



# Corporate Presentation

January 2023

# Forward Looking Statements

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# Corporate Highlights



Our vision is to **change standard of care for patients with immunologic diseases**

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**Lead clinical-stage asset, atacicept**, is a potential **disease-modifying agent** with well-characterized clinical safety; MOA targets B cells and plasma cells with **pipeline-in-a-drug potential**

Phase 2b program in **IgA Nephropathy (IgAN)**, clinical data in hand show **best-in-disease potential**, with **positive data read-out in January 2023**

**Initiated Phase 3 program in Lupus Nephritis (LN)**, enabled by positive FDA feedback upon review of Phase 2 systemic lupus erythematosus (SLE) data and integrated safety data

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**Second late-stage asset, anti-BK virus mAb**, is a potential **first-in-class agent** targeting high unmet medical need condition with **encouraging proof-of-concept data** and expect to start a Phase 2b or 3 trial in 2023

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Strong financial profile, **~\$134M cash, cash equivalents**, and **short-term investments as of 09.30.22** and **access to a \$25M credit facility** sufficient to fund operations to **Q2 2024**

# Potential Value Creation Over Next 18 Months

Program	Indication	Catalyst	2022	2023	2024+
Atacicept	IgA Nephropathy	Presented data on Gd-IgA1, anti-Gd-IgA1, and immune complexes from Phase 2a JANUS trial	✓		
		Completed enrollment in Phase 2b ORIGIN trial	✓		
		Present 24-week data from ORIGIN trial		✓	
		Present 36-week data from ORIGIN trial			
		Initiate Phase 3 trial			
		Present open-label data from ORIGIN trial			
		Present topline Phase 3			
	Lupus Nephritis	Initiated Phase 3 COMPASS trial	✓		
		Present topline COMPASS data			
MAU868	BK Viremia in Renal Transplant	Presented full results from Phase 2 trial	✓		
		Initiate Phase 2b or 3 trial			

Vera holds worldwide, exclusive rights to develop and commercialize atacicept and MAU868

# Management Team: Successful Clinical and Commercial Track Record



**Marshall Fordyce, MD**

President and CEO

- >15 years drug dev leadership
- 7 new drug approvals, Project Lead for tenofovir alafenamide program



**Celia Lin, MD**

Chief Medical Officer

- >10 years drug dev in Clinical Development and Medical Affairs
- Led Ph3 global trial execution in various therapeutics areas



**Sean Grant, MBA**

Chief Financial Officer

- >15 years in corporate strategy, finance, and capital raising
- Former healthcare banker with capital raising and M&A experience



**Joanne Curley, PhD**

Chief Development Officer

- >20 years drug dev, former VP project and portfolio management



**Lauren Frenz, MBA**

Chief Business Officer

- 15 years industry experience, including global commercial planning and multiple blockbuster launches at Gilead
- Strategic advisory at SVB Leerink



**Joe Young, CPA, MBA**

Chief Accounting Officer

- Leader of accounting & finance operations for public and private biotech companies, >20 years
- Big 4 audit background



**Tom Doan**

SVP, Clinical Operations

- >20 years of clinical operations experience
- Former Clinical Operations Therapeutic Area Head of Inflammation at Gilead



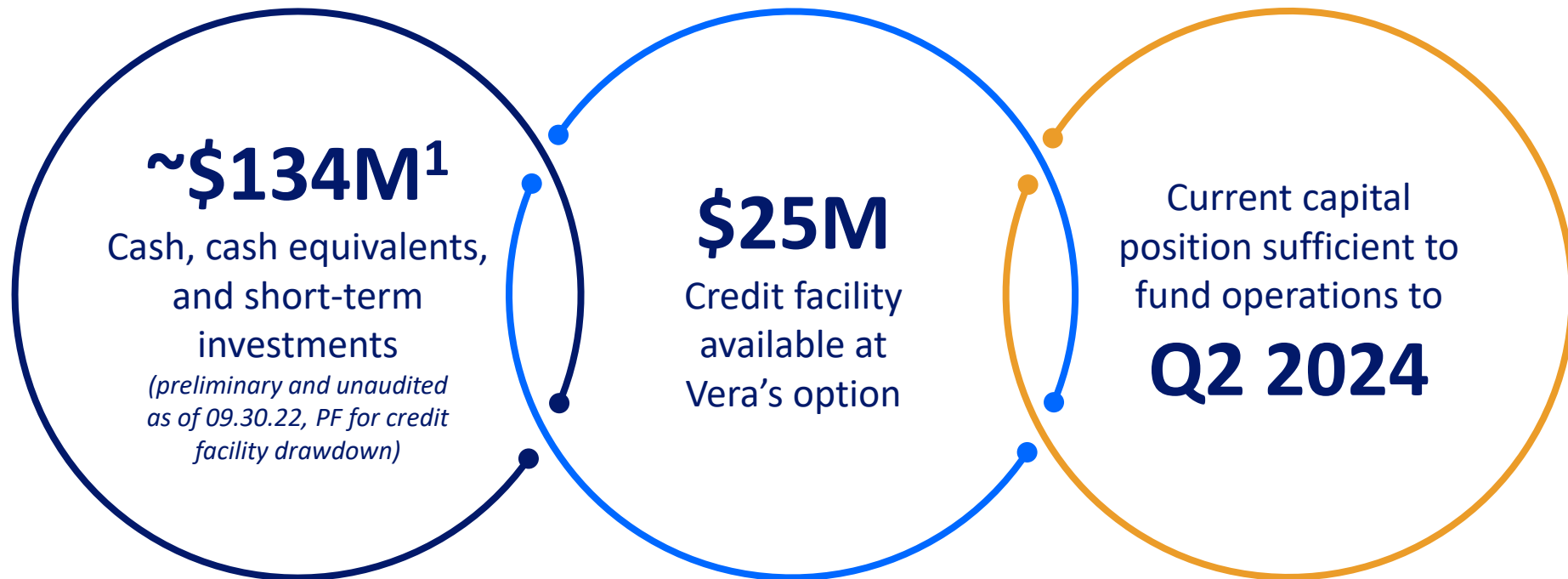
**Neeraj Pakala, PhD, MBA**

SVP, Prod Dev and Manufacturing

- >20 years CMC experience including tech transfer and managing contract manufacturing organizations





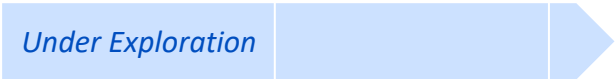



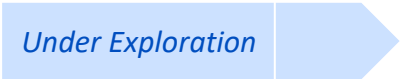



# Financial Position



1. \$114.4M of cash, cash equivalents, and marketable securities as of Sep 30, 2022. \$134M is pro forma for \$20M drawdown of Oxford debt facility in Nov 2022.

# Pipeline: Two Phase 3 Pivotal Trials Underway in 2023

Program	Indication	Phase 1	Phase 2	Phase 3	Next Milestone	Global Rights
<b>Atacicept</b> Fusion protein that blocks BLyS and APRIL	IgAN				Phase 2b week 36 data Q2 2023	
	Lupus Nephritis				Phase 3 primary endpoint 2026	
	Other Indications				Undisclosed	
<b>MAU868</b> Monoclonal antibody that neutralizes BK virus	BK Viremia in Renal Transplant				Phase 2b or 3 trial initiation 2023	
	BKV Cystitis in HSCT				Undisclosed	

BLyS = B lymphocyte stimulator; APRIL = a proliferation-inducing ligand; BAFF = B cell activating factor; HSCT = hematopoietic stem cell transplant.





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**Atacicept for IgAN**



# Large Unmet Medical Need and Significant Commercial Opportunity



Serious and progressive autoimmune disease of the kidney; average age of diagnosis 30 years old, severely impacting quality of life

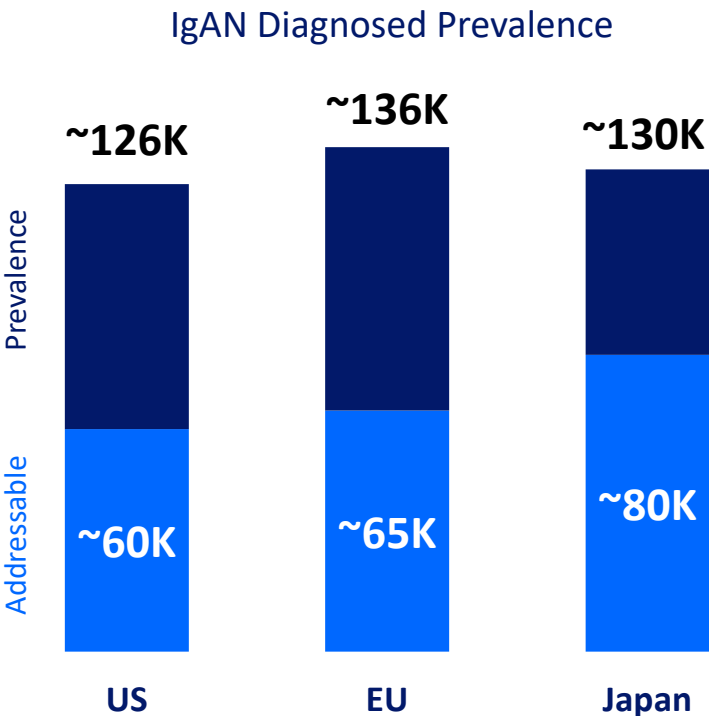


Orphan disease indication in the US and EU<sup>1</sup>



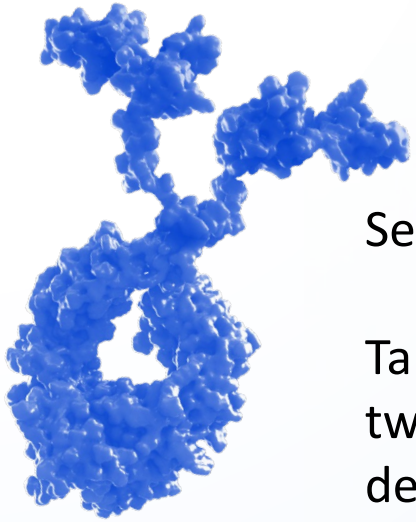
Up to 50% of IgAN patients progress to ESRD, resulting in need for dialysis or transplant

~\$6-10B Annual Market Opportunity in US, EU, and Japan for Novel IgAN Therapeutics<sup>2</sup>



1. Orphan Disease Designation not yet obtained for atacicept in IgAN; 2. ClearView Healthcare Partners Analysis. Prevalence and addressable population estimates based on peak year forecast. ESRD = end-stage renal disease.

