UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): June 14, 2024

Kyverna Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-41947**	**83-1365441**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

5980 Horton St., STE 550 **Emeryville, California**	**94608**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (510) 925-2492

N/A
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.00001 per share	KYTX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On June 14, 2024, Kyverna Therapeutics, Inc. (the "Company") hosted an industry symposium at EULAR in Vienna with a data update on KYV-101, its lead CAR T-cell therapy candidate. A copy of the Company's presentation is being furnished as Exhibit 99.1. The Company's presentation is current as of June 14, 2024, and the Company disclaims any obligation to update this material in the future.

The information in this Current Report on Form 8-K, including Exhibit 99.1 attached hereto, is furnished pursuant to Item 7.01 and shall not be deemed "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section. It may only be incorporated by reference in another filing under the Exchange Act or the Securities Act of 1933, as amended, if such subsequent filing specifically references the information furnished pursuant to Item 7.01 of this Current Report on Form 8-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit	Description
99.1	Presentation - Anti-CD19 CAR T-Cell Therapy in Rheumatologic Autoimmune Diseases and Beyond, dated June 14, 2024.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

KYVERNA THERAPEUTICS, INC.

Date: June 14, 2024

By: /s/ Ryan Jones
Name: Ryan Jones
Title: Chief Financial Officer

Exhibit 99.1

Anti-CD19 CAR T-Cell Therapy in Rheumatologic Autoimmune Diseases and Beyond

Welcome and Introductions

Peter Maag, PhD
Chief Executive Officer, Kyverna Therapeutics
June 14, 2024

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Time	Session Title	Presenter
8:15-8:20	Welcome and Introduction	Peter Maag, PhD Kyverna Therapeutics
8:20-8:35	Long-Term Clinical Experience and Mechanistic Insights	Gerhard Krönke, MD Charité – University Medicine Berlin
8:35-8:50	Experience in Advancing CAR T Trials in Rheumatologic Diseases	Peter A. Merkel, MD, MPH University of Pennsylvania
8:50-9:05	KYV-101 Experience Across Multiple Diseases and Sites	James Chung, MD, PhD Kyverna Therapeutics
9:05-9:30	Panel Discussion • Gerhard Krönke, MD – Charité – University Medicine Berlin • Richard Furie, MD – Northwell Health • Dominic Borie, MD, PhD – Kyverna Therapeutics • James Chung, MD, PhD – Kyverna Therapeutics	Moderator: Peter A. Merkel, MD, MPH University of Pennsylvania

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Disclaimer and Forward-Looking Statements

This presentation contains forward-looking statements that are based on management's beliefs and assumptions and on information currently available to management of Kyverna Therapeutics, Inc. ("Kyverna", "we", "our," or the "Company"). All statements other than statements of historical facts contained in this presentation are forward-looking statements. Forward looking statements include, but are not limited to, statements concerning: the Company's future results of operations and financial position, business strategy, drug candidates, planned preclinical studies and clinical trials, results of preclinical studies and named patient activities, ongoing clinical trials, research and development costs, plans for manufacturing, regulatory approvals, timing and likelihood of success, as well as plans and objectives of management for future operations. These forward-looking statements are subject to risks and uncertainties, including the factors described under the Risk Factors section of the Company's most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q that the Company has filed or may subsequently file with the U.S. Securities and Exchange Commission. Actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements. When evaluating Kyverna's business and prospects, careful consideration should be given to these risks and uncertainties. These statements speak only as of the date of this presentation, and Kyverna undertakes no obligation to update or revise these statements.

This presentation also contains estimates made by independent parties relating to industry market size and other data. These estimates involve a number of assumptions and limitations and you are cautioned not to give undue weight on such estimates. We have not independently verified the accuracy or completeness of such information and we do not take any responsibility with the accuracy or completeness of such information.

This presentation contains references to trademarks and marks belonging to other entities. Solely for convenience, trademarks and trade names referred to in this presentation may appear without the ® or TM symbols, but such references are not intended to indicate, in any way, that the applicable licensor will not assert, to the fullest extent under applicable law, its rights to these trademarks and trade names. The Company does not intend its use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of the Company by, any other companies.

This presentation includes results from named patient activities. Named patient activities are not part of our clinical trials for KYV-101 and data from these trials and activities are reported by the relevant investigators and physicians. Such data are not obtained using a single protocol or designed to be aggregated or reported as study results and may be highly variable. While we do not expect to be able to use the results from these investigator-initiated trials or named patient activities in our applications for marketing approval to the U.S. Food and Drug Administration or other foreign regulatory agencies, we believe that this strategy may provide some competitive advantage as we will be able to acquire additional clinical insights beyond highly focused clinical trials in specific geographies.

