 1H 2023

eGFR = estimated glomerular filtration rate.

Atacicept: Potential Value Creation Over Next 18 Months



Vera holds worldwide, exclusive rights to develop and commercialize atacicept

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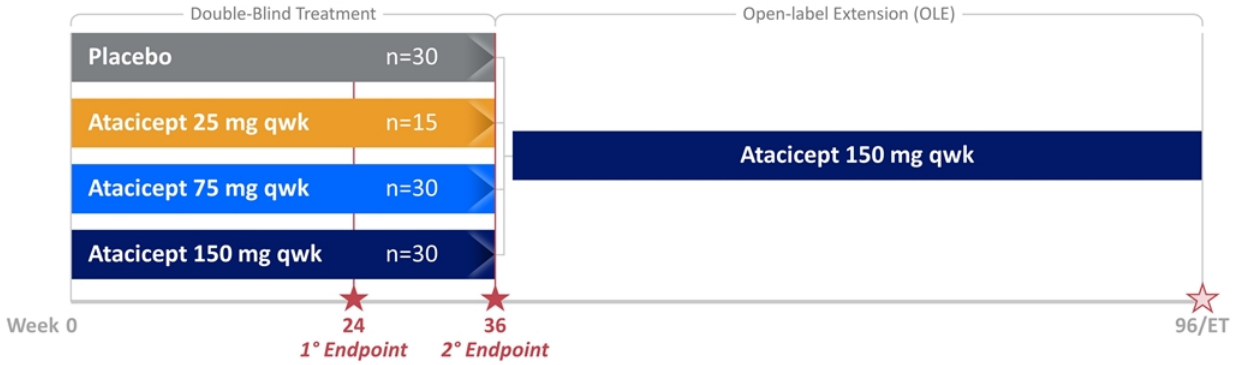
ORIGIN Phase 2b IgAN Trial: Study Design and Objectives

Multinational, randomized, placebo-controlled trial powered for 28% Δ between pooled 75/150 mg arms vs placebo



Inclusion Criteria

- Patients ≥18 years old with IgAN on renal biopsy and high risk of disease progression
- Stable and optimized RAASi for 12 weeks
- UPCR-24h >0.75 g/g or UP >0.75 g per 24h
- eGFR ≥30 mL/min/1.73 m^2
- 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
- Safety

ET = end of treatment.

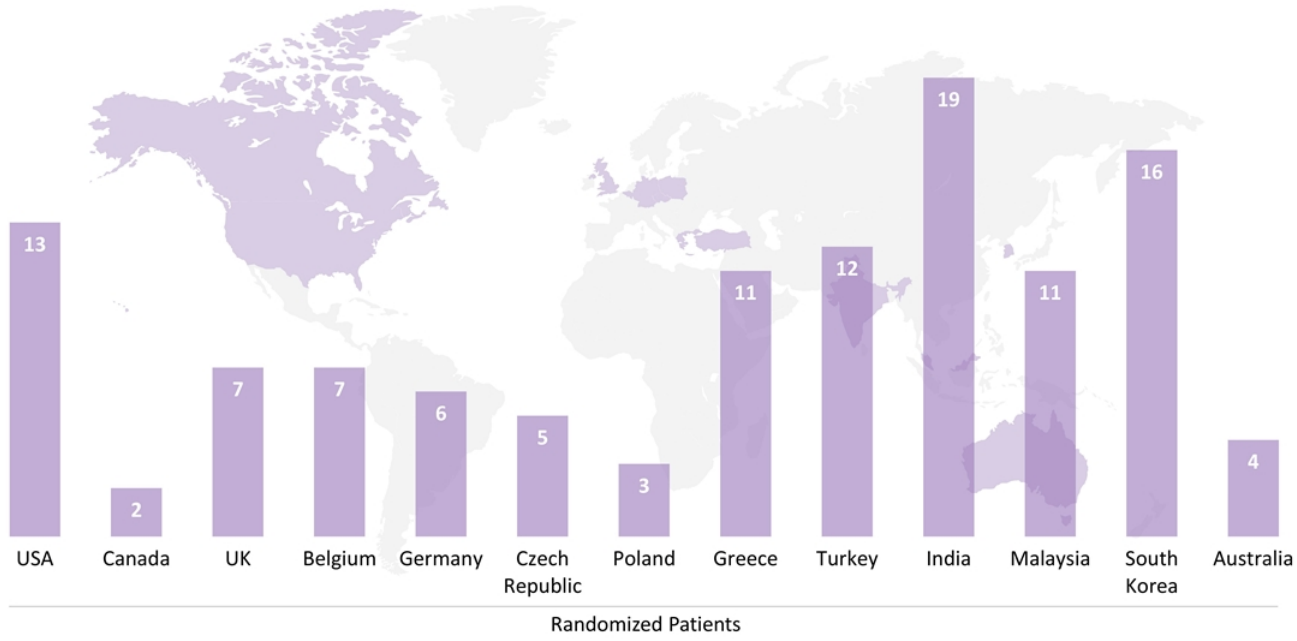
30% Reduction in Proteinuria is Known to be Clinically Meaningful in IgAN Patients

