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Challenge Your Thinking

A Phase 2, Multicenter, Open-Label Study to Evaluate the Safety and Efficacy of JADE101 in Participants with Immunoglobulin A Nephropathy

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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 extended half-life, with the goal of delivering a convenient, infrequent subcutaneous dosing profile.
- This open-label Phase 2 study will characterize the safety and efficacy of JADE101 in adults with biopsy-confirmed IgAN.

METHODS

- Primary objective: to evaluate the safety and tolerability of JADE101 in participants with IgAN
- Secondary objective: to evaluate the effect of JADE101 on UPCR in participants with IgAN
- Exploratory objective: characterize the pharmacokinetics, pharmacodynamic biomarker changes (free APRIL, serum Igs, Gd-IgA1) and immunogenicity.

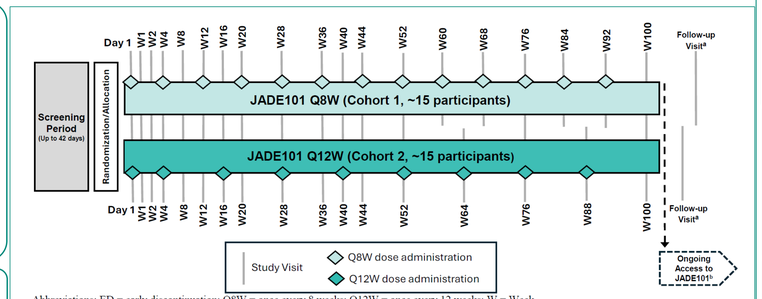
JUNIPER: a Phase 2, Multicenter, Open-Label Study

Purpose:
- To evaluate safety and efficacy of JADE101 in participants with IgAN

Study population:
- Approximately 30 eligible participants from 5 countries randomized 1:1 (15 participants in each cohort) to one of the 2 dose-intervals

IP: JADE101
- All participants will receive JADE101 subcutaneously (SC)
- **Cohort 1:** 700 mg loading dose followed by **Q8W** maintenance dosing (350 mg) starting at Week 4
- **Cohort 2:** 700 mg loading dose followed by **Q12W** maintenance dosing (350 mg) starting at Week 4

Study duration: up to 122 weeks (Cohort 1) or 118 weeks (Cohort 2)
- **Screening period:** up to 42 days
- **Treatment period:** 100 weeks
- **Post treatment follow-up:** 24 weeks after the last dose of JADE101



Abbreviations: ED = early discontinuation; Q8W = once every 8 weeks; Q12W = once every 12 weeks; W = Week
Note: Participants who discontinue study drug early should attend an ED Visit within 8 weeks (Q8W) or 12 weeks (Q12W) of the last dose and a Follow-up Visit 24 weeks after the last dose. Participants who will discontinue/withdraw from the entire study should complete the ED Visit assessments prior to study withdrawal.
a The Follow-up Visit will be 24 weeks after the last dose of study drug.
b Participants who plan to receive ongoing access to JADE101 through an open-label extension study, a compassionate use program, or another appropriate mechanism will not attend the Follow-up Visit for this study.

STUDY UPDATE

- Currently enrolling
- Geographic footprint (US, New Zealand, South Korea, Taiwan, Australia)

ACKNOWLEDGEMENTS

- Jade Biosciences thanks the participants and sites in this study

QUESTIONS?
Email:
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Endpoints

Primary endpoint
- Incidence of treatment-emergent adverse events (TEAEs)

Secondary endpoint
- Change from baseline in UPCR (measured from 24-hour urine collection) on the natural log scale over time

Exploratory endpoints
- Percentage of participants achieving 24-hour urine protein < 0.5 g/day over time
- Change from baseline in eGFR over time
- Percentage of participants with hematuria resolution over time
- Serum JADE101 concentrations, free APRIL, immunoglobulins including Gd-IgA1, and other PD parameters over time
- Incidence and titer of serum anti-drug antibody (ADA)

Key Inclusion Criteria

Participant characteristics
- Male or female participants 18–60 years old
- Body weight 40–100 kg
- Source-verified, biopsy-confirmed primary IgAN
- Biopsy window:
  - ≤ 2 years for participants with eGFR 30–44 mL/min/1.73 m²
  - ≤ 5 years for participants with eGFR ≥45 mL/min/1.73 m²
- Serum IgG ≥ 6 g/L (≥ 600 mg/dL)

IgAN disease status
- UPCR ≥ 0.75 g/g measured from 24-hour urine
- eGFR ≥ 30 mL/min/1.73 m²

Background therapy
- Stable, maximally tolerated ACEi or ARB per SOC for at least 12 weeks prior to screening
  - Participants unable to tolerate ACEi/ARB may be eligible if overall IgAN management (including BP control) is per SOC
- If receiving SGLT2i, ERA, or MRA, must be on a stable dose for at least 12 weeks prior to screening

Key Exclusion Criteria

Disease characteristics
- Secondary forms of IgAN, as assessed by the treating physician
- Diagnosis of IgA vasculitis / Henoch–Schönlein purpura
- Known or clinically suspected coexisting CKD other than IgAN
- Known or clinically suspected rapidly progressive glomerulonephritis (RPGN)

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, lupus nephritis)
  - Hypertensive vascular changes are acceptable
- Kidney biopsy MEST or MEST-C score of T2 or C2 (Oxford IgAN classification)
  - If MEST scoring not performed: Presence of > 50% tubulointerstitial fibrosis, or Presence of crescents in > 25% of glomeruli

Clinical conditions
- Presence of or history of nephrotic syndrome, defined as 24-hour urine protein > 3.5 g/day with concurrent hypoalbuminemia
- Blood pressure > 140 mmHg systolic or > 90 mmHg diastolic
- HbA1c ≥ 6.5% at screening
- Confirmed diagnosis of Type 1 or Type 2 diabetes mellitus
- Any infectious disease, primary or secondary immunodeficiency disorder

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