Kyverna's 6 Years of Dedication to Autoimmune Disease

MAY 2018

KYVERNA FOUNDED FOR AUTOIMMUNE DISEASES

Kyverna's CD19 CAR T-cell Hypothesis

NATURE MEDICINE
BRUDNO[1]
February 2020
Nature Medicine
Article
Safety and Feasibility of Anti-CD19 CAR T Cells With Fully Human Binding Domains in Patients With B-Cell Lymphoma

NIH

NEJM
SCHETT[2]
August 2021
New England Journal of Medicine
Correspondence
CD19-Targeted CAR T Cells in Refractory Systemic Lupus Erythematosus

NATURE MEDICINE
SCHETT[3]
September 2022
Nature Medicine
Correspondence
Anti-CD19 CAR T Cell Therapy for Refractory Systemic Lupus Erythematosus

Kyverna's First IND Cleared

MAY 2024

50 PATIENTS TREATED WITH CAR IN KYV-101

Note: Timeline not to scale.
CAR, chimeric antigen receptor; IND, investigational new drug.
1. Brudno JN, et al. *Nat Med*. 2020;26:270-280. 2. Mougiakakos D, et al. *N Engl J Med*. 2021;385:567-569. 3. Mackensen A, et al. *Nat Med*. 2022;28:2124-2132.

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Is a Reset of the Immune System Possible?

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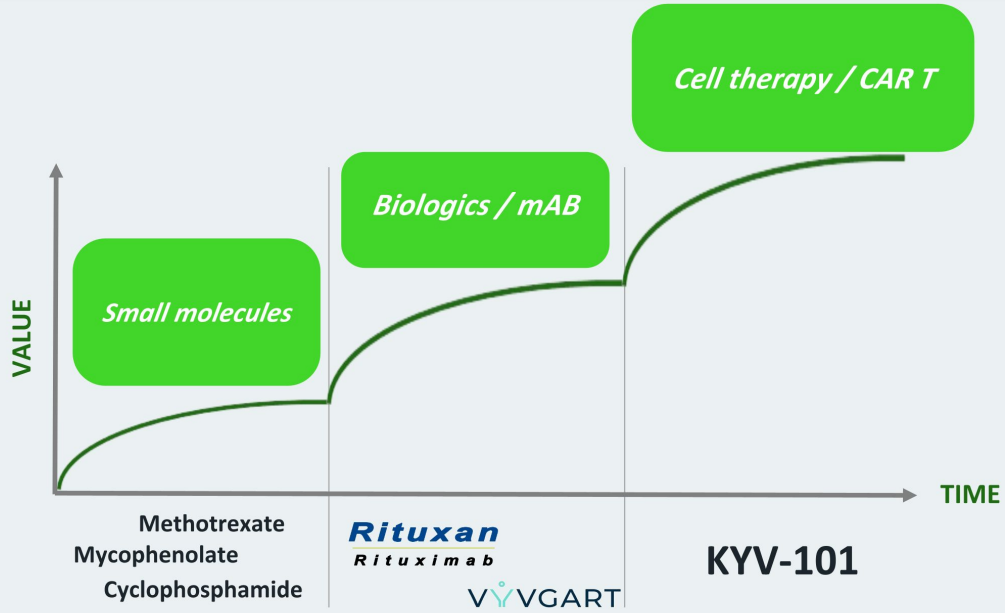
Cell Therapy Is Shifting the Paradigm in Autoimmune Diseases



CAR, chimeric antigen receptor, mAB, monoclonal antibodies.

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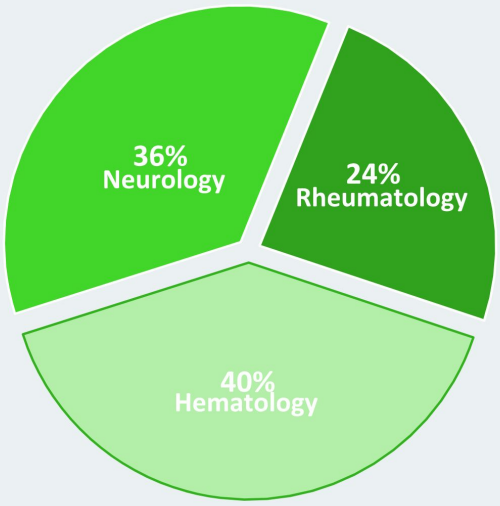
Early KYV-101 Data Demonstrate Promising Outcomes Across Multiple Indications

Total of 50 Patients Treated With CAR in KYV-101[1,2]



Early Experience

- CAR T-Cell Expansion ✓
- B-Cell Depletion ✓
- Autoantibody Reduction ✓
- Disease Impact ✓
- DIFR ✓
  (Durable Immunomodulator-Free Response)

CAR, chimeric antigen receptor.
1. Brudno JN, et al. *Nat Med.* 2020;26:270-280. 2. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience.