- 30% reduction in proteinuria at week 36 is associated with improvement of renal function in IgAN as measured by eGFR slope[1]
- Reduction of 30% could delay ESRD by over 10 years[2]

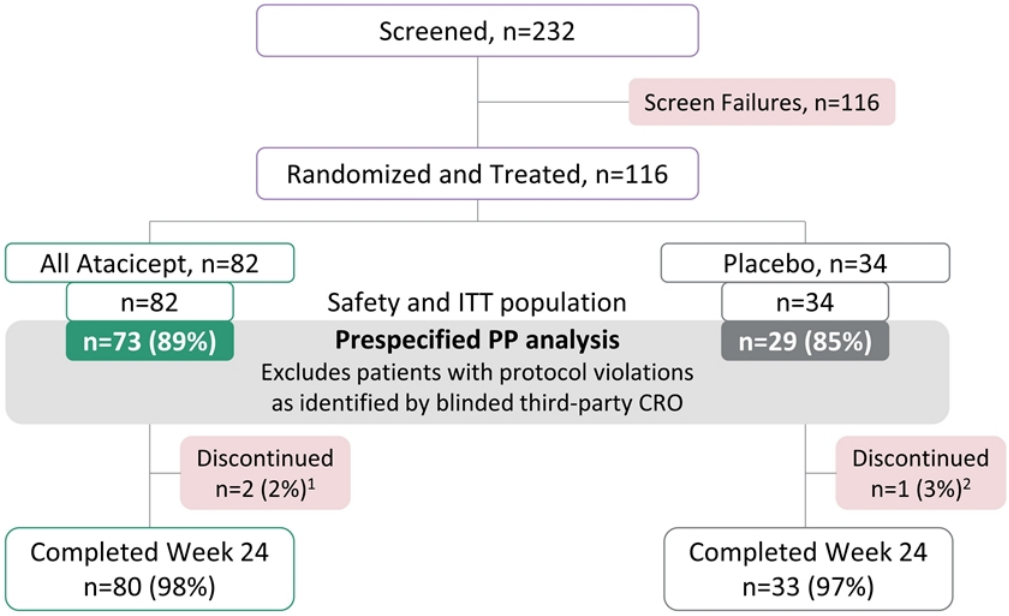
- Early change in proteinuria at week 36 is an approvable surrogate endpoint for FDA accelerated approval, based on precedent set by Calliditas' Tarpeyo
- eGFR slope at 2 years is the key confirmatory endpoint for full approval

1. Inker LA, et al. Am J Kidney Dis 2021;78:340-9.E1; 2. Barratt Lab, University of Leicester.
ESRD = end stage renal disease.

