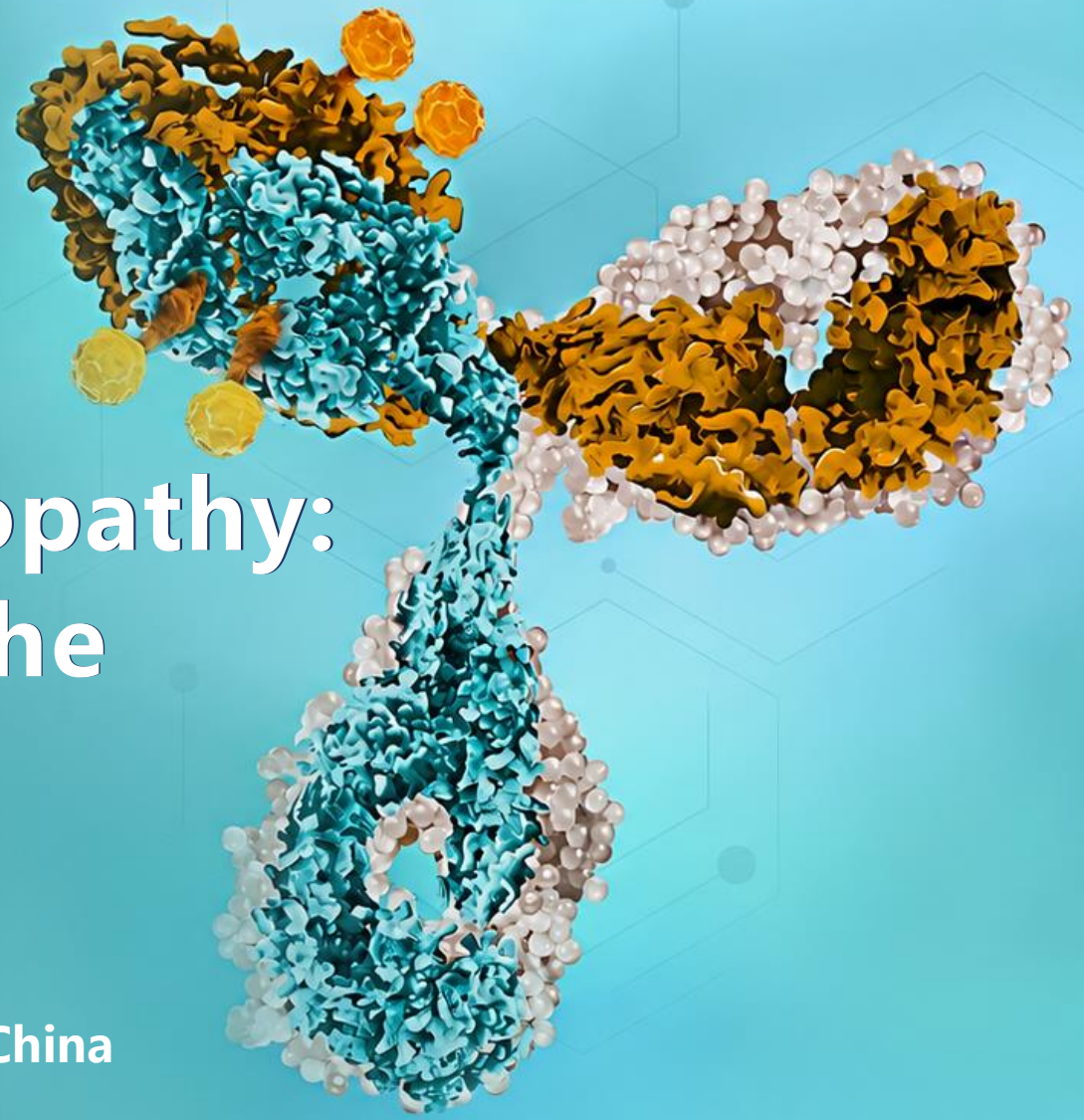
KIDNEY WEEK 2026

October 21–25 | Denver, CO



# Telitacicept for IgA Nephropathy: Final Two-Year Results of the Phase 3 TELIGAN Trial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**On behalf of the TELIGAN trial investigators group**

# IgA nephropathy is a leading cause of CKD and ESKD worldwide

Most common primary glomerulonephritis,[1] accounting for **39.7%** of all kidney biopsy cases of primary glomerulonephritis in China[2]

The main group affected is young and middle-aged adults, with the peak age of onset being **26 to 48** years old[2-5].

The majority of **patients with IgAN are expected to develop kidney failure** within their lifetime[6]

KDIGO 2025 IgA nephropathy guidelines Treatment Goal:

Annual GFR loss less than **1mL/min/1.73m²/yr**

Proteinuria remission: less than **0.5g/d** and ideally less than **0.3g/d**

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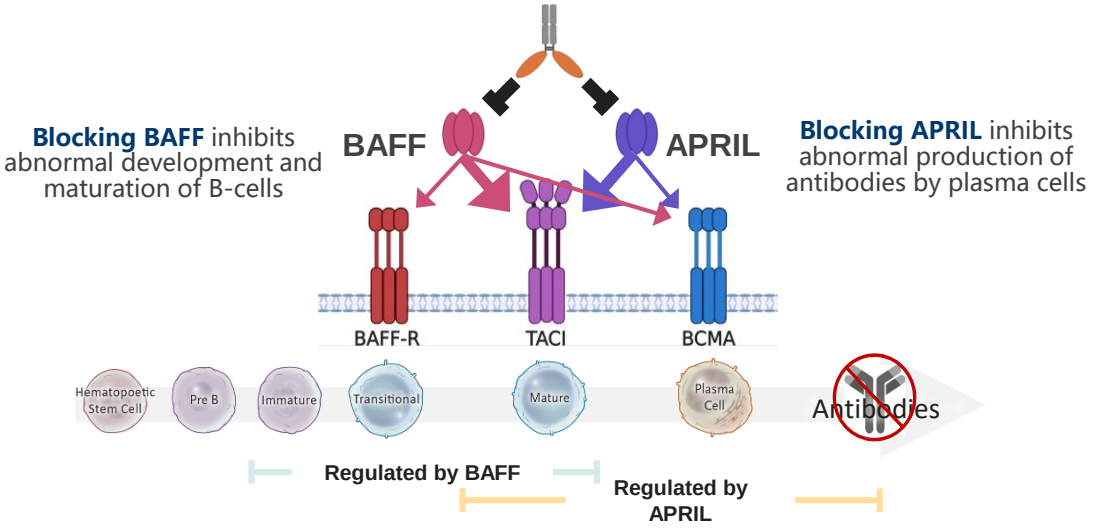
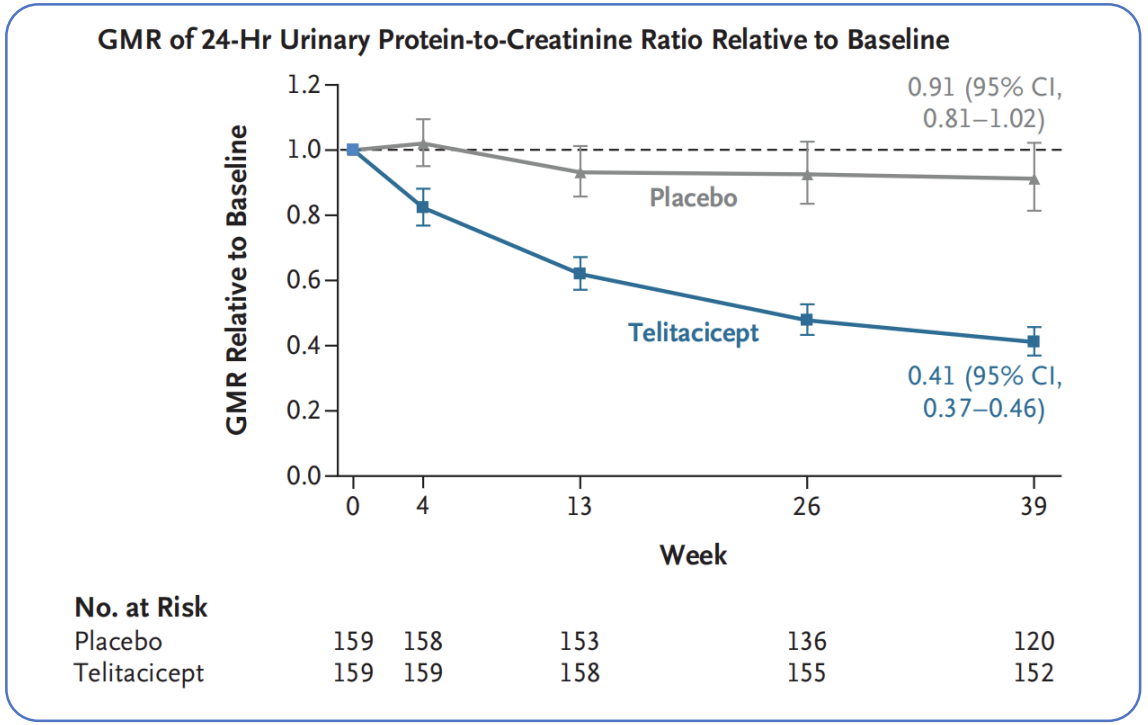
# Telitacicept inhibits both BAFF and APRIL

## Telitacicept: a novel TACI-Fc fusion protein dual inhibition of BAFF/APRIL




APRIL, a proliferation-inducing ligand; BAFF, B-cell activating factor; BCMA, B-cell maturation antigen;

TACI, transmembrane activator and calcium modulator in cyclophilin ligand interaction.


1. *Jicheng Lv, et al. N Engl J Med, 2026, 394: 1916-1924.*

# TELIGAN Trial Design

## A multicenter, randomized, double-blind, placebo-controlled phase 3 trial in China

### Key inclusion criteria

- Biopsy-confirmed IgA nephropathy;
- Age ≥18 years;
- 24h-UPCR ≥0.8 g/g or 24-hour urine protein ≥1.0 g/day;
- eGFR ≥30 mL/min/1.73 $m^2$ (CKD-EPI);
- ACEi or ARB with or without SGLT2i for ≥12 weeks; and maximum tolerated RASi dose for ≥4 weeks;

**Screening period**

**(within 35 days)**

Randomization 1:1

Stratification

24h-UTP: <2.0 vs. ≥2.0 g/day;

eGFR: 30 to <60 vs. ≥60 ml/min/1.73 $m^2$ ;

SGLT2i: yes vs. no;

### full dose therapy

**0-39 weeks**

**Telitacicept 240 mg, Q1W**

**Placebo, Q1W**

### low dose maintenance therapy

**40-104 weeks**

**Telitacicept 240 mg, Q2W**

**Placebo, Q2W**

**First Dose**

**Endpoint in Stage A**

**Endpoint in Stage B**

- **Stage A** is a double-blind treatment period to determine the efficacy and safety of Telitacicept in reduction of proteinuria in participants at 39-week from baseline with Telitacicept vs. placebo Q1W.