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Acknowledgments – Creating the Kyverna Village

- **Patients and Their Families**
  for their courage and trust
- **Care Givers and Collaborators**
  for their partnership
- **Kyverna Employees**
  for their hard work and dedication

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KYV-101 Experience Across Multiple Diseases and Sites

Anti-CD19 CAR T-Cell Therapy in Rheumatologic Autoimmune Diseases and Beyond

James Chung, MD, PhD
Chief Medical Officer, Kyverna Therapeutics
June 14, 2024

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Commitment to Generating Clinical Insights Along 3 Pillars Strategy

3 Pillars of Emerging Experience

Patient-Centric "Named Patient Use"

In patients with highly-refractory, serious autoimmune disease with limited or no treatment options

Indications include MG, SSc, and rare autoimmune diseases such as SPS and autoimmune encephalitis

Kyverna-Sponsored (KYSA) Clinical Trials

Phase 1/2 rheumatology protocols in US and EU
LN, SSc: enrolling

Phase 2 neurology protocols in US and EU
MG, MS: in activation

Investigator-Initiated Clinical Trials

Focuses on the interests and unmet needs as defined by scientific community

Informs indication selection

Drives long-term collaboration with top-tier academic centers

LN, lupus nephritis; MG, myasthenia gravis; MS, multiple sclerosis; SPS, stiff person syndrome, SSc, systemic sclerosis.

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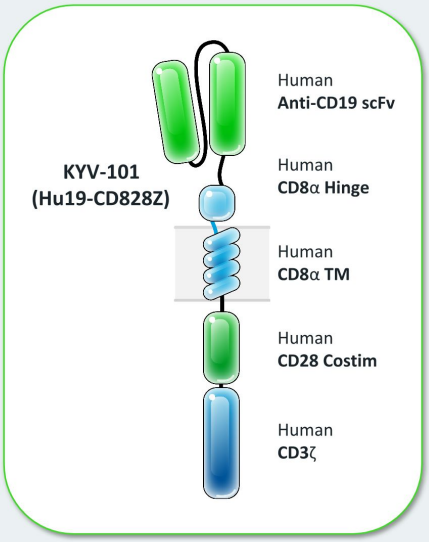
First-in-Class, KYV-101, an Autologous, Fully Human, Anti-CD19 CAR T-Cell Therapy



Engineered for improved safety profile

- Developed at the NIH to improve upon axicabtagene ciloleucel (YESCARTA®)[1,2]
  - Fully human single-chain variable fragment compared with murine
  - CD8 hinge and TM domains compared with CD28 hinge and TM domains

Safety of CAR construct validated by clinical data

- 20 patients with B cell lymphoma treated in Phase 1 trial by NIH[1]
  - Lower cytokine levels, neurotoxicity and immunogenicity
- 30 patients with autoimmune indications[3]
  - Low levels of cytokine release (CRS, ICANS)

CAR, chimeric antigen receptor; costim, costimulatory; CRS, cytokine release syndrome; ICANS, immune effector cell-associated neurotoxicity syndrome; NIH, National Institutes of Health; scFv, single-chain variable fragment; TM, transmembrane.

1. Brudno JN, et al. *Nat Med*. 2020;26:270-280. 2. Alabanza L, et al. *Mol Ther* . 2017;25(11):2452-2465. 3. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience.

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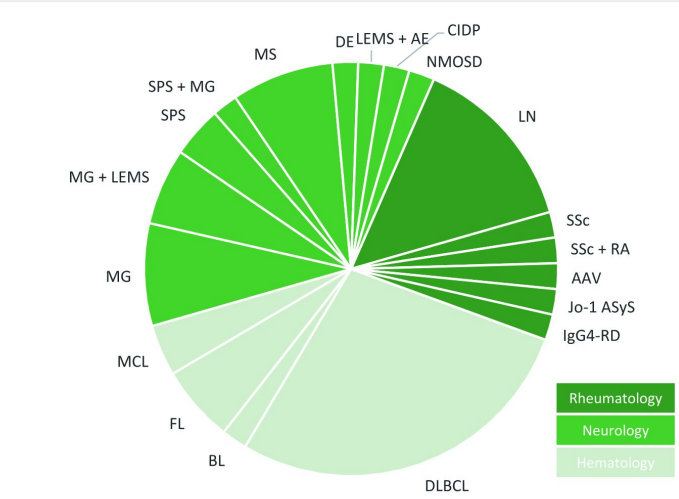
KYV-101 CAR Experience Across Multiple Indications (N=50)