# 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



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

On January 3, 2023, we reported positive week 24 primary results

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

# Atacicept in IgAN: Development Program Timeline

JANUS Phase 2a Topline Results<sup>1</sup>

June 2020

 origin Phase 2b Trial: Week 24 Topline Results

Reported January 3, 2022

 origin Phase 2b Trial: Week 36 Results

Expected Q2 2023

Initiation of Phase 3 Trial

Expected 1H 2023

 origin Phase 2b Trial: Open-Label Results

Expected 2023+

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.

# Summary of Positive Phase 2b Week 24 Results

## ✓ **Atacicept met primary endpoint**

- Achieved statistical significance in 150 mg dose group with 33% reduction in proteinuria from baseline with 28% placebo-adjusted reduction ( $p=0.047$ ) at an early week 24 timepoint
- Trend towards deepening reductions in proteinuria at week 36 with available data

## ✓ **Stable eGFR through week 24 for patients on atacicept**

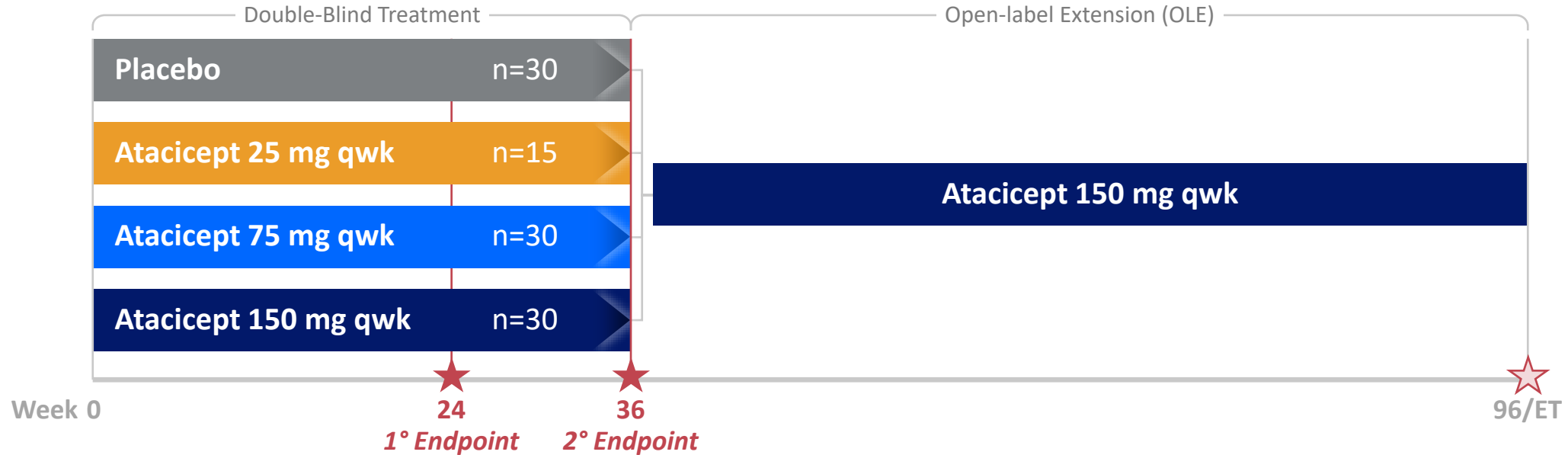
## ✓ **Gd-IgA1 reduction of 60% at week 24 with atacicept 150 mg**

## ✓ **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**

# ORIGIN Phase 2b IgAN Trial: Study Design and Objectives

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



## Inclusion Criteria

- Patients  $\geq 18$  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  $\geq 30$  mL/min/1.73 m<sup>2</sup>
- Blood pressure  $\leq 150/90$  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; RAASi = renin-angiotensin-aldosterone system inhibitor; UPCR = urine protein:creatinine ratio.

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



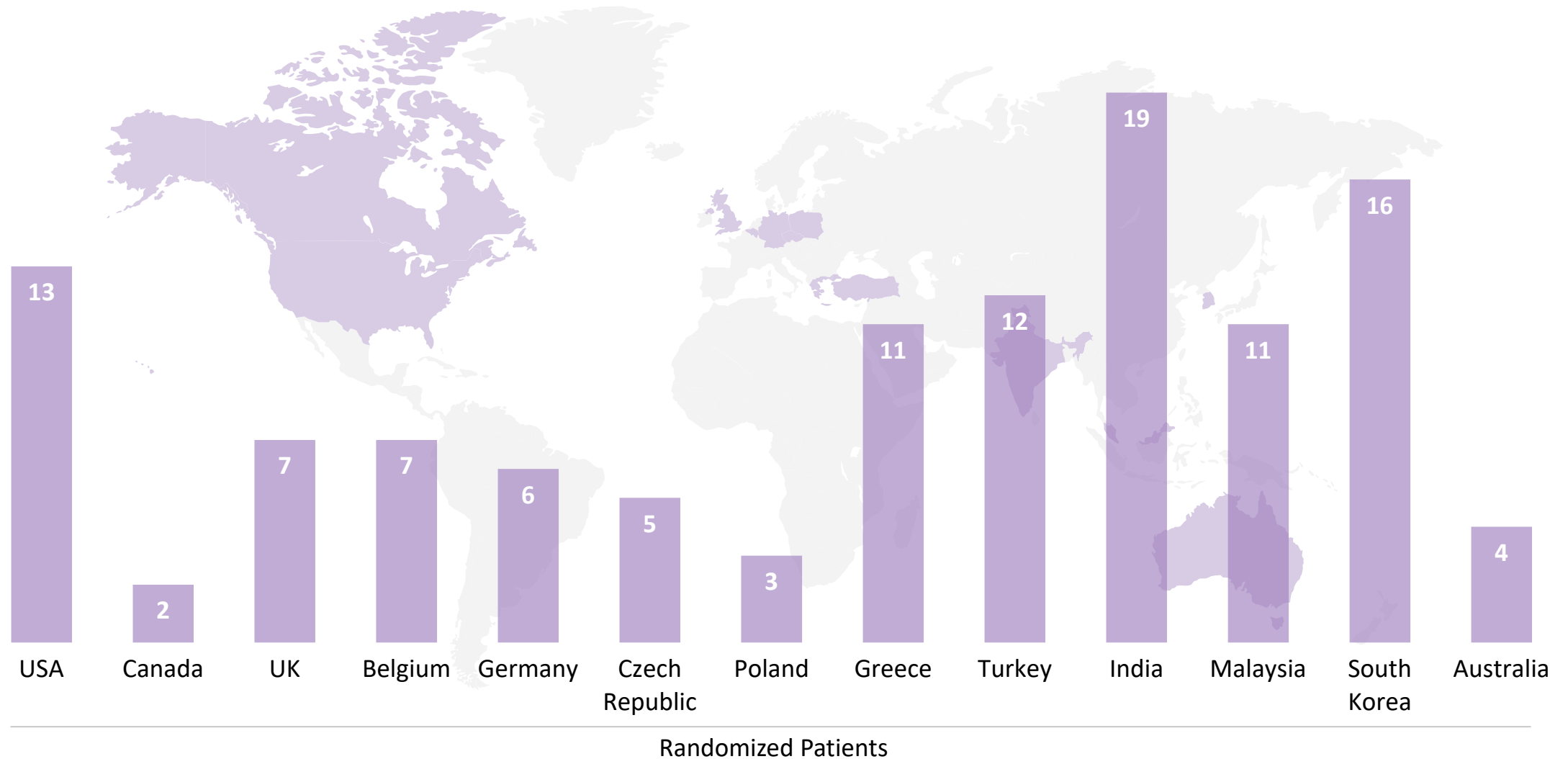
- 30% reduction in proteinuria at week 36 is associated with improvement of renal function in IgAN as measured by eGFR slope<sup>1</sup>
- Reduction of 30% could delay ESRD by over 10 years<sup>2</sup>



- First approved drug for IgAN, Tarpeyo™, showed **~18% proteinuria reduction from baseline at week 24<sup>3</sup>** and 34% at week 36,<sup>4</sup> setting the precedent for accelerated approval in IgAN
- The next PDUFA date in IgAN is for Traverser's sparsentan, which showed 35%  $\Delta$  active control-adjusted reduction in proteinuria at week 36<sup>5</sup>