- **Stage B** is a double-blind treatment period throughout to determine the long term kidney benefit of Telitacicept in participants by comparing eGFR slope at 104-week to baseline with Telitacicept vs. placebo treatment.

*ACEi, angiotensin-converting enzyme inhibitor;ARB, angiotensin receptor blocker; CKD, chronic kidney disease; eGFR, estimated glomerular filtration rate; SGLT2i, sodium-glucose cotransporter 2 inhibitor; 24h-UPCR, 24-hour urine protein-to-creatinine ratio; 24h-UTP, urinary total protein*

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# Stage B Endpoints over 104 Weeks

## Primary Endpoint

- The annualized total eGFR slope estimated over 104 weeks;

## Key Secondary Endpoints

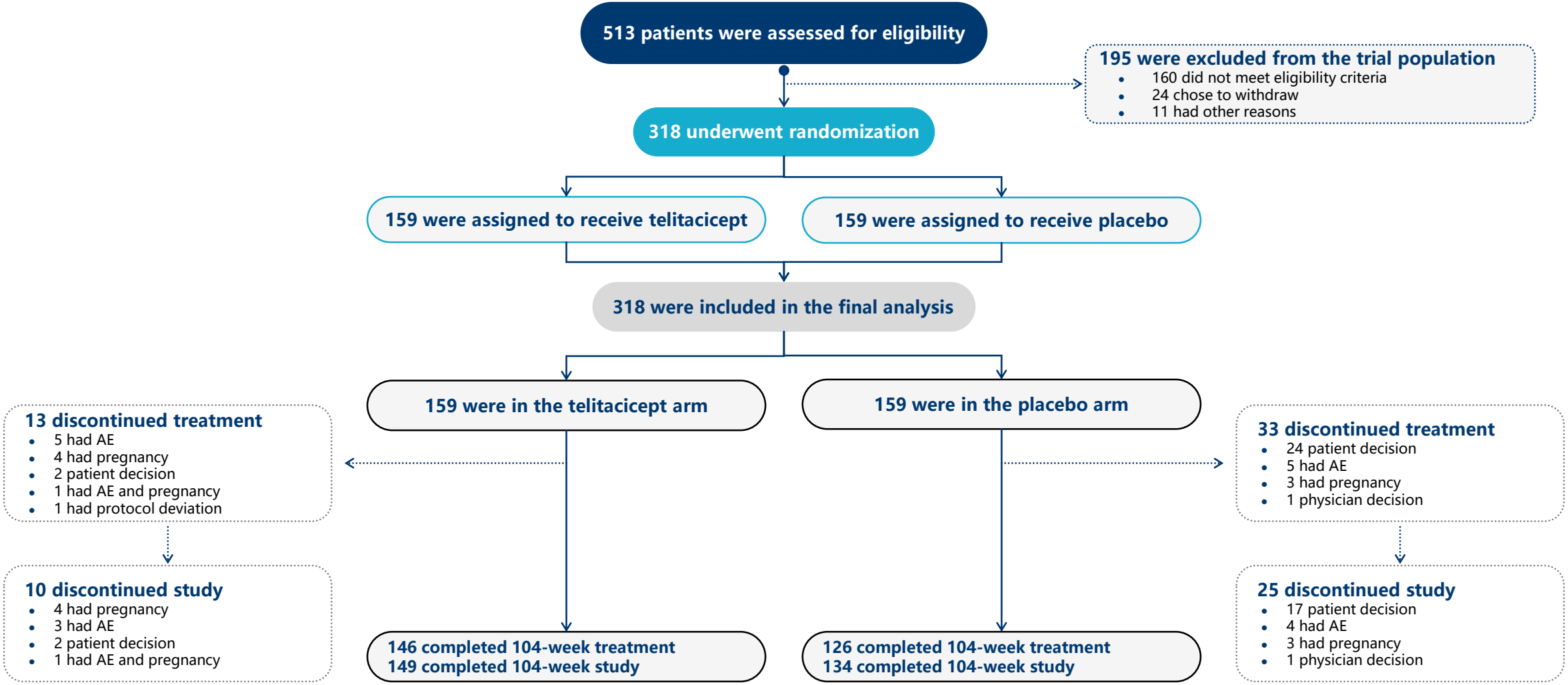
- Time to first confirmed eGFR decline of ≥ 30%* and ≥ 40%* from baseline;
- Time to the composite kidney endpoint defined as renal dialysis*, eGFR <15 mL/minute/1.73 $m^2$*, kidney transplantation, or death from kidney failure;
- Change from baseline in 24-hour UPCR;

## Post-hoc Analyses

- The proportion of patients achieving a 24h-UPCR of less than 0.3 g/g and 0.5 g/g;
- The proportion of patients with hematuria over 104 weeks;
- Changes in serum galactose-deficient IgA1 (Gd-IgA1);

