

A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Jade101 Administered Subcutaneously in Participants with IgAN

R. Lafayette¹, D. Rizk², S. Barbour³, A. Liew⁴, MG. Wong⁵, H. Trimarchi⁶, H. Suzuki⁷, H. Zhang⁸, C. Piscia-Nichols⁹, T. DeVries⁹, L. Li⁹, E. Conner⁹, A. King⁹, and J. Barratt¹⁰

¹ Stanford University School of Medicine, Stanford, CA, United States ² The University of Alabama at Birmingham Heersink School of Medicine, Birmingham, AL, United States

³ The University of British Columbia Faculty of Medicine, Vancouver, BC, Canada ⁴ Mount Elizabeth Hospital, Singapore, Singapore ⁵ University of Sydney, Sydney, Australia

⁶ Hospital Britanico de Buenos Aires, Buenos Aires, Argentina ⁷ Juntendo University Urayasu Hospital, Urayasu city, Japan ⁸ Peking University First Hospital, Beijing, China

⁹ Jade Biosciences, San Francisco, United States of America and Vancouver, Canada ¹⁰ University of Leicester, Leicester, England, United Kingdom

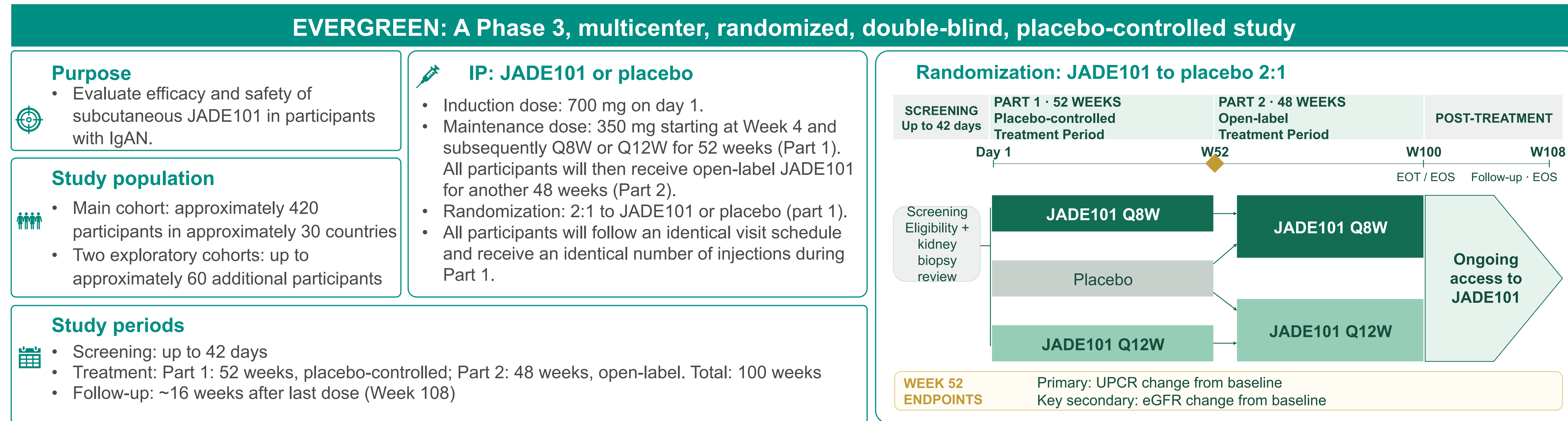


BACKGROUND AND AIMS

- Immunoglobulin A nephropathy (IgAN) is a progressive immune-mediated kidney disease with a high lifetime risk of kidney failure.
- Blocking A proliferation-inducing ligand (APRIL), a key driver of pathogenic IgA production, is potentially disease modifying in IgAN by reducing IgA, galactose-deficient IgA1 (Gd-IgA1) and proteinuria, ultimately stabilizing kidney function.
- JADE101 is a novel fully human APRIL-neutralizing monoclonal antibody (mAb) designed with ultra-high affinity and an extended half-life, with the goal of delivering a convenient, infrequent subcutaneous dosing profile.
- This placebo-controlled Phase 3 study is designed to characterize the efficacy and safety of JADE101 in participants with biopsy-confirmed primary IgAN.