50 Patients Across Diverse Indications Treated With the KYV-101 CAR Construct



15
Autoimmune Indications:
6 in rheumatology and
9 in neurology

AAV, ANCA-associated vasculitis; AE, autoimmune encephalitis; ASyS, antisynthetase syndrome; BL, Burkitt lymphoma; CAR, chimeric antigen receptor; CIDP, chronic inflammatory demyelinating polyradiculoneuropathy; DLBCL, diffuse large B cell lymphoma; DE, DAGLA encephalitis; FL, follicular lymphoma; IgG4-RD, IgG4-related disease; LEMS, Lambert-Eaton myasthenic syndrome; LN, lupus nephritis; MCL, mantle cell lymphoma; MG, myasthenia gravis; MS, multiple sclerosis; RA, rheumatoid arthritis; SSc, systemic sclerosis; SPS, stiff person syndrome; KYV-101 CAR refers to both KYV-101 and NIH clinical experience with the underlying CAR used to create KYV-101.

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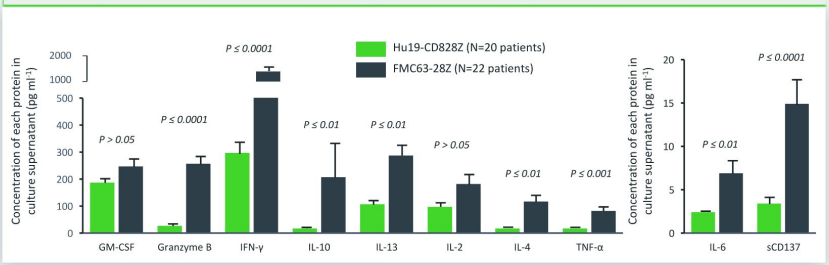
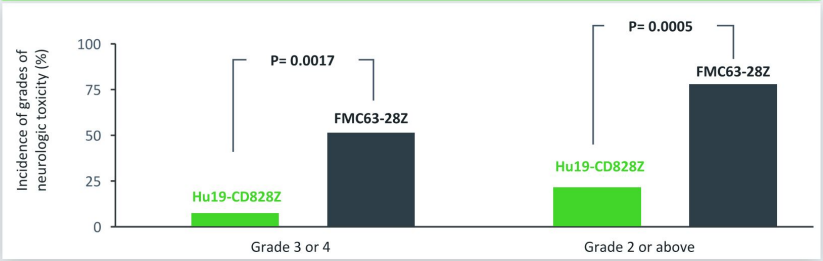
KYV-101 CAR Safety and Efficacy Experience From Hematology (N=20 NIH Phase 1)

Reduced Cytokine Production in Oncology Observed Compared to YESCARTA® Construct



Reduced Neurologic Toxicity Observed Compared to YESCARTA® Construct



KYV-101 Key Lessons

- CAR demonstrated an improved safety profile in a 20-patient study without compromising efficacy
- Data supported dose-selection for autoimmune disease setting

CAR, chimeric antigen receptor; GM-CSF, granulocyte-macrophage colony-stimulating factor; IFN, interferon; IL, interleukin; TNF, tumor necrosis factor; KYV-101 CAR refers to the underlying CAR used to create KYV-101.

1. Brudno JN et al. *Nat Med.* 2020;26:270-280.

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KYV-101 CAR-Related Safety Data Shows No CRS or ICANS Grade ≥3 in First 30 Patients

Source	Indication	N	Any Grade CRS	Any Grade ICANS[a]	CRS Grade ≥3	ICANS Grade ≥3
KYV-101 experience[1]	**Rheum & Neuro**	**30**	**25**	**3**	**0**	**0**
Schett Group case series[2]	SLE, IIM, SSc	15	9	1	0	0
Hu19-NIH Ph1 Lymphoma study[3]	DLBCL, FL, BL, MCL	20	18	NR[d]	2	1
ZUMA-1 (axi-cel)[4]	DLBCL 3L	101	94	65	13	28
TRANSCEND (liso-cel)[5]	DLBCL 3L	268	122	95	11	32[b]
JULIET (tisa-cel)[6]	DLBCL 3L	115	85	69	26[c]	22