*≥ 4 weeks*

# Screening, Randomization and Follow-up



# Baseline Characteristics

| Characteristics | Telitacicept (N=159) | Placebo (N=159) |
|---|---|---|
| Age — yr | 37.8 ± 9.44 | 38.6 ± 9.95 |
| Sex — no.(%) | | |
| Male | 77 (48%) | 70 (44%) |
| Female | 82 (52%) | 89 (56%) |
| BMI — kg/m² | 25.0 ± 4.4 | 25.4 ± 4.3 |
| Interval from biopsy to randomization — mo‖ | 38.70 (11.30, 78.65) | 36.60 (7.95, 69.16) |
| 24-hr UPCR— g/g‖ | 1.23(0.96 –1.66) | 1.29(1.00–1.80) |
| Estimated glomerular filtration rate (eGFR) | | |
| Mean — mL/min/1.73m² | 76.53 ± 26.95 | 74.43 ± 27.20 |
| Distribution — no.(%) | | |
| 30 to 60 | 53(33%) | 57(36%) |
| ≥60 | 106(67%) | 102(64%) |
| Hematuria — no. (%) | 113(71%) | 112(71%)# |
| Gd-IgA1 — RU/mL | 50.16 ± 40.37 | 42.22 ± 36.66 |
| Diabetes — no. (%) | 30 (19%) | 26 (16%) |
| Blood pressure — mmHg | | |
| Systolic | 116.6 ± 11.0 | 117.9 ± 10.8 |
| Diastolic | 77.8 ± 8.2 | 78.3 ± 8.1 |
| Use of SGLT2 inhibitor — no.(%) | 56(35%) | 55(35%) |

BMI, body-mass index; UPCR, urine protein-to-creatinine ratio; SGLT2, sodium–glucose cotransporter 2.
Plus-minus values are means ±SD
‖ Medians, with IQR.
# Baseline hematuria data were missing for 2 patients, leaving a denominator of 157.
*hematuria was defined as a urinary red-blood-cell count exceeding the upper limit of normal on routine urinalysis or a urine dipstick result of trace or greater.
Gd-IgA1 levels were available for 83 patients in the telitacicept group and 79 in the placebo group.

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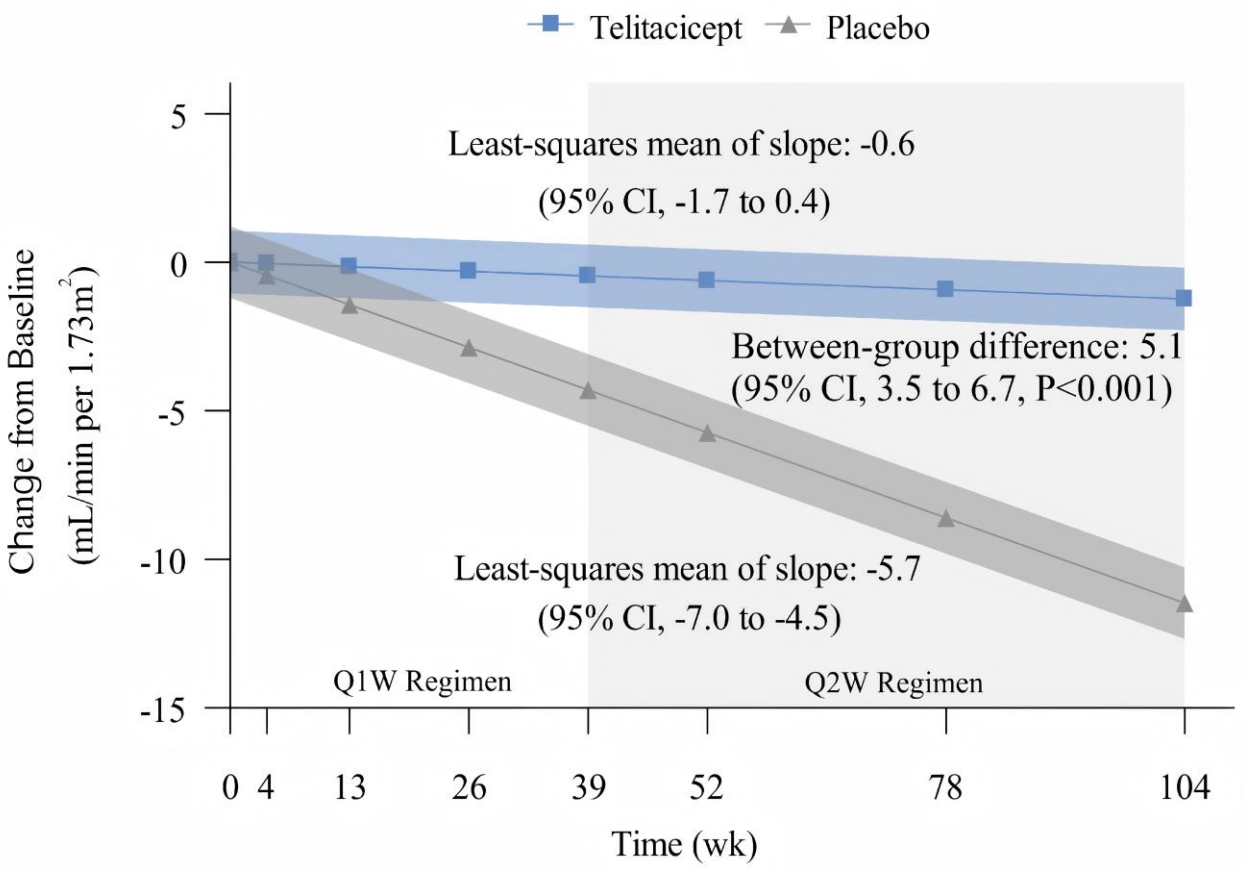
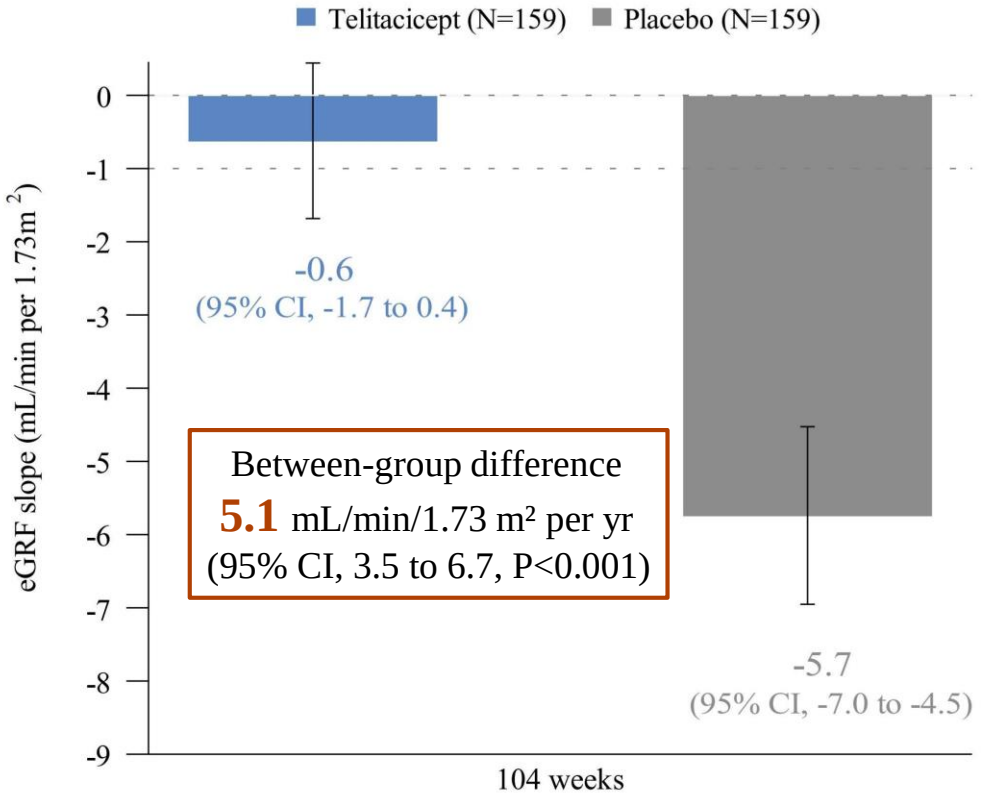
# Primary Endpoint:

## Annualized Total eGFR Slope Estimated over 104 Weeks

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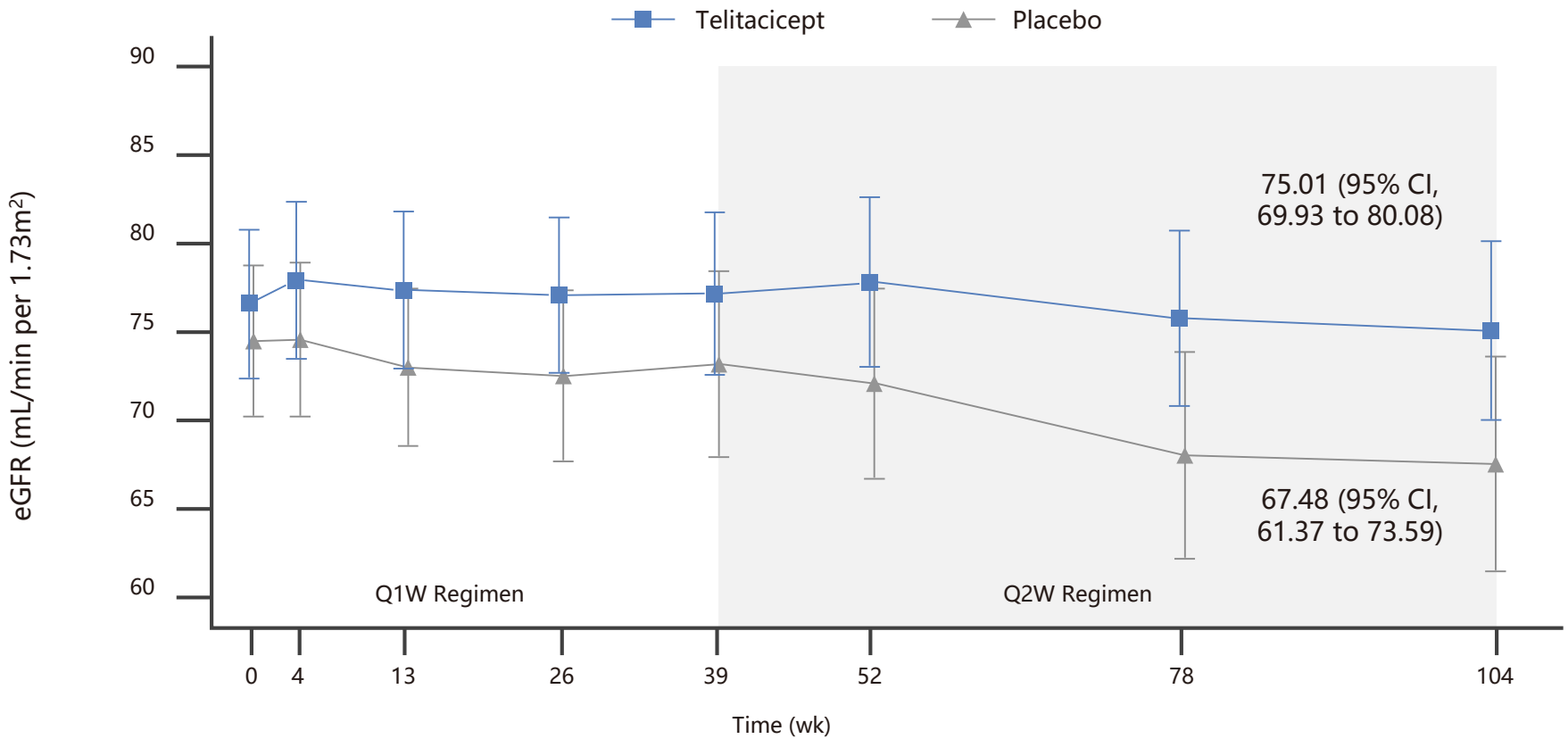
# Change in eGFR over 24 months