Multinational, Randomized, Placebo-controlled Phase 2b Trial



Patient Disposition

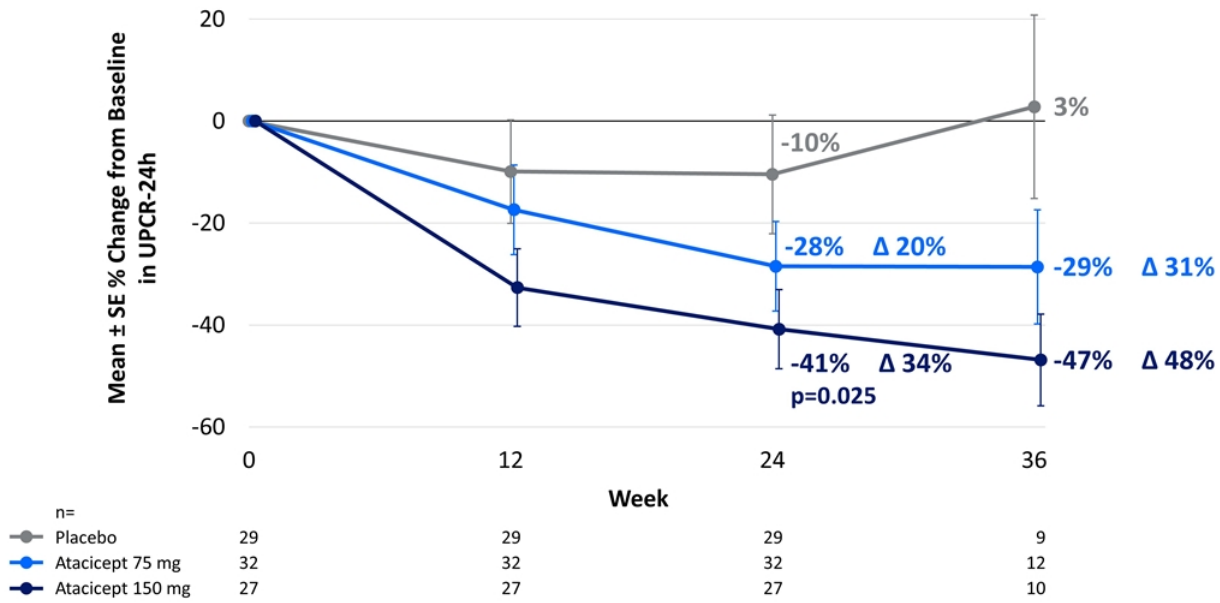


Safety data includes all post-week 24 visits available at data-cut December 23, 2022. ITT = intent to treat. PP = per protocol.
1. Discontinued to pursue elective surgery (1) and adverse event (1). 2. Initiated prohibited medication for concomitant disease.

Demographics and Baseline Characteristics

Mean ± SD or n (%)	Overall n=116	Atacicept 25 mg n=16	Atacicept 75 mg n=33	Atacicept 150 mg n=33	Placebo n=34
Age, y	39	40	41	38	39
Male sex	69 (59)	9 (56)	19 (58)	22 (67)	19 (56)
Race					
White	62 (53)	7 (44)	12 (36)	17 (52)	26 (76)
Asian	51 (44)	7 (44)	20 (61)	16 (48)	8 (24)
Other	3 (3)	2 (12)	1 (3)	0	0
eGFR, mL/min/1.73 m^2	63 ± 27.3	71 ± 28.7	64 ± 25.4	56 ± 22.7	66 ± 31.7
UPCR by 24h urine, g/g	1.6 ± 0.9	1.6 ± 0.8	1.7 ± 0.9	1.7 ± 1.0	1.6 ± 0.8
SGLT2i use	16 (14)	3 (19)	3 (9)	4 (12)	6 (18)

