

Interim Results of a Phase 1 Study to Evaluate the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of JADE101 in Healthy Volunteers.

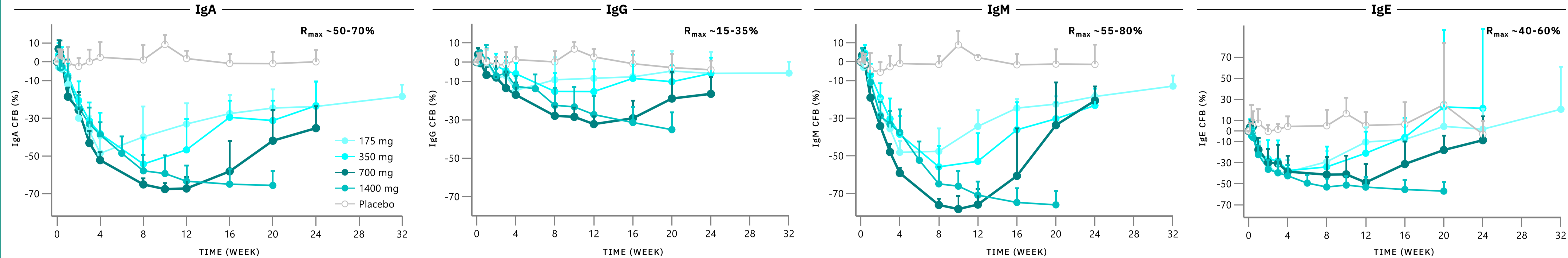
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BACKGROUND AND AIMS

- A proliferation-inducing ligand (APRIL) plays a critical role in driving the production of pathogenic Gd-IgA1 in IgAN.
- JADE101 is a novel APRIL-neutralizing monoclonal antibody (mAb) designed with ultra-high affinity and extended half-life.
- The JADE101-01 First-In-Human (FIH) study aims to characterize the safety, tolerability, pharmacokinetics (PK), pharmacodynamics (PD), and immunogenicity of JADE101 following single subcutaneous (SC) doses.

JADE101 Delivers Compelling Magnitude and Duration of IgA Reduction with Modest Impact on IgG Following a Single Dose



METHODS

- JADE101-01 is a Phase 1, randomized, double-blind, placebo-controlled, single-ascending dose study conducted at a single clinical research unit.

Study Population

Healthy Adult Volunteers (HVs)
N=8 per Cohort (6:2 active:placebo)