## Absolute Mean Value of eGFR




| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Telitacicept** | 159 | 158 | 155 | 151 | 147 | 141 | 138 |
| **Placebo** | 159 | 152 | 136 | 120 | 109 | 100 | 91 |

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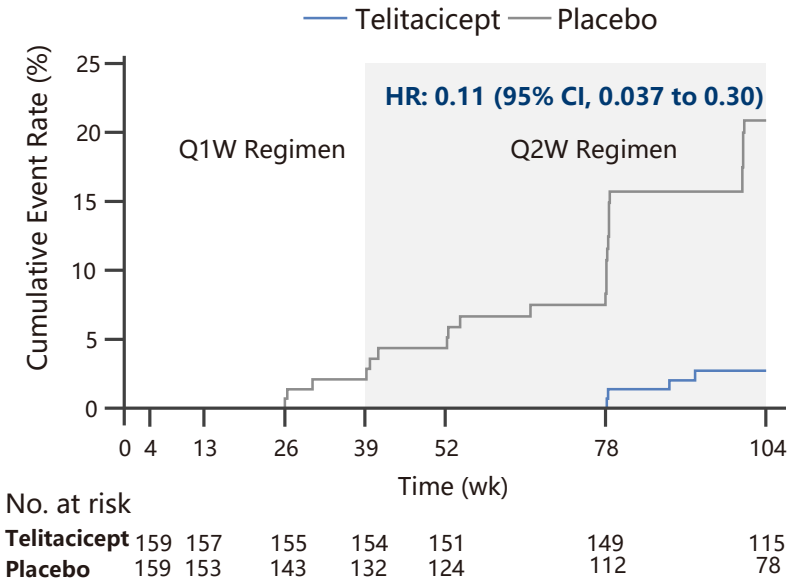
# Key Secondary Endpoints: kidney progression events

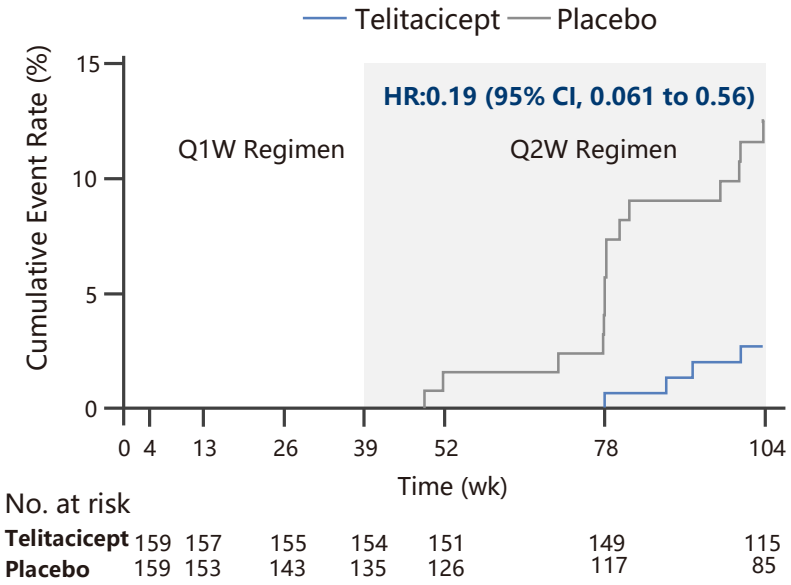
## Time to Confirmed ≥30% eGFR Decline




No. at risk

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Telitacicept** | 159 | 157 | 155 | 154 | 151 | 149 | | 115 |
| **Placebo** | 159 | 153 | 143 | 132 | 124 | 112 | | 78 |