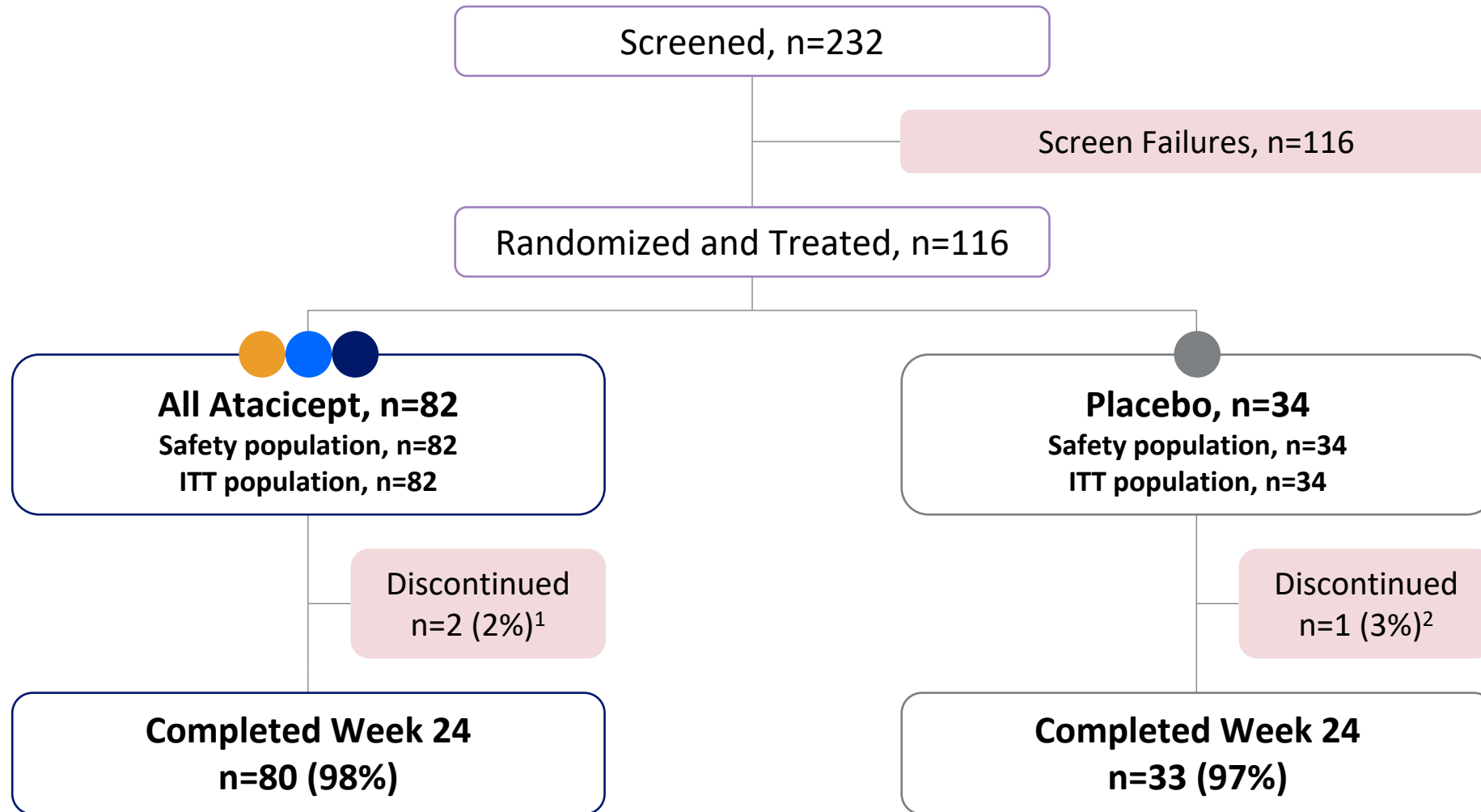
1. Inker LA, et al. Am J Kidney Dis 2021;78:340-9.E1; 2. Barratt Lab, University of Leicester; 3. Barratt J, et al. Kidney Int 2022;S0085-2538(22)00836-5; 4. . Tarpeyo [package insert]. 2021; 5. Traverser press release; Aug 16 2021.  
ESRD = end stage renal disease; PDUFA = Prescription Drug User Fee Amendment.

# 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.

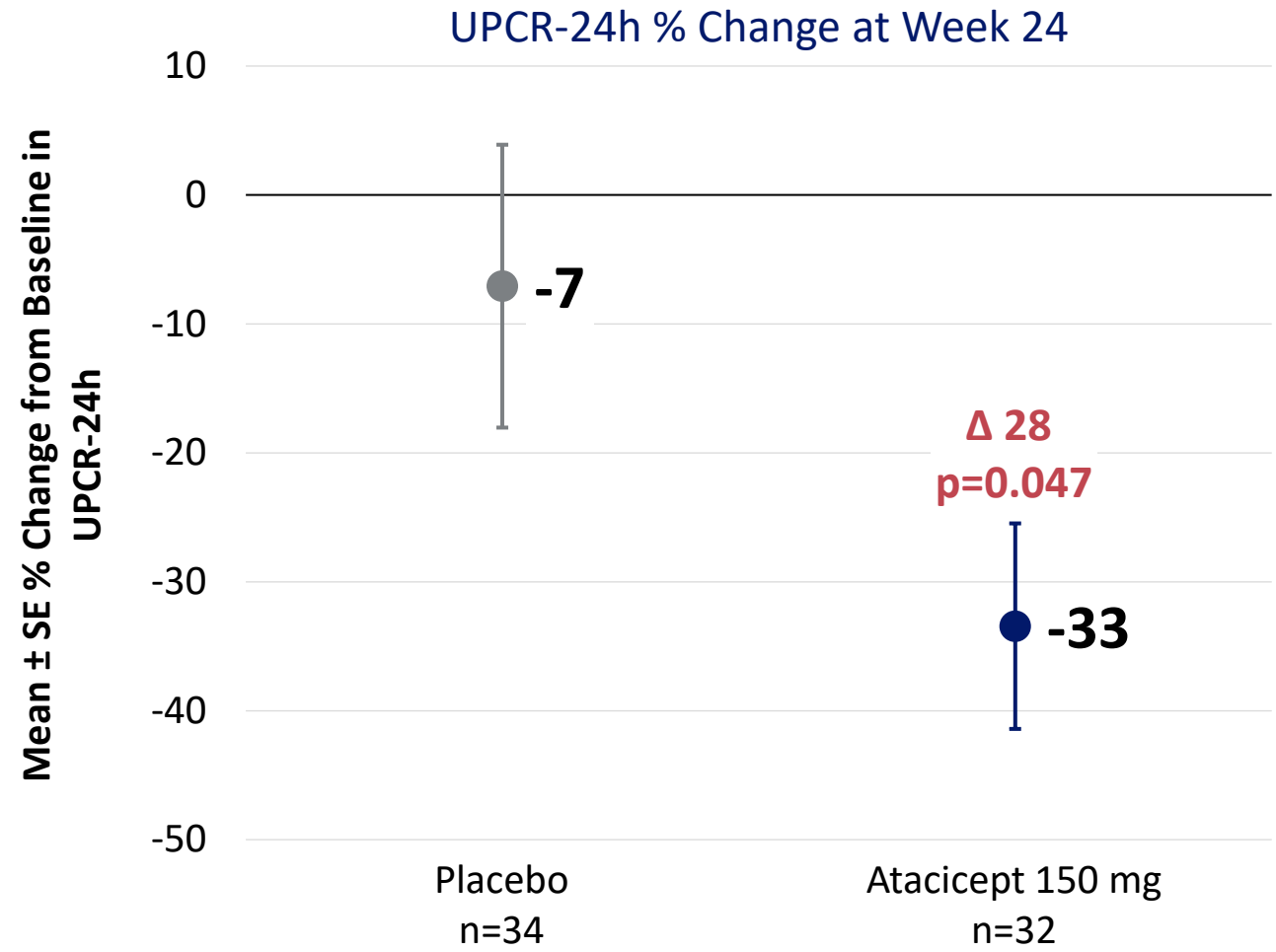
1. Discontinued to pursue elective surgery (1) and adverse event (1). 2. Initiated prohibited medication for concomitant disease.

# 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 <sup>2</sup>	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)

SGLT2 = sodium-glucose cotransporter-2.

# Atacicept 150 mg Achieved Statistically Significant UPCR Reduction

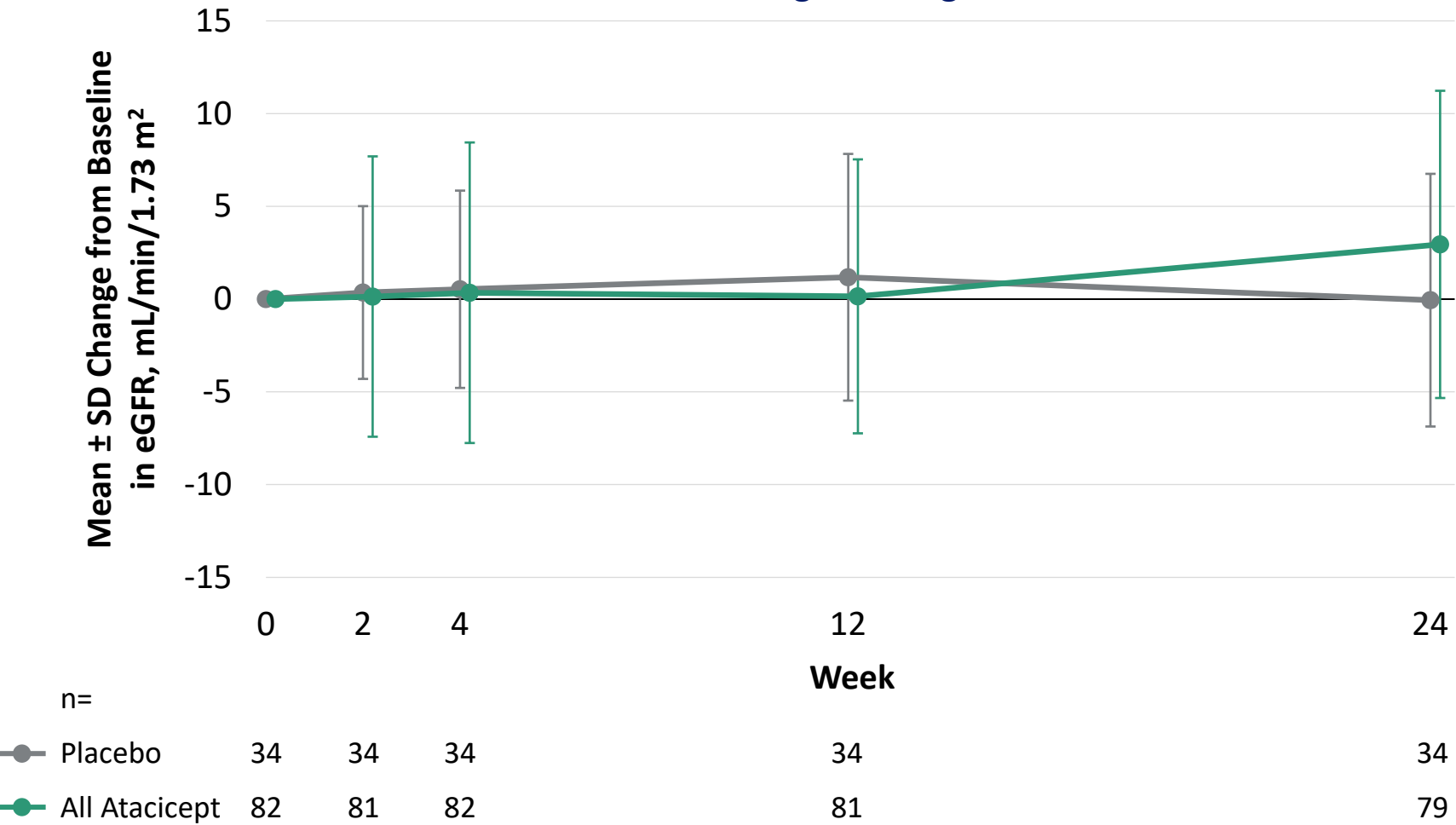


Trend towards deepening reductions in proteinuria at week 36

p-value and % change from baseline were estimated from the mixed effect model with repeated measurement (MMRM), including change from baseline in natural log transformed UPCR as the dependent variable, log transformed baseline UPCR, baseline eGFR category, treatment, visit, treatment and visit interaction terms as fixed effects, and patient as a random effect.