- CAR T-cell therapies are associated with class effects, including CRS and ICANS, which may be potentially serious or life-threatening, but generally resolve within the first month of treatment and are manageable with close monitoring by a treating physician

[a]References 3-6 are reported as neurological toxicities. [b]Reported at 12% of 268 patients. [c]Reported as 23% of 115 patients. [d]Grade 1 neurological AEs were not recorded in this trial. Three subjects had Grade 2 ICANS, and 16 patients had Grade <2 ICANS. These limited observations are derived from separate clinical settings, and with respect to the autoimmune data are based primarily on information from case reports rather than clinical trials. They do not represent head-to-head comparisons of CD19 CAR T-cell treatment in autoimmune indications as compared to oncology indications. Future clinical trials may not confirm the clinical safety observations discussed in these case reports and studies.

BL, Burkitt lymphoma; CRS, cytokine release syndrome; DLBCL, diffuse large B cell lymphoma; FL, follicular lymphoma; ICANS, immune effector cell-associated neurotoxicity syndrome; IIM, idiopathic inflammatory myopathies; MCL, mantle cell lymphoma; Neuro, neurology; NR, not reported; Rheum, rheumatology; SLE, systemic lupus erythematosus; SSc, systemic sclerosis.

1. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience with 28-day follow up as of June 04, 2024. 2. Müller F, et al. *N Engl J Med*. 2024;390(8):687-700. 3. Brudno JN, et al. *Nat Med*. 2020;26(2):270-280. 4. Neelapu SS, et al. *N Engl J Med*. 2017;377(26):2531-44. 5. BREYANZI® (lisocabtagene maraleucel) Prescribing Information 2024, Bristol-Myers Squibb. 6. KYMRIAH® (tisagenlecleucel) Prescribing Information 2022, Novartis Pharmaceuticals.

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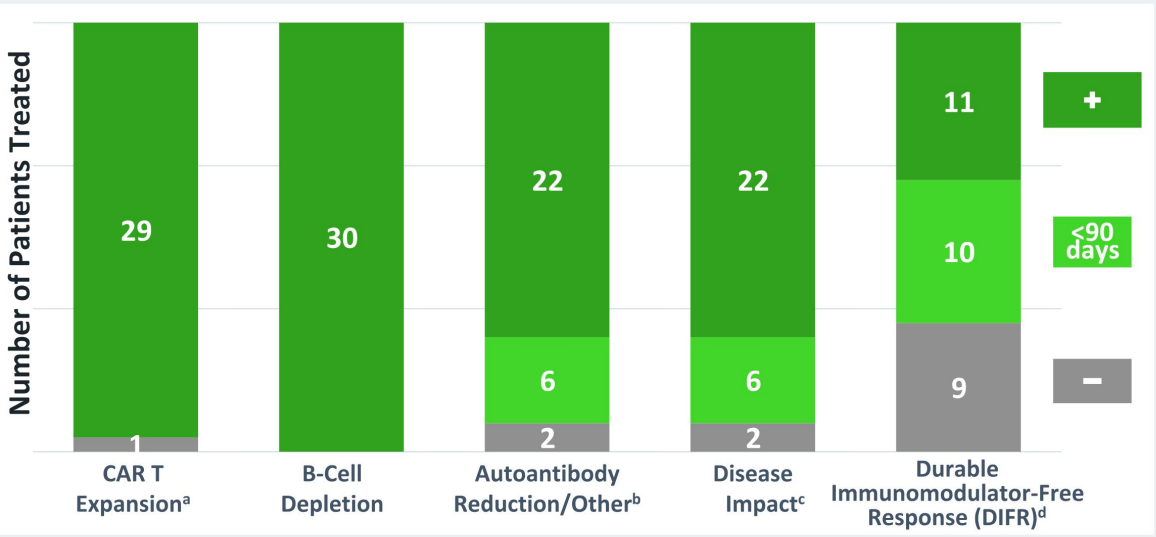
KYV-101 Demonstrates Promising Outcomes Across Multiple Indications (N=30)

KYV-101 Effects in 30 Patients With Autoimmune Diseases



[a]No CAR T expansion defined as Cmax < 6 cells/µL and area under curve 56 <100. [b]Other refers to impact on OCBs (MS patients) or reduced IgG4 levels (IgG4-RD patients). [c]Demonstration of reduced clinical and biological activity. [d]Durable response defined as no immunomodulator use for ≥3 preceding months at the time of data cut through June 4, 2024.
1. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience. Observations are derived from separate clinical settings and are based in part on information from case reports rather than clinical trials. Future clinical trials may not confirm the observations discussed in these case reports and studies.
CAR, chimeric antigen receptor; IgG4-RD, Immunoglobulin G 4-related disease; MS, multiple sclerosis.