UPCR % Change in Atacicept 75 and 150 mg Through Week 36

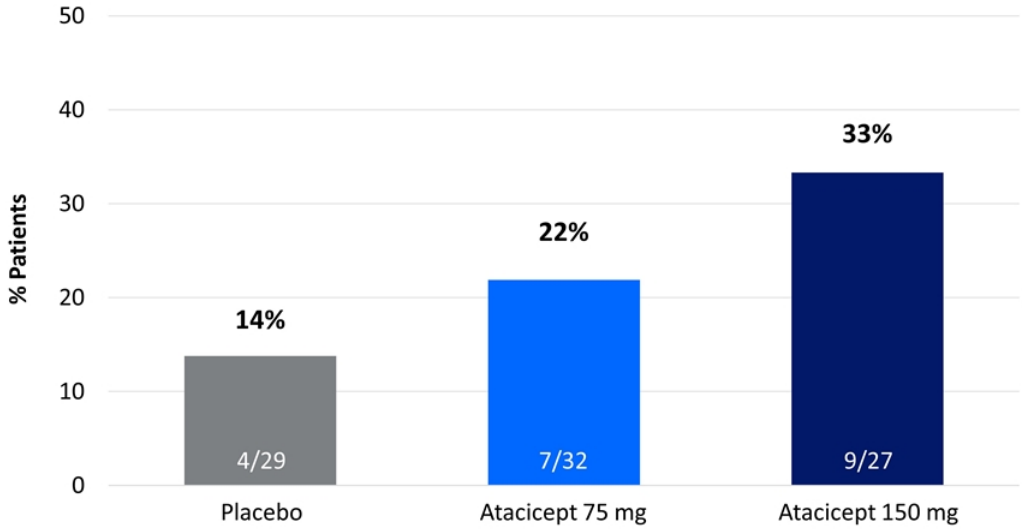


n=				
Placebo	29	29	29	9
Atacicept 75 mg	32	32	32	12
Atacicept 150 mg	27	27	27	10

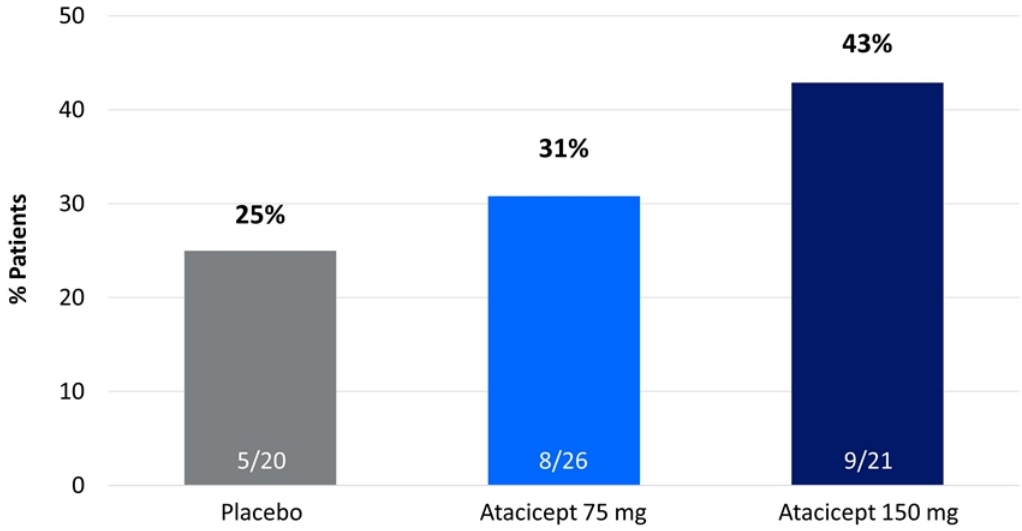
p-values, percentage changes from baseline, and treatment differences are computed using FDA endorsed mixed-effects modeling which takes into account the effects of baseline UPCR and eGFR.