METHODS

- Primary objective: to evaluate the effect of JADE101 versus placebo on UPCR in participants with IgAN on stable SoC.
- Key Secondary objective: to evaluate the effect of JADE101 versus placebo on the change from baseline in eGFR in participants with IgAN on stable SoC.



STUDY UPDATE

- The study is expected to start in Q4 2026

ACKNOWLEDGEMENTS

- Jade Biosciences thanks the investigators and site teams for their support in preparing this study.

QUESTIONS?

Email: Info@jadebiosciences.com

Endpoints	Key Inclusion Criteria	Key Exclusion Criteria
Primary endpoint Change from baseline in 24-hour urine UPCR at Month 12 (Week 52), on the natural log scale.	Participant characteristics - Male or female participants with age ≥18 years - Body weight at least 40 kg and BMI ≤ 40 kg/m² - Source-verified, biopsy-confirmed primary IgAN - For Type 2 diabetes, kidney biopsy within 3 years of screening - Serum IgG ≥ 6 g/L (≥ 600 mg/dL)	Disease characteristics - Secondary forms of IgAN - Ongoing systemic IgA vasculitis with systemic involvement that requires immunosuppression treatment - Known or clinically suspected coexisting CKD other than IgAN - Known or clinically suspected rapidly progressive glomerulonephritis (RPGN)
Key secondary endpoint - Change from baseline in eGFR at Month 12 (Week 52). Additional secondary endpoints - Percentage of participants achieving 24-hour urine UPCR < 0.5 g/g or < 0.3 g/g at Month 12 (Week 52) - Percentage of participants achieving a rate of loss of kidney function < 1.0 mL/min/1.73 m² per year from baseline at Month 12 (Week 52) - Percentage of participants achieving clinical remission at Month 12 (Week 52) defined as UPCR (measured from 24-hour urine collection) < 0.5 g/g and a rate of loss of kidney function < 1.0 mL/min/1.73 m² per year - Incidence of treatment-emergent AEs through Week 52.	IgAN disease status - Main cohort: - UPCR ≥0.75 g/g or 24-hour protein ≥1 g/day with eGFR ≥30 mL/min/1.73 m² - Exploratory cohorts: - UPCR ≥0.5 to <0.75 g/g and 24h total protein <1 g/day; rest criteria are same as main cohort - eGFR ≥20 to <30 mL/min/1.73 m²; rest criteria are same as main cohort	Kidney biopsy findings - Evidence of pathological findings in addition to IgAN on kidney biopsy (e.g., minimal change disease, diabetic kidney disease, membranous nephropathy, focal segmental glomerulosclerosis not secondary to IgAN, or lupus nephritis) - Hypertensive vascular changes are acceptable
Exploratory endpoints Hematuria, PK/PD, immunogenicity and quality of life through Week 52. Long-term safety, UPCR and eGFR through Week 100.	Background therapy - Stable, maximally tolerated ACEi/ARB for ≥12 weeks, unless intolerant. - If used, SGLT2i, ERA, MRA, hydroxychloroquine or GLP-1 (including GIP/GLP-1) therapy stable for ≥12 weeks.	Clinical / treatment criteria - Presence of or history of nephrotic syndrome with hypoalbuminemia (isolated nephrotic-range proteinuria is eligible) - Uncontrolled systolic BP >140 or diastolic BP >90 mmHg - Type 1 or uncontrolled Type 2 diabetes (HbA1c >8%) - Any infectious disease, primary or secondary immunodeficiency disorder - Any clinically significant, unstable, or uncontrolled medical condition - Prior anti-APRIL, anti-CD38 or anti-CD20 therapy - Received any live attenuated vaccines (eg, measles, mumps, and rubella [MMR]; varicella-zoster vaccines) within 30 days prior to the initial screening visit