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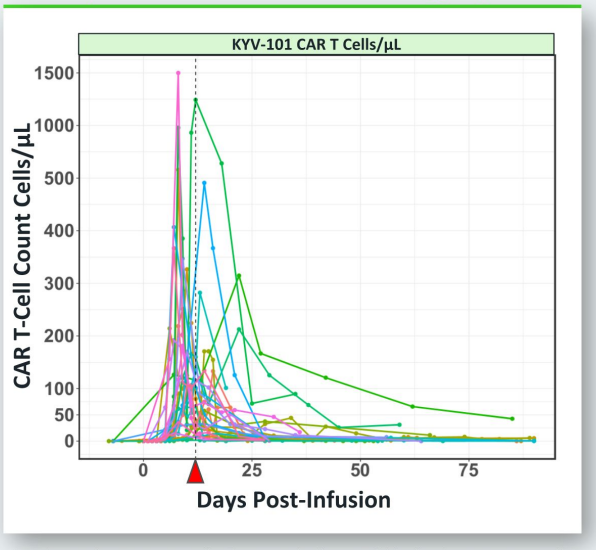
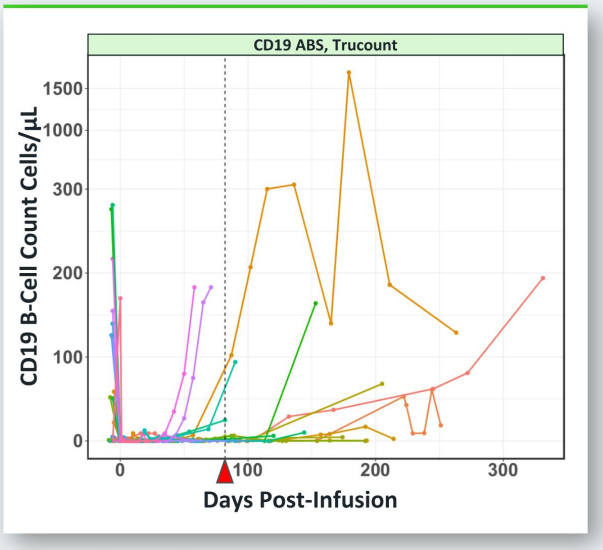
Trailblazing in Autoimmune Disease With 30 Patients Experience

CAR Expansion Consistent With Oncology Experience



Pharmacodynamic Activity and Return of B Cells



Note: Red triangles indicate median time to CAR T-cell peak expansion for all patients (left) and median time to CD19 B-cell reconstitution for patients whose B cells have returned (right).
ABS, absolute; CAR, chimeric antigen receptor.
1. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience as of May 24, 2024.

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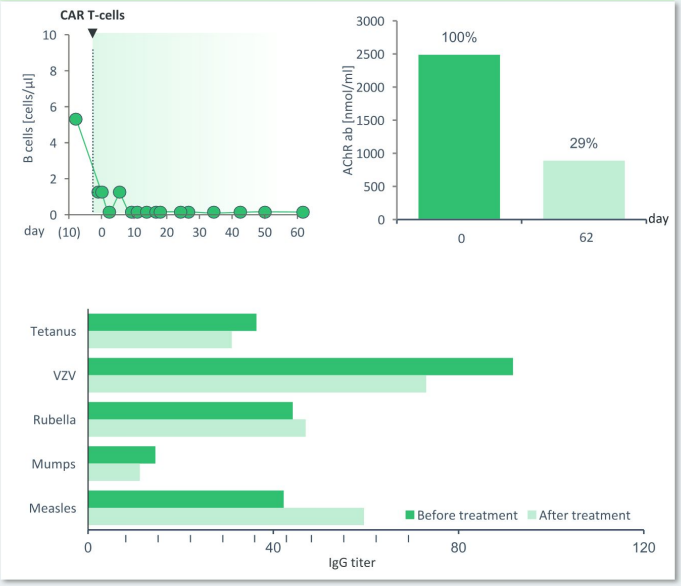
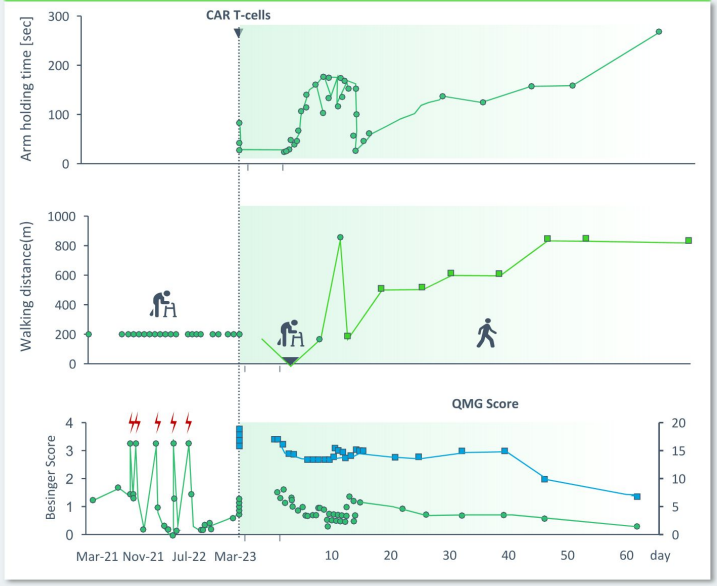
Myasthenia Gravis Named Patient #1 – Lancet Neurology