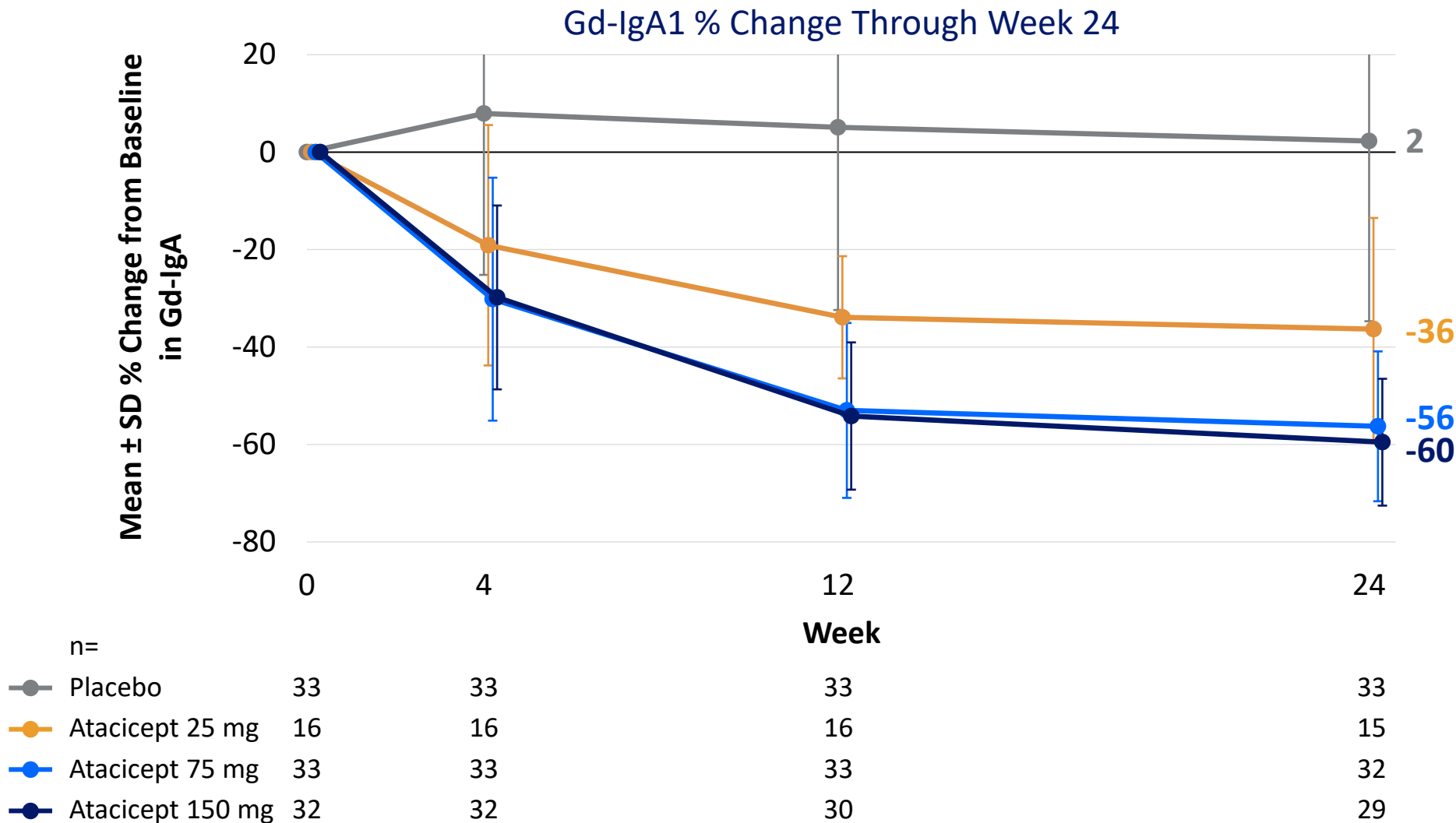
# Stable eGFR Through Week 24 in All Atacicept Group

eGFR Change Through Week 24

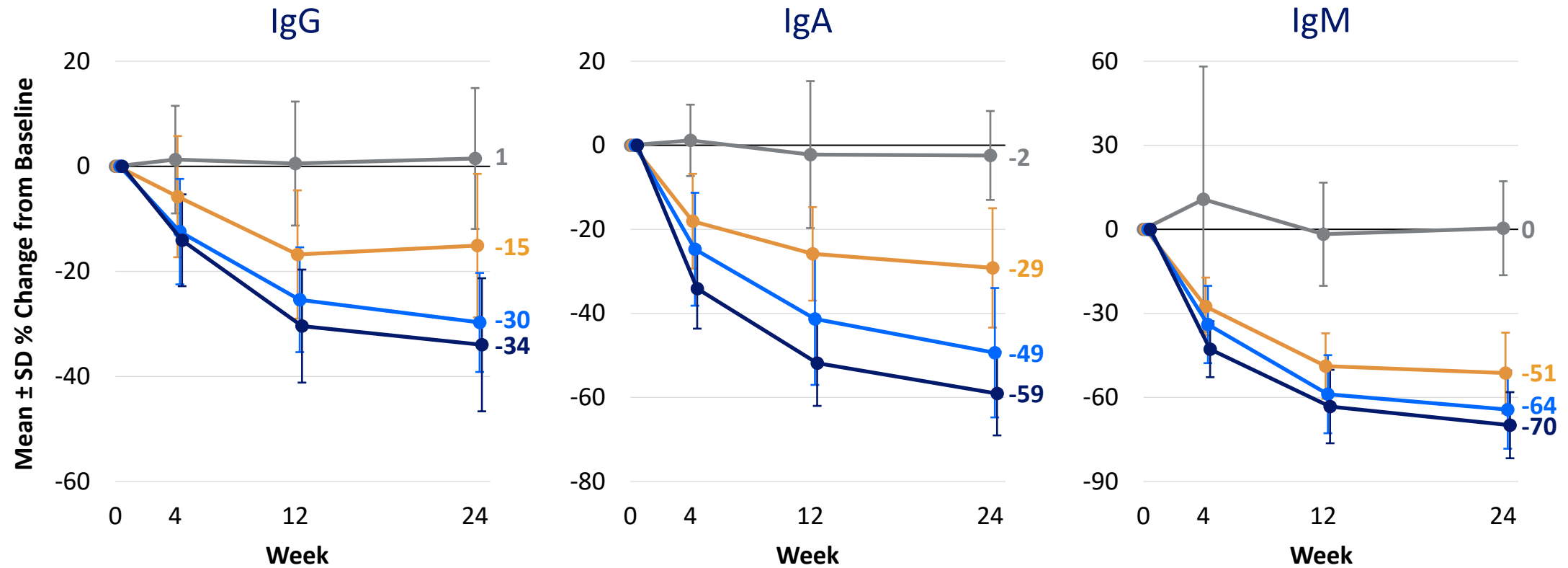


- Mean eGFR change from baseline +3 mL/min at week 24
- Similar results for atacicept 150 mg alone
- As expected, week 24 timepoint is too early to observe eGFR decline in placebo