Data Update: Prespecified PP Analysis

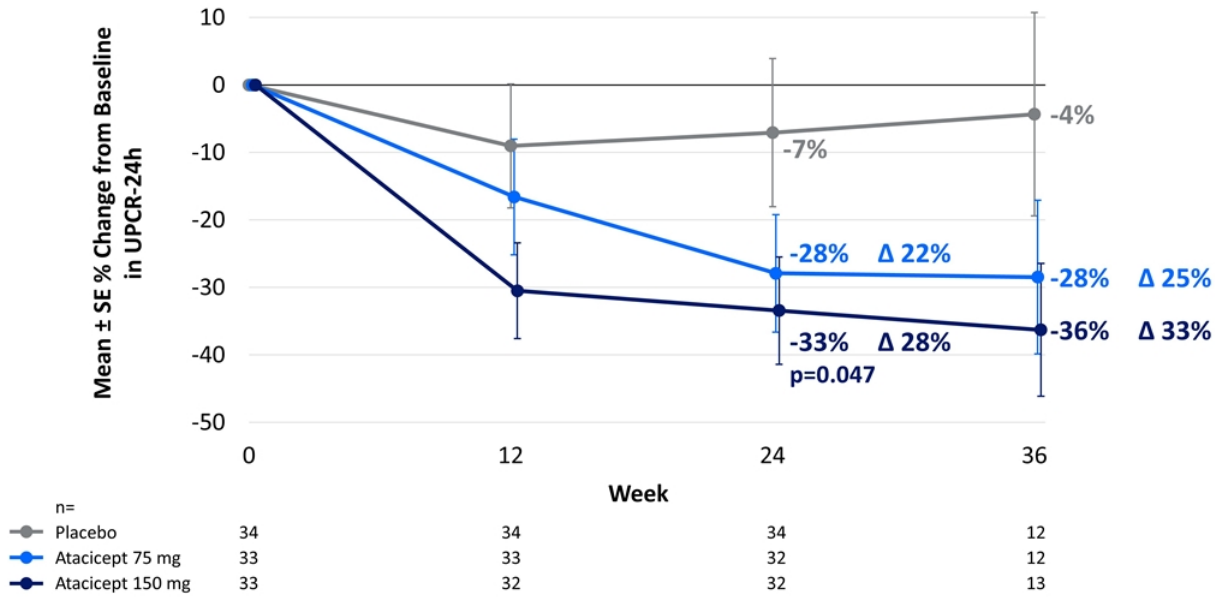
33% of Patients on 150 mg Had >50% UPCR Decrease at Week 24