Within 60 Days of Infusion, Observed Improved Symptoms and Mobility

Observed dramatic reduction in AChR-ab serum levels, while maintaining antibody titers



After 5 ICU admissions in 18 months, improvement in QMG score and mobility observed



Note. Named patient data. AChR-ab, acetylcholine receptor antibody; CAR, chimeric antigen receptor; ICU, intensive care unit; IgG, immunoglobulin G; QMG, quantitative myasthenia gravis; VZV, varicella-zoster virus.

1. Haghikia A, et al. *Lancet Neurol.* 2023;22:1104-1105

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Denise – 1 Year Anniversary

First KYV-101 autoimmune patient at 1 year

- Disease free
- No adverse events
- No background immunosuppressants or glucocorticoids
- B cells repopulated as of day 132

For detailed case description, see: Haghikia et al., *Anti-CD19 CAR T Cells for Refractory Myasthenia Gravis*, The Lancet J. of Neurology (Vol. 22 Dec. 2023) and Haghikia et al, *"World's First Successful Treatment of the Autoimmune Disease Myasthenia Gravis,"* The Medical University Hospital Magdeburg A.o.R. (Nov. 2023).

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Our Pipeline of CAR T-Cell Therapies for Autoimmune Diseases

Technology	Candidates	Target	Indication	Discovery / Validation	Preclinical	Clinical Phase 1	Clinical Phase 2	Clinical Phase 3	Partnership / Commercial Rights	Key Milestone Achieved
CAR T	KYV-101 Rheumatology	CD19	Lupus nephritis	KYSA-1 Phase 1/2 (US) KYSA-3 Phase 1/2 (EU)					kyverna	KYSA-1: IND cleared 11/22 Fast Track 05/23 KYSA-3: CTA cleared 06/23
			Systemic sclerosis	KYSA-5 Phase 1/2 (US)					kyverna	IND cleared 10/23
	KYV-101 Neurology	CD19	Myasthenia gravis	KYSA-6 Phase 2 (US)					kyverna	IND cleared 11/23 Fast Track 12/23 ODD 04/24
			Multiple sclerosis	KYSA-7 Phase 2 (US)					kyverna	IND cleared 12/23 Fast Track 01/24
CRISPR / Cas9 Allogeneic	KYV-201	CD19	Multiple indications						kyverna Intellia THERAPEUTICS	
CAR T & Other Approaches	Multiple	Multiple	IBD & other indications						kyverna	

Note: IBD includes Crohn's disease and ulcerative colitis.
Note: Fast track designation does not assure that we will experience a faster development process, regulatory review or regulatory approval process compared to conventional FDA procedures.
CAR, chimeric antigen receptor; CRISPR, clustered regularly interspaced short palindromic repeats; CTA, clinical trial application; FDA, Food and Drug Administration; IBD, inflammatory bowel disease; IND, investigational new drug; ODD, orphan drug designation.

