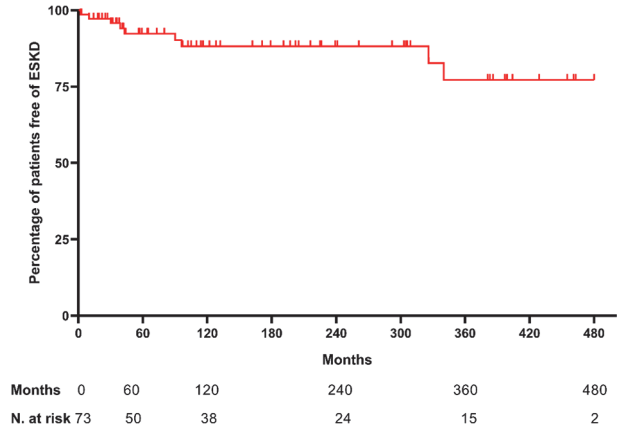
Abstract P94 Table 1 Predictors of ESKD. Univariable Cox regression analysis investigating clinical, laboratory and histologic predictors of ESKD

Variable	HR	95%CI	*P*-value
Age at LN onset	0.810	0.694 - 0.944	0.007
Female gender	0.314	0.087 - 1.126	0.075
ISN/RPS histological class III or IV	1.956	0.243 - 15.725	0.528
eGFR at kidney biopsy	0.967	0.943 - 0.991	0.008
24h proteinuria at kidney biopsy	1.018	0.928 - 1.117	0.704
24h proteinuria > 3g	0.864	0.203 - 3.684	0.843
Hypertension at kidney biopsy	1.283	0.359 - 4.584	0.701
Need for HD at kidney biopsy	5.541	0.664 - 46.237	0.114
C3 levels at kidney biopsy	1.010	0.984 - 1.036	0.459
C4 levels at kidney biopsy	0.974	0.866 - 1.096	0.666
Haematological involvement at kidney biopsy	3.588	0.740 - 17.395	0.113
Musculoskeletal involvement at kidney biopsy	0.427	0.114 - 1.605	0.208
Cutaneous involvement at kidney biopsy	0.943	0.248 - 3.582	0.931
CNS/PNS involvement at kidney biopsy	12.106	3.217 - 45.552	< 0.001
Serositis at kidney biopsy	3.396	0.911 - 12.657	0.069
SLEDAI2K at kidney biopsy	1.004	0.943 - 1.070	0.890
SLEDAI2K ≥ 25 at kidney biopsy	0.841	0.172 - 4.116	0.830



Abstract P94 Figure 1 Renal survival. Kaplan-Meier curve displaying the incidence of ESKD from the time of kidney biopsy

subjects displayed an aggressive disease: 2 (3%) children required haemodialysis, 27 (38%) had an estimated glomerular filtration rate (eGFR) <60 mL/min/1.73m^2. The overall median eGFR was 70 mL/min/1.73m^2 (IQR 43–96). Moreover, the median proteinuria was 4 g/24h (IQR 1.35–7.41), with 41 (59%) children displaying a nephrotic range proteinuria (i.e., >3 g/24h). The median follow-up was 13.3 years (IQR 4.7–25.4). A total of 10 patients (13.7%) reached ESKD, the majority of whom (12%) within 10 years from kidney biopsy; during the subsequent follow-up the incidence of ESKD stabilised (figure 1). At last follow-up, around 50% of patients displayed an eGFR <90 mL/min/1.73m^2. A younger age at LN onset, a lower eGFR and central nervous system involvement at the time of kidney biopsy were identified as predictors of ESKD by a univariable Cox regression model (table 1). The same features were significantly associated with the occurrence of CKD stage 3–5 at last follow-up at a univariable logistic regression analysis.

Conclusion LN often presents with severe kidney function impairment and aggressive systemic involvement in children. In our cohort, whose follow-up was among the longest reported in the literature, 12% of patients reached ESKD within 10 years from kidney biopsy. Significant predictors of poor kidney outcome in the long term were a younger age at LN onset, a lower eGFR and the presence of neurological manifestations at the time of kidney biopsy.