43% of Patients on 150 mg with Baseline UPCR ≥1 g/g Achieved <1 g/g at Week 24



UPCR % Change in Atacicept 75 and 150 mg Through Week 36

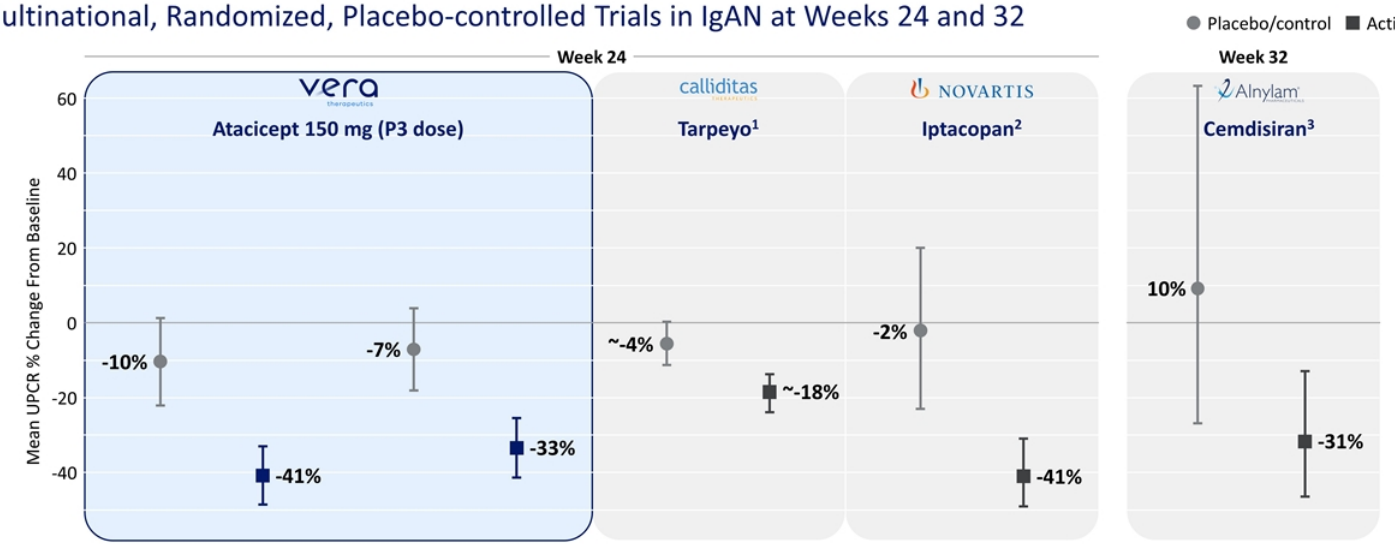


n=				
Placebo	34	34	34	12
Atacicept 75 mg	33	33	32	12
Atacicept 150 mg	33	32	32	13

p-values, percentage changes from baseline, and treatment differences are computed using FDA endorsed mixed-effects modeling which takes into account the effects of baseline UPCR and eGFR.

Atacicept P2 UPCR Data in Context – Best in Class Potential, Derisked for P3

Multinational, Randomized, Placebo-controlled Trials in IgAN at Weeks 24 and 32



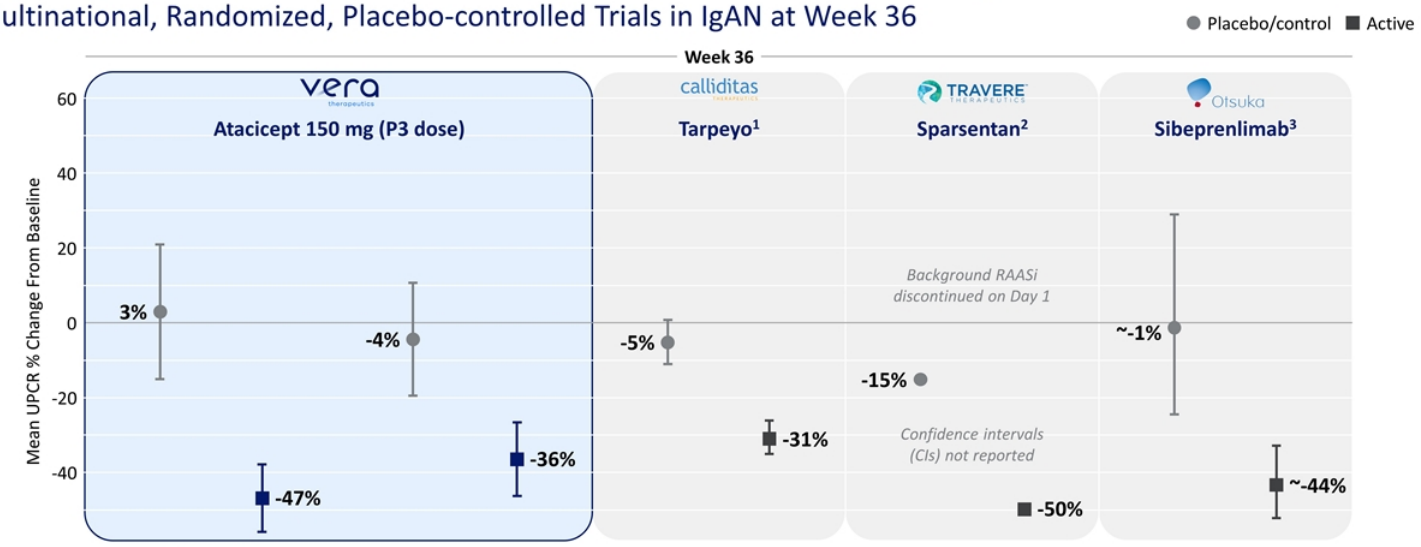
delta	Δ 34%		Δ 28%		NR		NR		Δ 37%	
n=	29	27	34	32	94	90	10	11	8	22
p-value	p=0.025		p=0.047		NR		NR		NR	
Analysis Type	Prespecified PP (full data)		ITT (full data)		FAS (full data)		Post-hoc, NR (interim data)		NR (full data)	
SGLT2i use	Yes				No		No		No	

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.