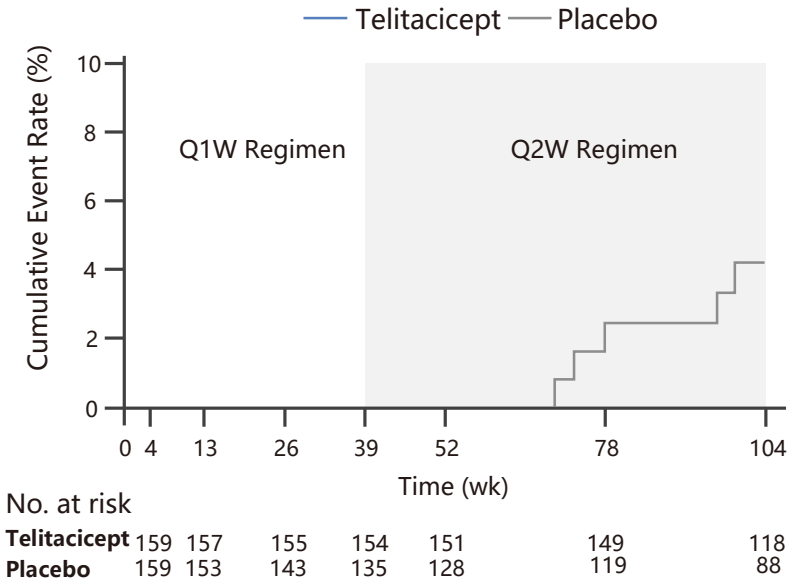
## Time to Confirmed ≥40% eGFR Decline




No. at risk

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Telitacicept** | 159 | 157 | 155 | 154 | 151 | 149 | | 115 |
| **Placebo** | 159 | 153 | 143 | 135 | 126 | 117 | | 85 |

## Time to Composite Kidney Failure Events*



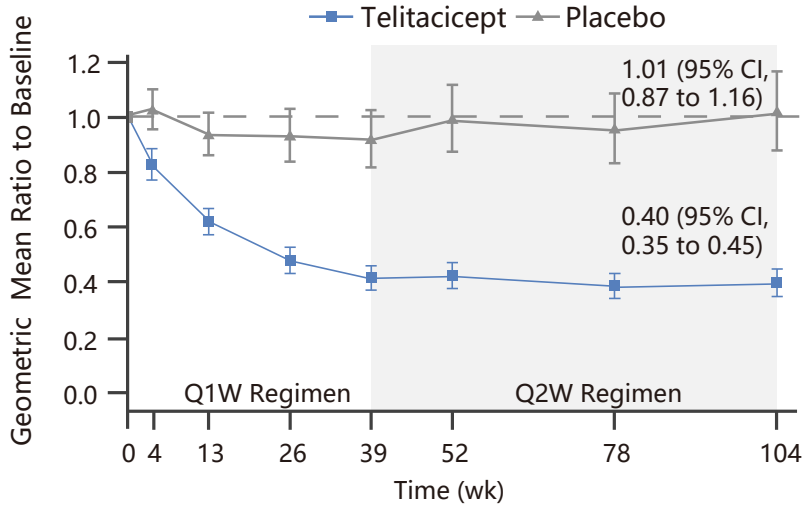

No. at risk

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Telitacicept** | 159 | 157 | 155 | 154 | 151 | 149 | | 118 |
| **Placebo** | 159 | 153 | 143 | 135 | 128 | 119 | | 88 |

**defined as maintenance renal dialysis (≥ 4 weeks), sustained eGFR <15 mL/minute/1.73 m2 (≥ 4 weeks), kidney transplantation or death from kidney failure.*

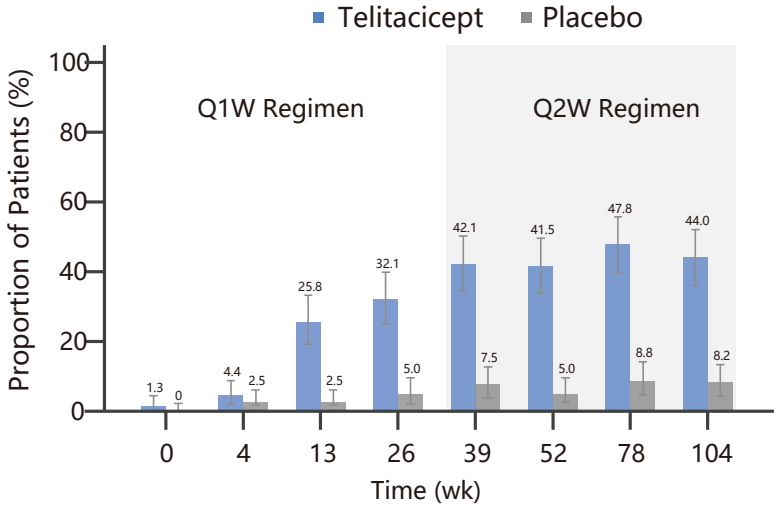
# Proteinuria and Gd-IgA1 on stage A and B