# Robust Reductions in Gd-IgA1 Through Week 24

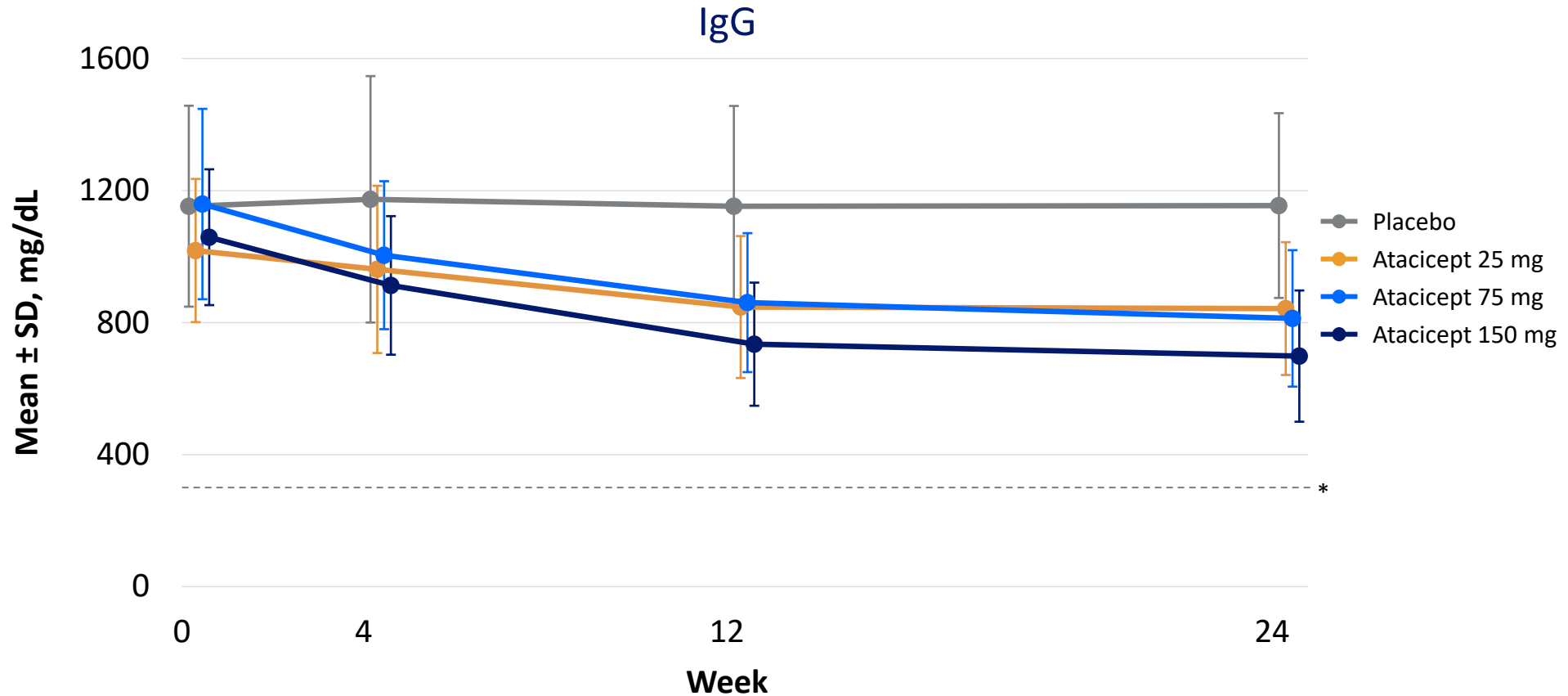


# Dose-dependent Reductions in Serum IgG, IgA, and IgM Through Week 24



n=														
Placebo	34	34	34	34	34	34	34	34	34	34	34	34	34	34
Atacicept 25 mg	16	16	16	15	16	16	16	15	16	16	15	14	14	14
Atacicept 75 mg	33	33	33	32	33	33	33	32	33	33	28	23	23	23
Atacicept 150 mg	33	33	32	32	33	33	32	31	33	32	22	19	19	19

# No Study Drug Discontinuation Due to IgG Levels on Atacicept



- No patient had study drug discontinuation, interruption, or sustained IgG <3 g/L (<300 mg/dL) through week 24

\*Per ORIGIN protocol, if serum IgG was <300 mg/dL on two consecutive timepoints at least 28 days apart, the study drug was discontinued.

One patient (atacicept 75 mg) below study-defined IgG threshold of <3 g/L at 2.99 g/L; >3 g/L upon repeat measurement; study drug continued weekly; no infections reported in this patient.



# Treatment-Emergent Adverse Events

Patients, n (%)	Atacicept 25 mg n=16	Atacicept 75 mg n=33	Atacicept 150 mg n=33	Placebo n=34
TEAEs	11 (69)	24 (73)	25 (76)	27 (79)
Study drug-related TEAEs <sup>1</sup>	6 (38)	16 (48)	18 (55)	14 (41)
Serious TEAEs	1 (6)	1 (3)	0	3 (9)
TEAEs leading to study drug discontinuation	0	0	1 (3) <sup>2</sup>	0
Deaths	0	0	0	0

1. Majority of study drug-related TEAEs were injection site reactions; one contributed to drug discontinuation

2. Discontinued after 3 injections due to injection site reaction and positive hepatitis B DNA that resolved without treatment 3 weeks later, normal liver function throughout.

# Infections Were Balanced Between Atacicept and Placebo

<b>Patients, n (%)</b>	<b>Atacicept 25 mg n=16</b>	<b>Atacicept 75 mg n=33</b>	<b>Atacicept 150 mg n=33</b>	<b>Placebo n=34</b>
Infections (all mild or moderate; no severe)	6 (38)	16 (48)	12 (36)	11 (32)
Occurring in >1 patient				
COVID-19 <sup>1</sup>	4 (25)	9 (27)	8 (24)	6 (18)
Upper respiratory tract infection	0	3 (9)	2 (6)	0
Viral infection	0	2 (6)	0	2 (6)
Nasopharyngitis	0	1 (3)	1 (3)	1 (3)
Urinary tract infection	2 (13)	1 (3)	0	0
Influenza	0	1 (3)	0	1 (3)
Tonsillitis	1 (6)	1 (3)	0	0





1. One patient with COVID-19 was hospitalized and recovered.

## Summary of Clinical Safety Data

- ✓ 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

# Atacicept Phase 2 Week 24 Data in Context

Multinational, Randomized, Placebo-controlled Trials

	 <b>Tarpeyo™ (approved)</b>	 <b>Sparsentan</b>	 <b>Sibeprenlimab</b>	 <b>Atacicept</b>
Dose Regimen & Administration	16 mg oral 9-month duration only	200 or 400 mg oral	2–8 mg/kg IV (Ph 2) 400 mg SC (Ph 3) (1 x 2 mL injection)	<b>150 mg SC qwk selected for Ph 3</b> (1 x 1 mL injection)
Mechanism	Corticosteroids can modulate B-cell numbers and activity	ETaR/AT1R antagonism	APRIL inhibition only	Dual BlyS/APRIL inhibition
Proteinuria Change	<b>Week 24</b> ~-18% vs ~-4% placebo <sup>1</sup>	Not reported	Not reported	-33% vs -7% placebo 28% Δ
	<b>Week 36</b> -34% vs -5% placebo 31% Δ <sup>2</sup>	-50% vs -15% control 35% Δ <sup>4</sup>	43% Δ pooled IV data <sup>5</sup> SC efficacy data not established	<b>To come</b>
Gd-IgA1 Change from Baseline	~-34% week 36 <sup>3</sup>	N/A	Not reported	-60% week 24
Safety Data	Most AEs that occurred at a greater incidence vs placebo were consistent with hypercortisolism	Not reported	No placebo comparison reported	Comparable to placebo

**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. Tarpeyo [package insert]. 2021; analysis includes all patients with UPCR data at week 36 regardless of use of prohibited medication; 3. Molyneux K, et al ASN Kidney Week 2022; 4. Traverse press release; 2021. <https://ir.traverse.com/news-releases/news-release-details/traverse-therapeutics-announces-positive-topline-interim-results>; 5. Kooienga L, et al ASN Kidney Week 2022; data presented at “month 9” assumed to be at week 36. ETaR = endothelin-1 type A receptor; AT1R = angiotensin II type 1 receptor.