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P95 FIRST TWO US PATIENTS WITH LUPUS NEPHRITIS (LN) TREATED WITH ANTI-CD19 CHIMERIC ANTIGEN RECEPTOR (CAR) T-CELL THERAPY: PRELIMINARY RESULTS FROM THE KYSA-1 PHASE 1, MULTICENTER STUDY OF KYV-101

[1]Amber Podoll, [2]Richard Furie, [3]Francis Kim, [3]Justin Chou, [3]Ranjita Sengupta, [4]Ruthee Bayer, [5]Jonathan Gutman, [3]James Chung. *[1]Dept. of Medicine-Renal Medicine, University of Colorado Anschutz Medical Campus, Aurora, USA; [2]Division of Rheumatology, Northwell Health, Great Neck, USA; [3]Kyverna Therapeutics, Emeryville, USA; [4]Dept. of Oncology Hematology, Northwell Health, Lake Success, USA; [5]Dept. of Medicine-Hematology, University of Colorado Anschutz Medical Campus, Aurora, USA*

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Objective LN is a major cause of morbidity and mortality in systemic lupus erythematosus (SLE). Anti-CD19 CAR T-cell therapy has demonstrated promising safety and efficacy in refractory LN (Mackensen, *Nat Med*, 2022). KYV-101 is a fully human autologous anti-CD19 CAR T-cell therapy designed and demonstrated to have a favorable safety profile (Brudno, *Nat Med*, 2020). This is a preliminary report of KYSA-1, an ongoing US phase 1, multicenter study of KYV-101 in refractory LN (NCT05938725).

Methods Adult patients with biopsy-proven class III or IV LN with inadequate response to ³2 conventional therapies are eligible. After apheresis and manufacturing, patients receive 3 days of lymphodepletion (LD) with fludarabine (30 mg/m^2/day) and cyclophosphamide (300 mg/m^2/day) starting on day –7 to –5, followed by a single infusion of KYV-101 on day 0 (dose level [DL] 1, 0.5×10^8 CAR T cells; DL2, 1×10^8 CAR T cells).

Abstract P95 Table 1 Laboratory and Clinical Outcomes for Patient 1 and 2 Through After CAR T-Cell Infusion

	Patient 1						Patient 2			
Parameter, units [reference range]	Pre-LD	Day 0	Day 14	Day 28	Day 56	Day 90	Pre-LD	Day 0	Day 14	Day 28
CD19+ B cells, cells/μL [107–698]	22	0	0	1	7	102	52	3	0	0
ANC, $\times10^9$/L [1.80–7.00]	4.5	0.5	3.7	3.6	3.8	4.7	3.8	1.7	1.1	6.2
Hemoglobin, g/dL [11.5–15.5]	12	9.1	9.5	11.7	12.6	12.9	9	7.9	9.2	9.3
Platelets, $\times10^9$/L [150–400]	93	54	78	103	175	201	341	213	245	453
CRP, mg/L [0–10]	83.3	67.5	4.8	2.8	11.8	9.7	10.9	7.6	6.4	5.4
Anti-dsDNA, IU [<25 = Negative]	297	294	356	304	216	241	293	432	386	281
C3, mg/dL [83–193]	54	59	65	94	135	146	62	58	82	100
C4, mg/dL [15.0–57.0]	9.2	13	18.7	28.8	44.2	41.6	4.9	5.3	9.7	12.8
Proteinuria, [UPCR]	1.4	1.5	0.6	0.9	0.5	0.5	1.3	1.9	1.2	0.6
SLEDAI-2K	19	22	14	13	8	8	12	8	16	10
IgG, mg/dL [757–1941]	620	546	452	429	291	287	1254	970	1017	873
IgM, mg/dL [33–393]	87	73	23	12	5	20	106	85	80	70
IgA, mg/dL [87–534]	118	113	62	46	37	37	370	307	275	190

ANC, absolute neutrophil count; C3, complement component 3; C4, complement component 4; CRP, C-reactive protein; dsDNA, double-stranded DNA; Ig, immunoglobulin; LD, lymphodepletion; SLEDAI-2K, Systemic Lupus Erythematosus Disease Activity Index 2000; UPCR, urine protein creatinine ratio.

Results Two patients have been treated at DL1 with 90 and 28 days of follow-up. Patient 1 is an 18-year-old female patient diagnosed with SLE at age 9 with class IV LN with persistent proteinuria refractory to multiple immunosuppressive therapies. Patient 2 is a 28-year-old female with SLE since 2021 who had failed numerous immunosuppressive therapies for persistently active class IV LN.