**GMR of 24h-UPCR to baseline**

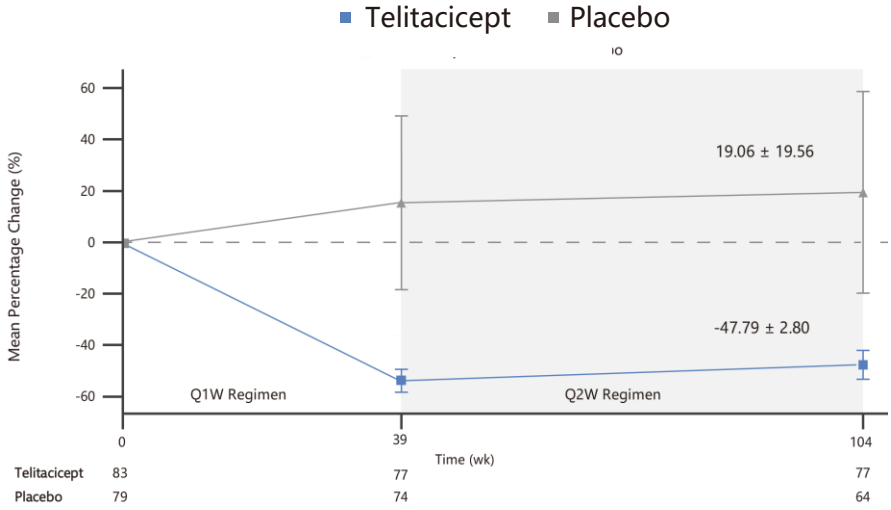



| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Telitacicept** | 159 | 158 | 155 | 151 | 147 | 141 | 138 |
| **Placebo** | 159 | 153 | 136 | 120 | 109 | 101 | 91 |

**Proportions of Patients achieving 24h-UPCR < 0.5 g/g**




**Galactose-deficient IgA1**




*GMR, geometric mean ratio;*

*24h-UPCR, 24-hour urine protein-to-creatinine ratio;*

# Safety outcomes

## Treatment Emergent Adverse Event

| Event — no. (%) | Telitacicept (N=159) | Placebo (N=159) |
|---|---|---|
| **TEAE** | 151 (95.0) | 142 ( 89.3) |
| **Infections** | 107 (67.3) | 107 (67.3) |
| **TESAE** | 13 (8.2) | 29 (18.2) |
| **Serious Infections** | 3 (1.9) | 7 (4.4) |
| **TEAE leading to treatment interruption** | 36 (22.6) | 54(34.0) |
| **TEAE leading to treatment discontinuation** | 3(1.9) | 7(4.4) |
| **TEAE leading to withdrawal** | 4 (2.5) | 7(4.4) |
| **TEAE leading to death** | 0 (0) | 0 (0) |

**SAE, serious adverse event; SS, safety set; TEAE, treatment-emergent adverse event.**

***Definition of AE severity:***

*a. Mild AE, The event was easily tolerated and generally did not interfere with daily activities.*

*b. Moderate AE, The event caused discomfort that interfered with daily activities.*

*c. Severe AE, The event resulted in incapacity to work or perform daily activities.*

** None patient had severe IgG <250mg/dl that need stopping the treatment*

# Safety outcomes

## Common drug related TEAEs
(incidence ≥5% in either group)

| Event — no. (%) | Telitacicept (N=159) | Placebo (N=159) |
|---|---|---|
| Upper respiratory tract infection | 83 (52.2) | 76 (47.8) |
| Urinary tract infection | 22 (13.8) | 14 (8.8) |
| Respiratory tract infection | 11 (6.9) | 7 (4.4) |
| Bronchitis | 6 (3.8) | 12 (7.5) |
| COVID-19 | 7 (4.4) | 8 (5.0) |
| Cough | 17 (10.7) | 14 (8.8) |
| Hyperkalemia | 4 (2.5) | 9 (5.7) |
| Hyperlipidemia | 6 (3.8) | 9 (5.7) |
| Diarrhea | 7 (4.4) | 10 (6.3) |
| Alanine aminotransferase increased | 10 (6.3%) | 5 (3.1%) |
| Injection site reaction† | 89 (56.0) | 30 (18.9) |
| Mild | 72 (45.3) | 21 (13.2) |
| Moderate | 14 (8.8) | 2(1.3) |
| Severe | 2 (1.3) | 0 |
| Injection site pruritus | 21 (13.2) | 3(1.9) |
| Injection site pain | 10 (6.3) | 9 (5.7) |
| Pyrexia | 10 (6.3) | 13 (8.2) |
| Blood immunoglobulin M decreased# | 41 (25.8) | 1 (0.6) |
| Blood immunoglobulin G decreased# | 21 (13.2) | 2 (1.3) |
| Weight increased | 10 (6.3) | 10 (6.3) |
| Weight decreased | 9 (5.7) | 4 (2.5) |

# Conclusions

- Telitacicept stabilized eGFR decline over 104 weeks.

**Annualized eGFR Slope**

**-0.6 mL/min/1.73m²/year**

- Telitacicept sustained proteinuria  remission.
- A favorable two-year safety profile.
- A full dose induction and low dose maintenance therapy is reasonable.

*eGFR, estimated glomerular filtration rate;*

# Acknowledgments

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|---|---|---|
| 01 | Peking University First Hospital | Lv Jicheng |
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| 03 | Peking University Shougang Hospital | Zhao Haidan |
| 06 | Beijing Tsinghua Changgung Hospital | Li Yuehong |
| 07 | Tianjin Medical University General Hospital | Yan Tiekun |
| 08 | The Second Hospital of Tianjin Medical University | Li Rong |
| 09 | The Second Hospital of Hebei Medical University | Li Shaomei |
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| 16 | Qilu Hospital of Shandong University | Yang Xiangdong |
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# Publication:

Telitacicept for high-risk IgA nephropathy in China: a phase 3 randomised, double-blind, placebo-controlled trial

*The Lancet* in press