# Disease-Modifying Therapies for IgAN: Dual BLyS/APRIL vs APRIL-Only Approaches



## Atacicept



## Sibeprenlimab



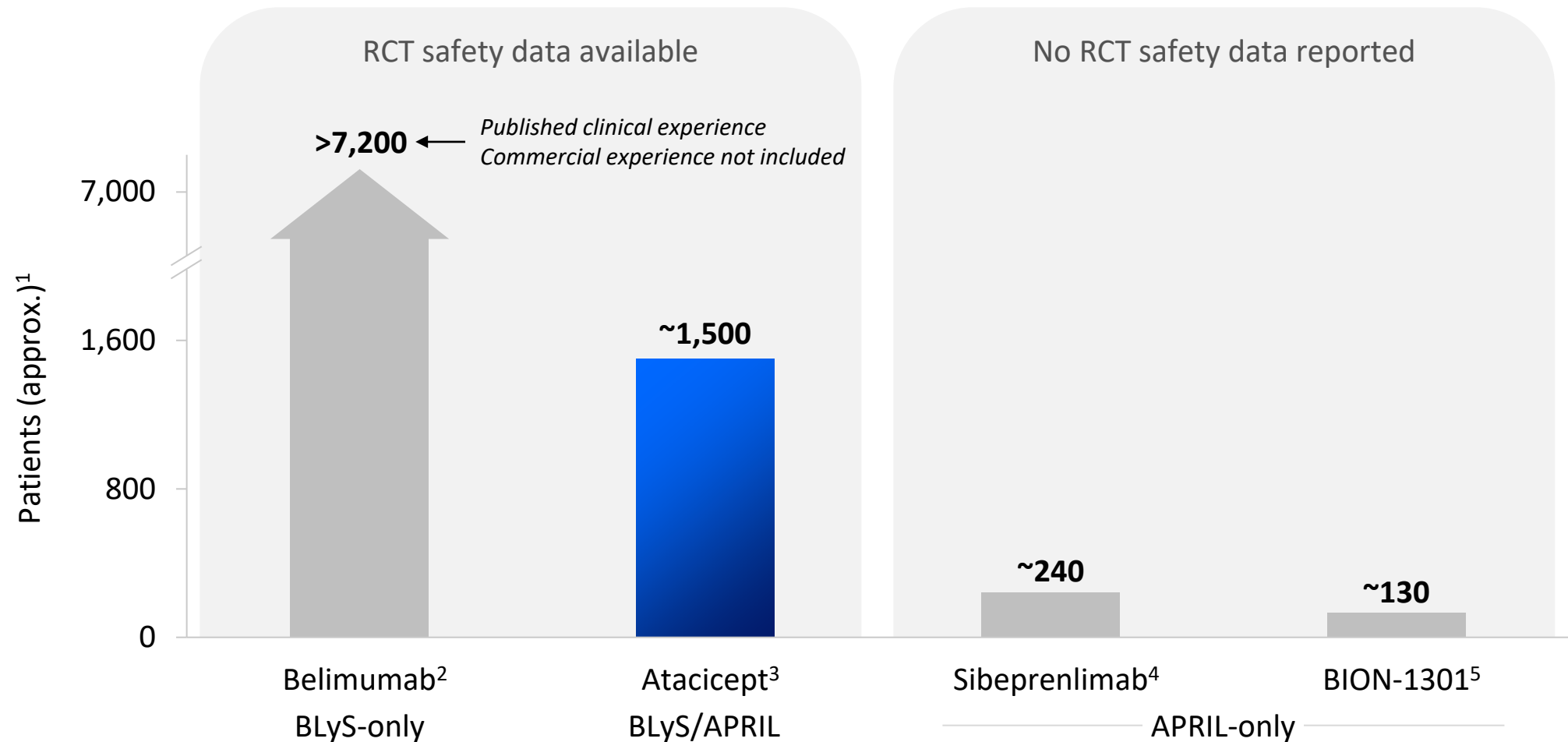
## BION-1301

Dose Regimen & Administration	<b>150 mg SC qwk selected for Ph 3</b> (1 x 1 mL injection)	2–8 mg/kg IV (Ph 2) 400 mg SC monthly (Ph 3) (1 x 2 mL injection)	450 mg IV q2wk (Ph 2) 600 mg SC q2wk (Ph 2, Ph 3) (2 x 2 mL injection)
Mechanism	Dual BLyS/APRIL inhibition	APRIL inhibition only	APRIL inhibition only
Global RCT	✓	✓	✗
N (total randomized & treated for Ph 2 study)	116	155 <sup>1</sup>	10 Cohort 1; 24 Cohort 2 <sup>2</sup>
Number of countries	13	15	3
Patient race	53% White, 44% Asian, 3% Other	23% White, 74% Asian, 3% Other	62% White, 32% Asian, 6% Other
SGLT2i use	14%	Not reported	Not reported
Baseline eGFR, mL/min/1.73 m <sup>2</sup>	mean 63	Not reported	median 69 Cohort 1; median 75 Cohort 2
Baseline UPCR, g/g	mean 1.7	Not reported	median 0.5 Cohort 1; median 0.8 Cohort 2
Proteinuria Change	Week 24 -33% vs -7% placebo 28% Δ	Not reported	-49% Cohort 1, -54% Cohort 2 vs baseline, n=17 (open-label case series) No placebo reported
	Week 36 <b>To come</b>	43% Δ pooled IV data (interim analysis) SC efficacy data not established	Not reported
Gd-IgA1 Change from Baseline	-60%, week 24, n=29	Not reported	-60 to -65%, week 24, n=7
Safety Data	Comparable to placebo	No placebo comparison reported	No placebo comparison reported

**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. Kooienga L, et al. ASN Kidney Week 2022. Data presented at “month 9” assumed to be at week 36; 2. Barratt J, et al. ASN Kidney Week 2022.

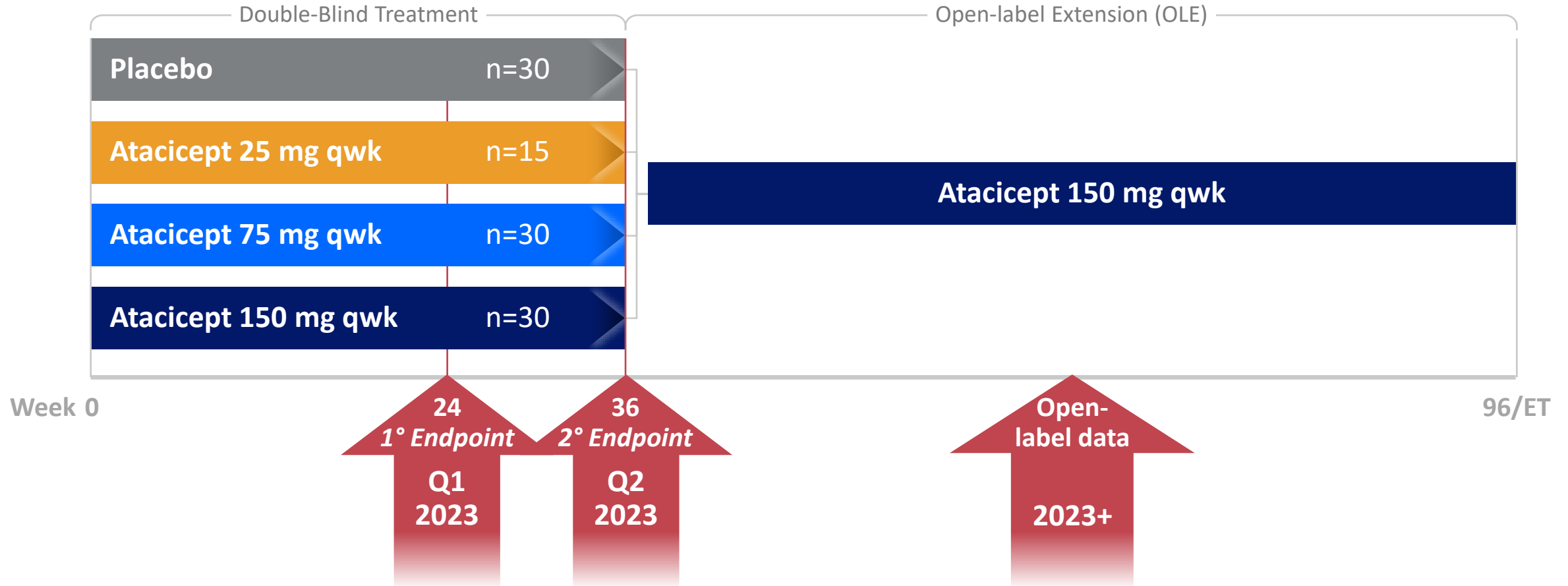
# Atacicept Has Well Characterized Safety Database vs APRIL-Only Approaches



1. Patients administered ≥1 dose of listed medication as of November 2022 review of published literature; 2. Based on published results involving safety per Levy et al Lupus 2021; excludes other clinical studies and post-marketing/commercial experience; 3. Atacicept Integrated Safety Analysis by Gordon et al Rheumatol Adv Pract 2019 plus IgAN JANUS and ORIGIN studies; 4. Two Ph1 healthy volunteer studies (Mathur et al Kidney Int Rep 2022, Zhang et al ASN 2021 poster), Ph2 ENVISION study in IgAN (Kooienga et al ASN 2022 poster); 5. Two Ph1 healthy volunteer studies (Chinook 4<sup>th</sup> CKD Summit 2022), Ph1/2 IgAN study (Barratt et al ASN 2022 poster), Ph1/2 multiple myeloma study (Bensinger et al ASCO 2019 abstract). RCT = randomized controlled trial.

# ORIGIN Phase 2b IgAN Trial: Ongoing Data Readouts in 2023

Multinational, randomized, placebo-controlled

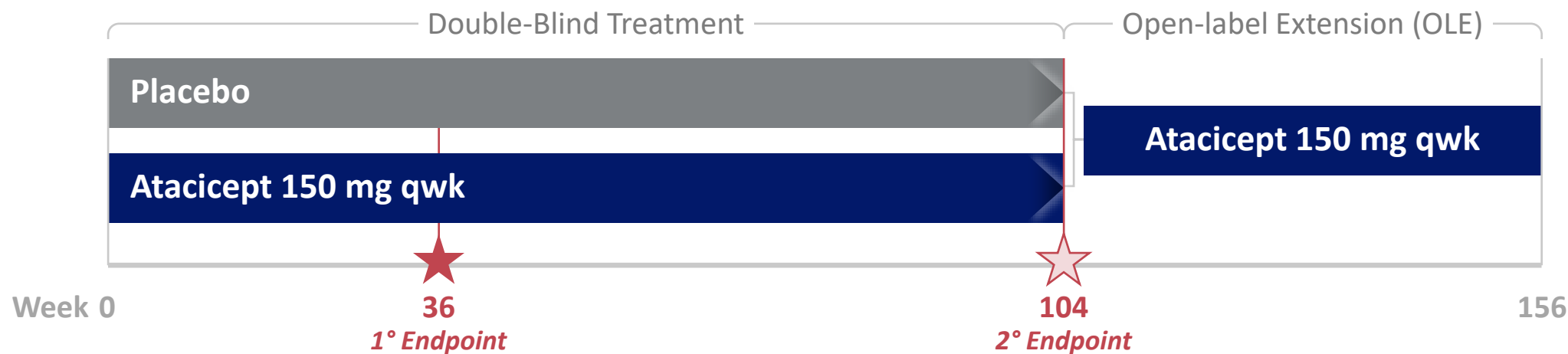


ET = end of treatment; RAASI = renin-angiotensin-aldosterone system inhibitor; UPCR = urine protein:creatinine ratio.



# 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  $\geq 18$  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  $\geq 30$  mL/min/1.73 m<sup>2</sup>
- Stable and optimized RAASi for 12 weeks
- Use of SGLT2i allowed
- Blood pressure  $\leq 150/90$  mmHg

## Endpoints

- Primary efficacy: UPCr-24h at week 36 ★ to support potential accelerated approval
- Key secondary: eGFR change up to week 104 ★
- Safety



## Regulatory Update

## Rapidly Advance Phase 3

## Atacicept 150 mg Dose Selection

## Atacicept for IgAN

- FDA meeting in Q4 2022 discussed preliminary alignment on Phase 3 study design to enable start in 1H 2023
- Final trial design pending FDA concurrence
- Can leverage ORIGIN worldwide sites
- Met statistical significance in ORIGIN study



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**Atacicept for LN**

# Lupus Nephritis: Multibillion Dollar Market Opportunity



Severe renal manifestation of SLE, high morbidity and mortality, many patients progress to ESRD



Current treatment involves combination of immunosuppressants and steroids

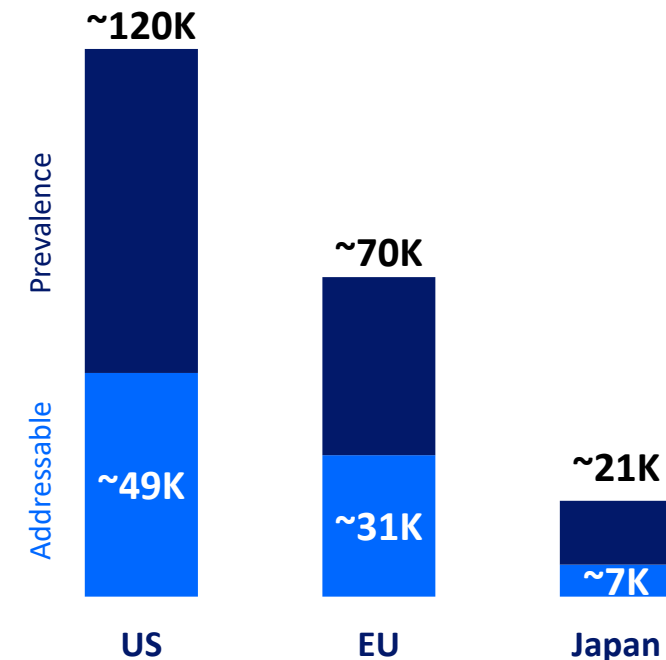


Two recently approved therapies, Benlysta (belimumab) and Lupkynis (voclosporin) leave room for improvement in risk/benefit for patients