After CAR T cell infusion, both patients experienced grade 1 cytokine release syndrome consisting of fever (patient 1 on days 5 and 6; patient 2 on days 10 and 11). No immune effector cell-associated neurotoxicity syndrome, DLTs, or serious AEs occurred. KYV-101 rapidly expanded and B cell depletion was observed with evidence of B-cell recovery observed in patient 1 starting on day 56. Both patients showed improvement in LD associated cytopenias and normalization of CRP and complement levels paralleled their clinical improvement (table 1).

Conclusion While preliminary, these data demonstrate that KYV-101 was well tolerated with evidence of clinical improvement underscoring the potential of anti-CD19 CAR T-cell therapy for treating LN. To date, 9 autoimmune patients have been treated with KYV-101 and a phase 1/2 trial of LN in Europe, KYSA-3, is also ongoing.

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P96 PROGNOSTIC FACTORS FOR CHRONIC KIDNEY DISEASE IN PATIENTS WITH CLASS V LUPUS NEPHRITIS IN 4 REFERENCE CENTERS IN MEXICO

[1]Ivette Ruiz-Leija, [2]David Herrera-Van Oostdam, [1]Jaime Borjas, [3]Enrique Faugier, [3]Sandra Rodríguez-Aguayo, [4]Tayde Gracia-Aréchiga, [4]Miguel Saavedra-Salinas, [5]Fedra Irazoque, [5]Lilia Andrade, [2]Carlos Abud-Mendoza, [2]Grupo de Estudio Potosino de Nefritis Lúpica (LUNPOS). *[1]Dept. of Nephrology, Hospital Central Dr. Ignacio Morones Prieto, San Luis Potosí, Mexico; [2]Dept. of Rheumatology, Hospital Central Dr. Ignacio Morones Prieto, San Luis Potosí, Mexico; [3]Dept. of Rheumatology, Hospital Infantil de Mexico 'Federico Gómez', Mexico City, Mexico; [4]Dept. of Rheumatology, Centro Médico Nacional 'La Raza' IMSS, Mexico City, Mexico; [5]Dept. of Rheumatology, Centro Médico Nacional '20 de Noviembre' ISSSTE, Mexico City, Mexico*

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Objective Analyze prognostic factors for chronic kidney disease progression in Mexican patients with class V lupus nephritis (LN), comparing them with mixed classes.

Methods Retrospective cohort, 74 patients 12–80 years old from 4 different hospitals: 33% LN class V, 23% LN class III +V and 43.2% LN class IV+V.

Results Sixty-two females (83.7%), mean age 33 years old (12–63), 59.5% had hypertension, 6.8% had type 2 diabetes and 8.1% had antiphospholipid antibody syndrome. Twelve-month follow-up eGFR <60 mL/min/1.73m^2 was similar among classes III+V and IV+V LN 40.8% vs class V LN 40%. Even with higher initial eGFR (61 vs 105 mL/min/1.73m^2 p=0.017) and despite adequate treatment, eGFR at 12 months follow-up in class V patients remained the same proportion (56 vs 96 mL/min/1.73m^2 p= 0.105). The percentage of patients with class III+V and IV+V vs class V with eGFR <60 mL/min/1.73m^2 at 12-month follow-up was similar: 40.8% vs 40% (p=0.946). eGFR <60 mL/min/1.73m^2 decline was seen in 55.1% of classes III+V and IV+V group and in 40% of class V group. There was no significant difference in factors for baseline proteinuria at 3, 6, 12, or 24 months in both groups, although those with higher levels of

Abstract P96 Table 1

Variable	NL III+V/IV+V	NL V	p value
Age (years)	31.8 (13.2)	36 (12.4)	0.119
eGFR on admission (mL/min/1.73m^2)	61 (64)	105 (78)	0.017
eGFR 12 months follow-up (mL/min/1.73m^2)	73 (69)	94 (71)	0.128
Proteinuria on admission (g/day)	3.8 (5.0)	3.2 (5.8)	0.575
Proteinuria 12 months follow-up (g/day)	1.5 (2.6)	1.0 (3.0)	0.71
Hypertension	29 (59.2%)	15 (60%)	0.946
Complete remission	20 (40.8%)	16 (64%)	0.059
Partial remission	10 (20.4%)	3 (12%)	0.522
Relapse	3 (6.1%)	5 (20%)	0.11
No response	21 (42.9%)	6 (24%)	0.11
eGFR <60 mL/min at 12 months	20 (40.8%)	10 (40%)	0.946
Proteinuria >0.5 g/day at 12 months	35 (71.4%)	15 (60%)	0.32
Proteinuria >3.5 g/day at 12months	9 (18.4%)	5 (20%)	1.0