1. Barratt J, et al. Kidney Int 2022;S0085-2538(22)00836-5; 2. Rovin BH, et al. ASN Kidney Week 2022, abstr FR-OR59; 3. Alnylam RNAi Roundtable 2022. FAS = full analysis set; ITT = intent to treat; NR = not reported; PP = per protocol.

Atacicept P2 UPCR Data in Context – Best in Class Potential, Derisked for P3

Multinational, Randomized, Placebo-controlled Trials in IgAN at Week 36



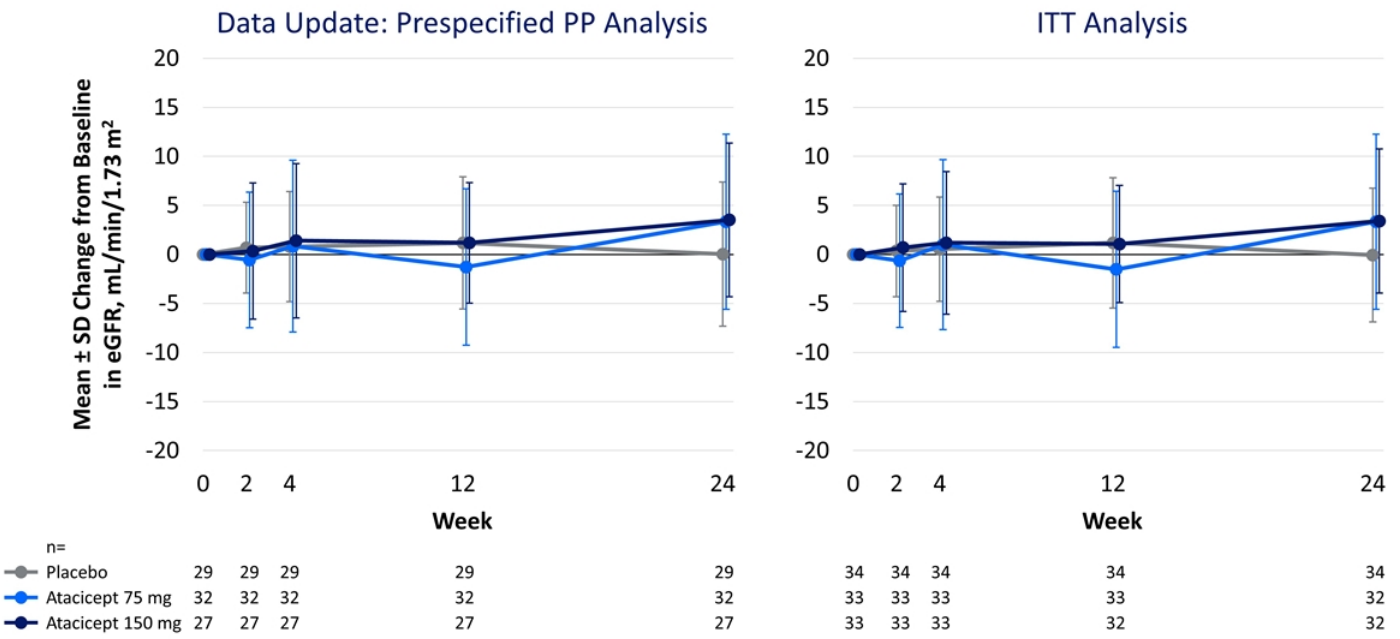
delta	Δ 48%		Δ 33%		Δ 27%		Δ 41%	Δ 43%*	
n=	9	10	12	13	89	90	280	72	
p-value	NR		NR		p=0.0003		p<0.0001	NR	
Analysis Type	Prespecified PP (interim data)		ITT (interim data)		FAS (full data)		NR (interim data)	Descriptive only (interim data)	
SGLT2i use	Yes				No		No	No	

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.