- Benlysta renal response at week 104: 30% (active) vs 20% (placebo)<sup>1</sup>
- Lupkynis renal response at week 52: 41% (active) vs 23% (placebo)<sup>2</sup>

**~\$3–6B Annual Market Opportunity in US, EU, and Japan for Novel LN Therapeutics<sup>3</sup>**

LN Diagnosed Prevalence



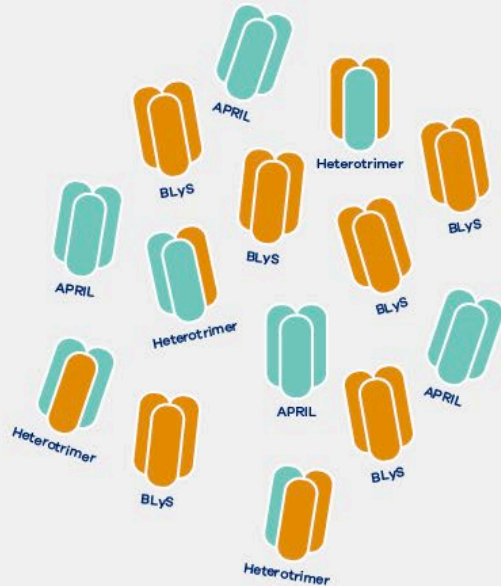
1. Furie R, et al. N Engl J Med 2020. 2. Arriens C, et al. Ann Rheum Dis 2020. 3. ClearView Healthcare Partners Analysis. Prevalence and addressable population estimates based on peak year forecast.



# Atacicept Blocks Elevated B Cell Cytokines Driving the Underlying Disease in Lupus Nephritis

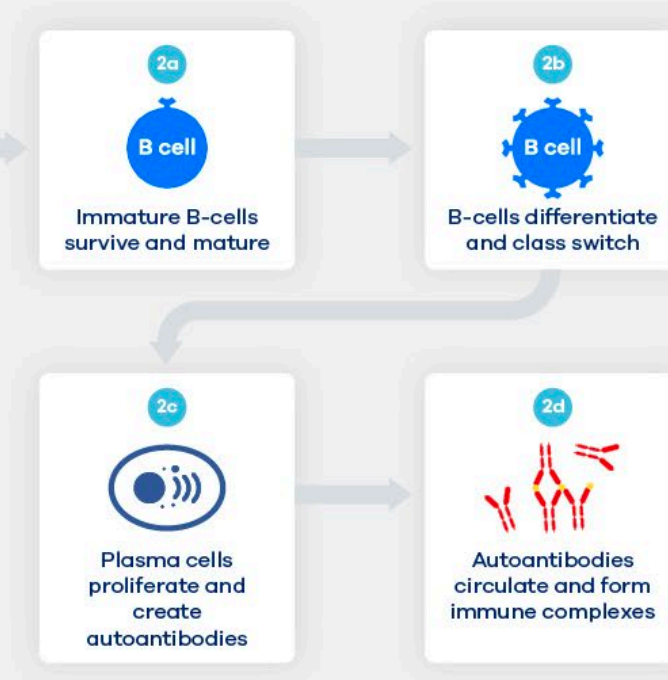
## Cytokine Abnormalities

- 1 Patients with Systemic Lupus Erythematosus may have higher levels of BLyS and APRIL, contributing to the pathogenesis of Lupus Nephritis



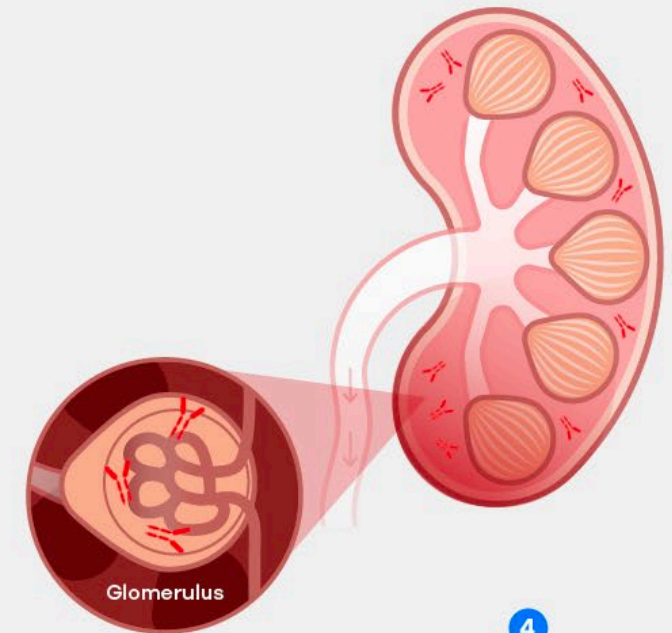
## B-Cell Dysregulation

- 2 BLyS and APRIL promote the survival, maturation and differentiation of B-cells and plasma cells - that then produce disease-causing antinuclear and anti-DNA autoantibodies



## Glomerulonephritis

- 3 Autoantibodies and immune complexes deposit in glomeruli

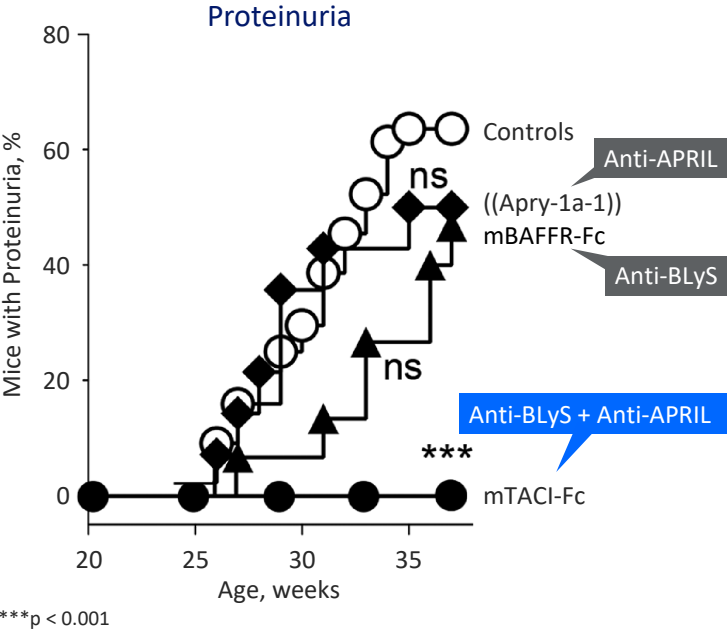


- 4 Progressive renal injury

 Steps that Atacicept targets

# Atacicept Has Potential to Outperform Approved BLyS-Only Drug

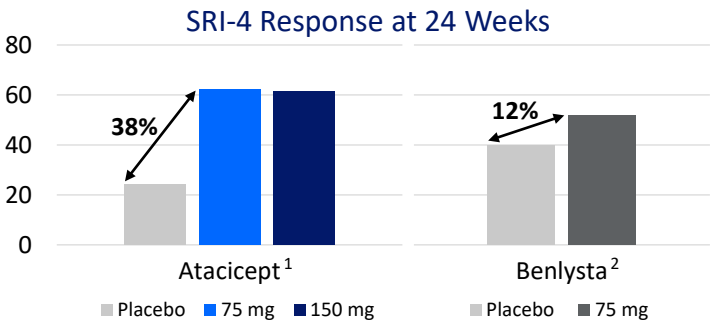
## Pre-Clinical Evidence: BLyS-APRIL >> BLyS or APRIL alone



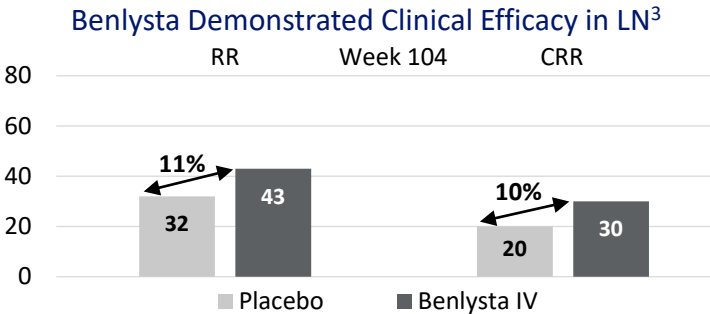
In mouse model of LN, only atacicept effectively prevented proteinuria compared to BLyS or APRIL alone

Haselmayer P, et al. Eur J Immunol 2017, Figure 2, page 1080.

## Clinical Evidence: BLyS-APRIL >> BLyS or APRIL alone



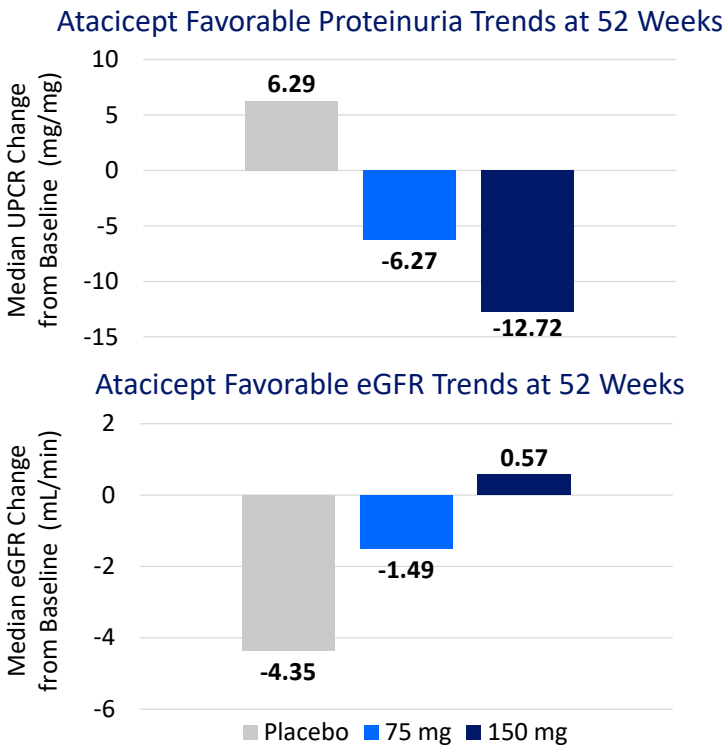
In similar serologically active SLE patients, BLyS-APRIL inhibition may provide better efficacy vs BLyS alone\*



BENLYSTA approved in LN, but RR still <50%; we believe there is room for improvement with dual blockade<sup>3</sup>

1. Merrill JT, et al. Arthritis Rheumatol 2018. 2. van Vollenhoven RF, et al. Ann Rheum Dis 2012. 3. Furie R, et al. N Engl J Med 2020.