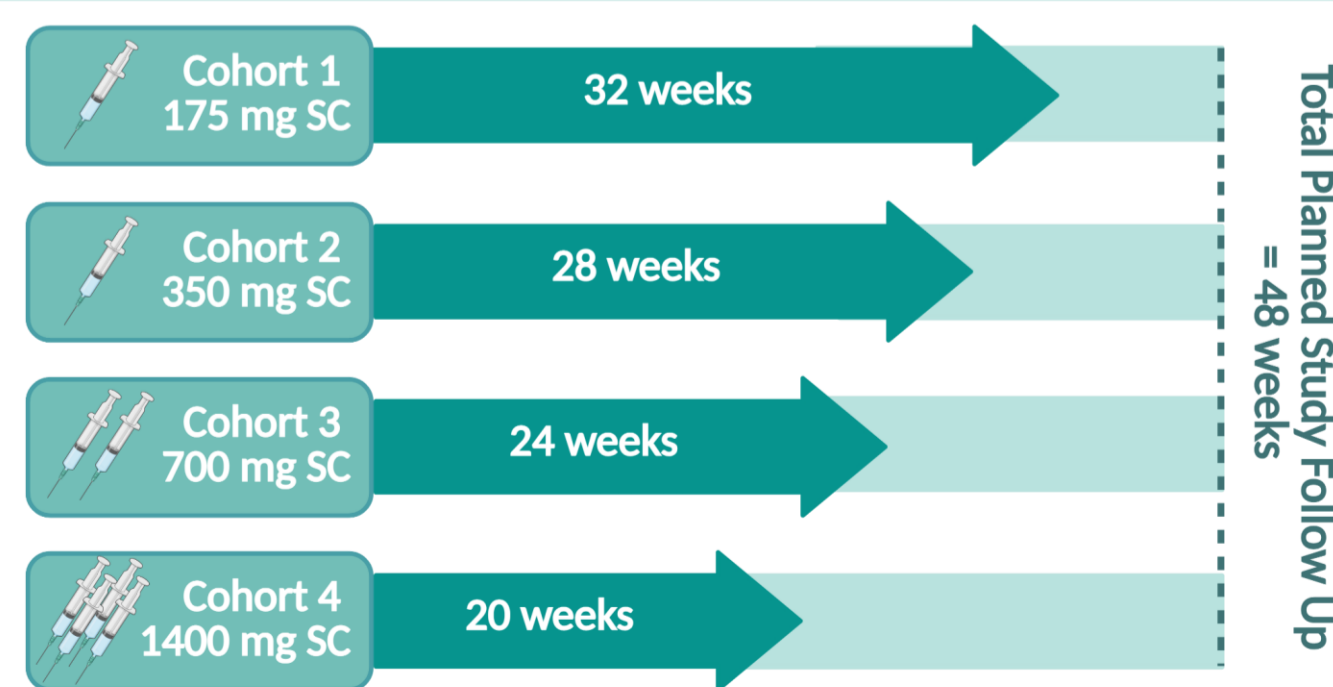
Endpoints

Primary: Safety and Tolerability

Secondary: Pharmacokinetics

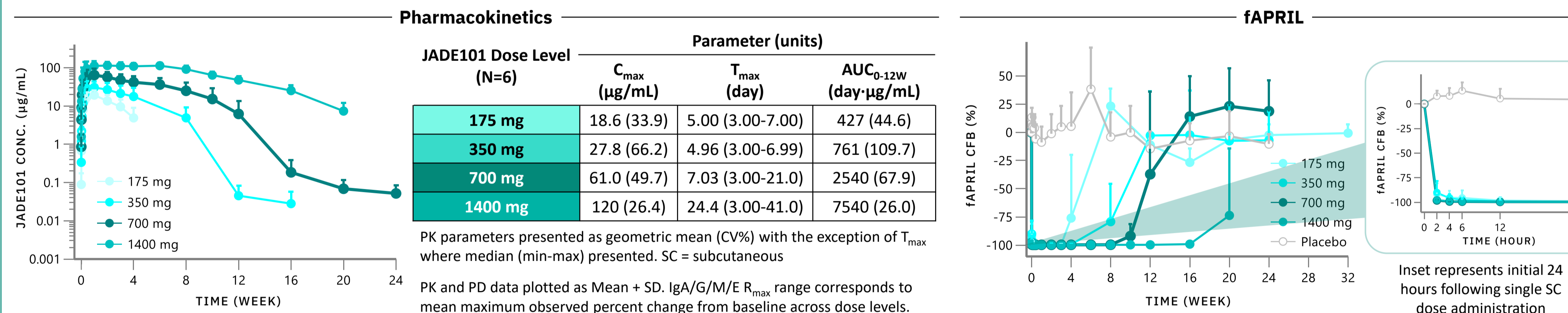
Exploratory Pharmacodynamics: IgA, IgG, IgM, IgE, fAPRIL & Immunogenicity

Dose Levels and Interim Follow-up*



*Interim Data cut off: April 14, 2026
JADE101-01: NCT07059312

JADE101 Exhibits Dose-Dependent Extended PK Exposure, Rapid and Potent fAPRIL Neutralization



JADE101 is Generally Safe and Well-Tolerated at all Tested Doses in Healthy Volunteers

Demographics						Safety					
JADE101 and placebo	175 mg (N = 8)	350 mg (N = 8)	700 mg (N = 8)	1400 mg (N = 8)	Overall (N = 32)	JADE101 and placebo	175 mg (N = 8)	350 mg (N = 8)	700 mg (N = 8)	1400 mg (N = 8)	Overall (N = 32)
Age, (yr), Mean (SD)	38.0 (7.86)	44.5 (9.87)	28.0 (9.04)	37.6 (13.70)	37.0 (11.51)	≥1 TEAE	6 (75.0%)	6 (75.0%)	5 (62.5%)	7 (87.5%)	24 (75.0%)
Female N (%)	2 (25)	6 (75)	3 (38)	5 (63)	16 (50)	≥1 SAE	0%	0%	0%	0%	0%
White N(%)	5 (63)	6 (75)	4 (50)	3 (38)	18 (56)	≥1 severe TEAE	0%	0%	0%	0%	0%
Asian N (%)	2 (25)	1 (13)	3 (38)	1 (13)	7 (22)	Discontinued due to TEAE	0%	0%	0%	0%	0%
BMI, (kg/m ²) Mean (SD)	25.5 (2.70)	26.7 (2.87)	25.9 (3.05)	24.2 (3.25)	25.6 (2.97)	TEAEs occurring in ≥ 2 participants	Headache (8 participants; 25%); upper respiratory tract infection (7 participants; 21.9%); injection site erythema, oropharyngeal pain, and pyrexia (3 participants; 9.4%); abdominal pain upper, medical device site dermatitis, medical device site rash, musculoskeletal stiffness, nausea, and presyncope (2 participants each; 6.3%)				
						Local tolerability / Immunogenicity	Well-tolerated locally by SC injection with mild (9%)/moderate(3%) injection site erythema, mild injection site pain (3%) and bruising (3%). / No clinically meaningful immunogenicity, and no apparent impact of ADA on PK/PD.				

CONCLUSIONS

- Interim results from the FIH study support a favorable safety and tolerability profile with rapid circulating fAPRIL suppression driving deep and prolonged IgA reduction after a single dose of JADE101.
- Biomarker responses in HVs is anticipated to translate to patients with IgAN, leading to potent suppression of IgA and Gd-IgA1 production, reduction in proteinuria and stabilization of eGFR.
- The biomarker-rich and translationally predictive data from this FIH evaluation establishes the foundation for subsequent clinical development of JADE101, a potentially disease-modifying therapy in IgAN with convenient, SC dosing being evaluated as infrequently as every 12 weeks.
- The Phase 2 evaluation of JADE101 in participants with IgAN is ongoing (NCT07541287).

ACKNOWLEDGEMENTS

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QUESTIONS

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