1. Barratt J, et al. Kidney Int 2022;S0085-2538(22)00836-5; 2. Travere Corporate Overview January 2023; confidence intervals not available; 3. Kooienga L, et al. ASN Kidney Week 2022.

*Not a geometric mean, statistical analysis was not performed. FAS = full analysis set; ITT = intent to treat; NR = not reported; PP = per protocol.

eGFR Changes in Atacicept 75 and 150 mg Through Week 24



n=										
Placebo	29	29	29	29	29	34	34	34	34	34
Atacicept 75 mg	32	32	32	32	32	33	33	33	33	32
Atacicept 150 mg	27	27	27	27	27	33	33	33	32	32

Summary of Clinical Safety Data Through Week 24

- Atacicept was generally well tolerated in IgAN patients, with no reported deaths, low rate (2%) of serious AEs overall, and 1 patient (1%) discontinued atacicept due to AE
- Infections were balanced between atacicept and placebo
- No serious AEs in atacicept 150 mg group
- No patient had study drug discontinuation or interruption due to hypogammaglobulinemia

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Atacicept for IgAN

- FDA meeting in Q4 2022 enabled alignment on Phase 3 study design to accelerate Phase 3 start
- Can leverage ORIGIN worldwide sites
- Met statistical significance in ORIGIN study
- Same SC formulation and dose as used in Phase 2, similar study design as ORIGIN Phase 2

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ORIGIN Subgroup Analyses Will Inform Phase 3 Design and Management to Maximize Competitive Positioning

origin

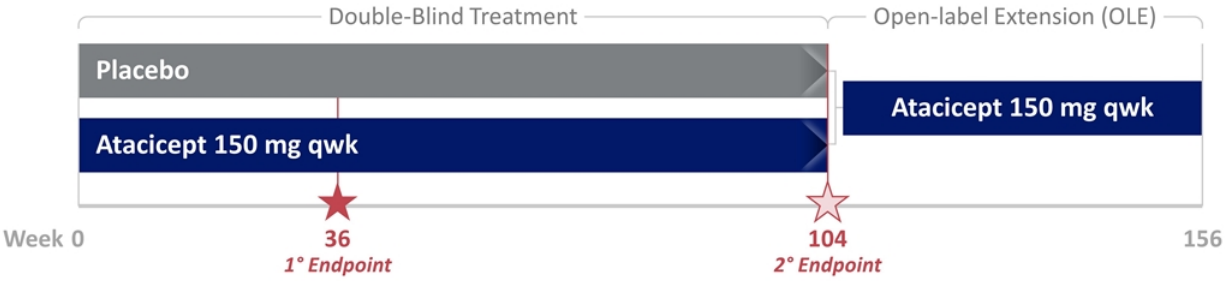
- Tested atacicept's anticipated commercial formulation and setting (at home SC self administration) in patients with wide-spectrum disease severity and racially diverse backgrounds
- Incorporated evolving SOC SGLT2i use in a multinational RCT

Proprietary subgroup analyses that will inform Phase 3 design and management include:

vera therapeutics

Initiation of Phase 3 Pivotal Trial Expected in 1H 2023

Atacicept Once Weekly SC Injection Formulation in Phase 3, Same as Phase 2b



Inclusion Criteria

- Patients ≥18 years old with IgAN on renal biopsy and high risk of disease progression
- UPCR-24h 1.0 g/g or UP 1.0 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 36 ★ to support potential accelerated approval
- Key secondary: eGFR change up to week 104 ☆
- Safety

Atacicept in IgAN: Development Program Anticipated Timeline

1. Reported original analysis at Barratt J, et al. Nephrol Dial Transplant 2020, abstr MO039 and Barratt J, et al. ASN Kidney Week 2020, abstr SU-OR35; conducted by Merck KGaA.

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