## Clinical Evidence: Improved renal function in SLE patients



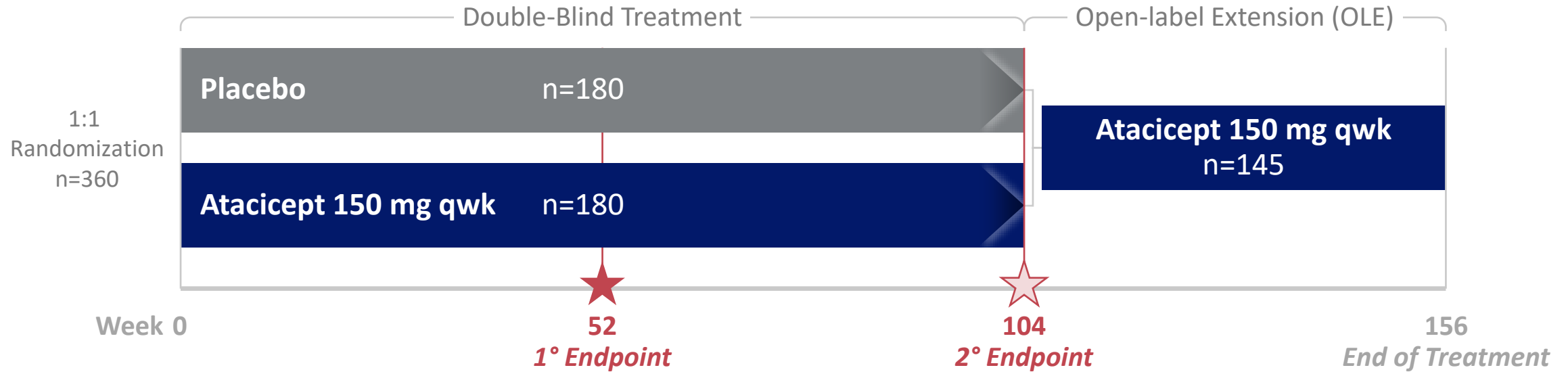
Phase 2 APRIL-SLE trial showed improved eGFR and proteinuria trends at 52 weeks in moderate-severe SLE

Isenberg D, et al. ERA-EDTA 2022 oral.

\*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. RR = response rate.

# Phase 3 Trial of Atacicept for Lupus Nephritis (COMPASS): Study Design

Multinational, Randomized, Placebo-controlled Pivotal Trial



## Endpoints

- Primary: complete renal response at week 52
- Secondary
  - Alternate definition of renal response at week 52
  - Complete renal response at week 104
  - Time to death or renal-related event
  - Time to UPCR of  $\leq 0.5$  mg/mg





**vera**  
therapeutics

**MAU868 for BKVN  
(BK Virus Nephropathy)**

# BK Virus Infection: Potential for a Blockbuster Market Opportunity



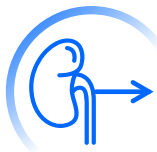
**BK Virus (BKV) leads to significant morbidity and mortality in transplant patients**



**80–90% of healthy adults have been infected with BKV and the virus remains latent in healthy adults**



**BKV can be reactivated** when a patient is immunocompromised



**BKV impacts** two immunocompromised populations including **kidney transplant patients** and **HSCT recipients**



**No approved anti-BKV treatments in the US**

**Unserved Market ~\$1B+ Commercial Opportunity WW in 2036<sup>1</sup>**

**Kidney Transplants: ~80,000 RTx per year WW**

<b>Viruria (30–50%)</b>	<b>40,000 pts</b> – measurable BKV
<b>Viremia (10–20%)</b>	<b>15,000 pts</b> – kidney at risk
<b>Nephropathy (3–4%)</b>	<b>3,200 pts</b> – irreversible damage
<b>Rejection (1–2%)</b>	<b>1,500 pts</b> – <i>kidney loss</i>

**HSCT Procedures: ~100,000 HSCT per year WW**

<b>Allogeneic (50%)</b>	<b>50,000 pts</b> – higher risk of BKV
<b>Viremia (10–35%)</b>	<b>22,500 pts</b> – risk of cystitis
<b>Cystitis (6–16%)</b>	<b>10,500 pts</b> – hemorrhagic cystitis

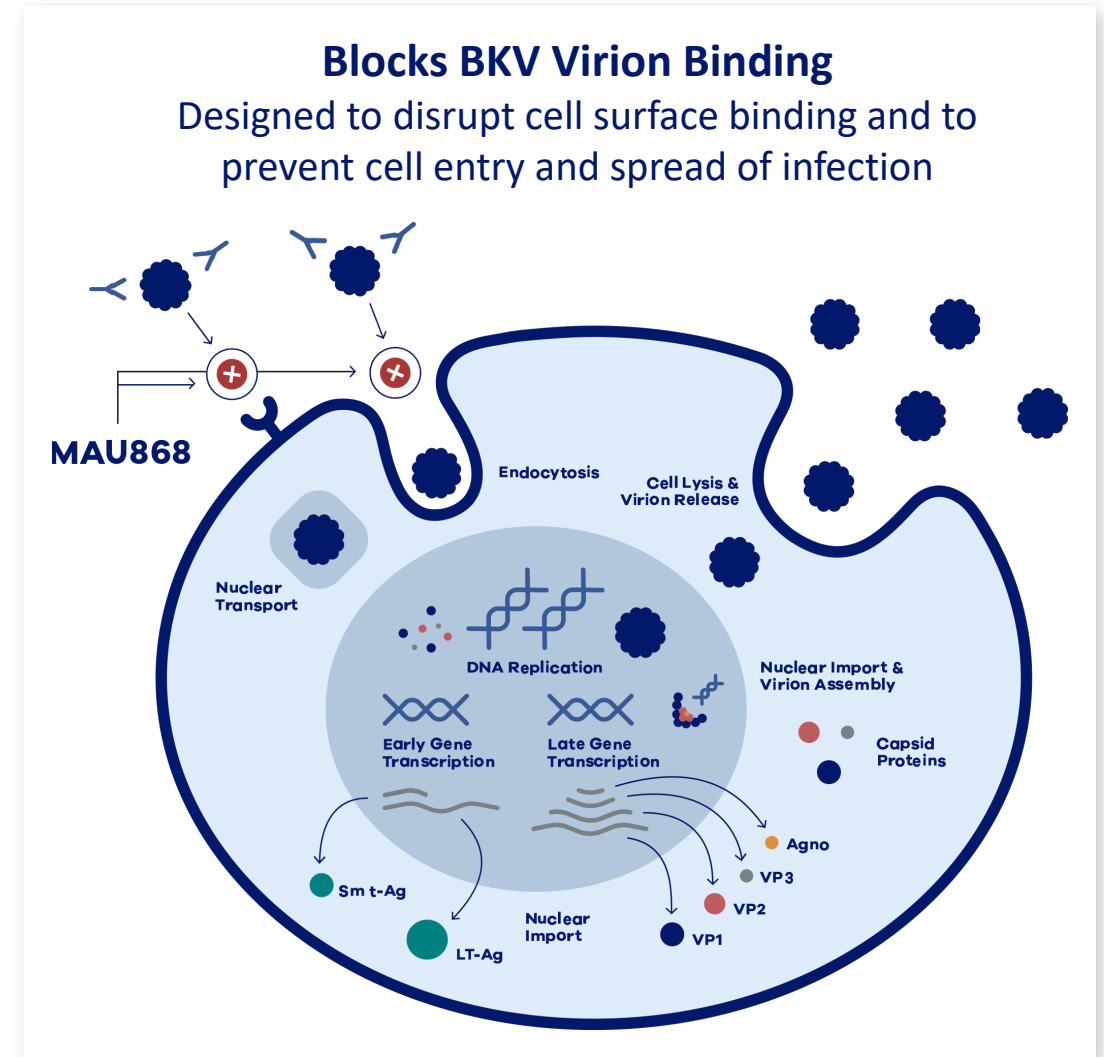
- BKV nephropathy is the **leading cause of allograft loss**
- BKV in HSCT patients have **increased risk of severe hemorrhagic cystitis**

1. Back Bay Analysis. HSCT = hematopoietic stem cell transplant.

# MAU868: Potential First-in-Class Neutralizing Antibody Targeting BKV

- **Novel Target:** mAb that neutralizes infection by blocking BKV virion binding to host cells
- **Active Against All Genotypes:** Subnanomolar potency against all major genotypes
- **Proven Mechanism:** Neutralization of virus infection effective in other approved mAb therapies
- **More Potent than IVIG:** ~10,000-fold more potent *in vitro*

IVIG = intravenous immune globulin.



# Antiviral Effect and Renal Effect of MAU868 vs Placebo at Week 12

Randomized, Placebo-controlled Phase 2 Trial

	MAU868 n=20	Placebo n=8	P-value
Log reduction in BK viremia, median (IQR) DNA copies/mL	-1.14 (-1.88, -0.50)	0.37 (-0.72, 0.04)	0.051
Patients with reduction in BK plasma viral load, n (%)			
by ≥1 log	11 (55)	1 (13)	0.040
to <lower limit of quantification	4 (20)	0	0.172
to <10 <sup>4</sup> DNA copies/mL	15 (75)	3 (38)	0.061
Change in eGFR <sub>CK-EPI</sub> , median (IQR) mL/min/1.73m <sup>2</sup>	2.0 (-5.0, 4.0)	-6.0 (-8.5, -0.5)	0.217

Jordan S et al. Am J Transplant. 2022; 22 (suppl 3).