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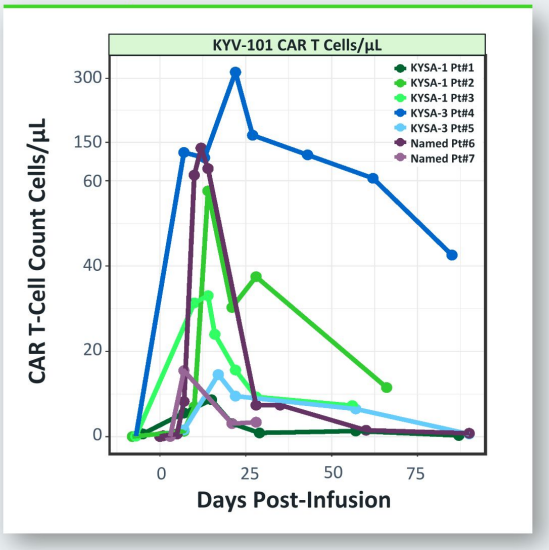
Demonstrating the Transformative Impact of KYV-101 on Lupus Nephritis Disease Control

Patient[a]	Prior IS	CAR T-Cell Dose	Post KYV-101 Infusion[b]
KYSA-1 Pt 1	RTX, AZA, CYC, Tac, MTX, Sir, Bel, MMF, Pred, HCQ	50 M	No IS; Pred 10mg/d → MMF -> BID, HCQ Pred 50mg/d
KYSA-1 Pt 2	Sol, AZA, CYC, Bel, Voc, MMF, Pred, HCQ	50 M	No IS; Pred 5mg/d
KYSA-3 Pt 4	CYC, Bel, MMF, Pred, HCQ	100 M	**No IS or GC**
KYSA-3 Pt 5	AZA, CYC, Bel, Ani, RTX, MTX, MMF, Pred, HCQ	100 M	**No IS or GC**
KYSA-1 Pt 3	CYC, Bel, Voc, Tac, RTX, Sol MMF, Pred, HCQ	50 M	No IS; Pred 5mg/d
Named Pt 6	CYC, Bel, Ani, HCT, Lef, MMF, Pred	100 M	No IS; Pred 2.5mg/d
Named Pt 7	MMF/Tac, RTX, Bel, Obi, GC	100 M	No IS; Pred 17.5mg/d

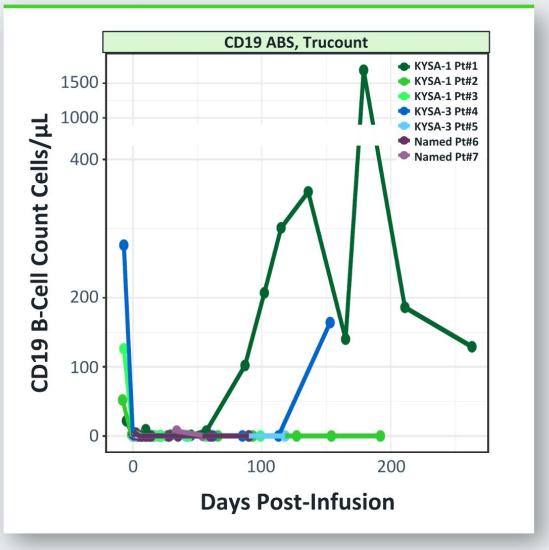
[a]Patient order based on time from CAR T infusion. [b]Data Cutoff: May 24, 2024. Pred dose post-infusion listed as last reported dose after taper.
1. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience. Observations are derived from separate clinical settings and interim results. Future clinical trials may not confirm the observations discussed in these case reports and studies.
Ani, anifrolomab; AZA, azathioprine; Bel, belimumab; CYC, cyclophosphamide; GC, glucocorticoids; HCQ, hydroxychloroquine; HCT, hydrocortisone; IS, immunosuppressive agent; Lef, leflunomide; M, million; MMF, mycophenolate mofetil; MTX, methotrexate; Obi, obinutuzumab; Pred, predniso(lo)ne; RTX, rituximab; Sir, sirolimus; Sol, solumedrol; Tac, tacrolimus; Voc, voclosporin.

Early Lupus Nephritis Patient Data: Pharmacokinetics and B-Cell Count

CAR Expansion Consistent With Oncology



Pharmacodynamic Activity and Return of B Cells



1. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience.
ABS, absolute; CAR, chimeric antigen receptor.

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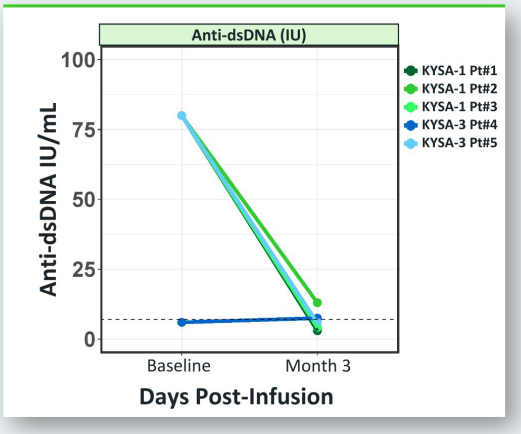
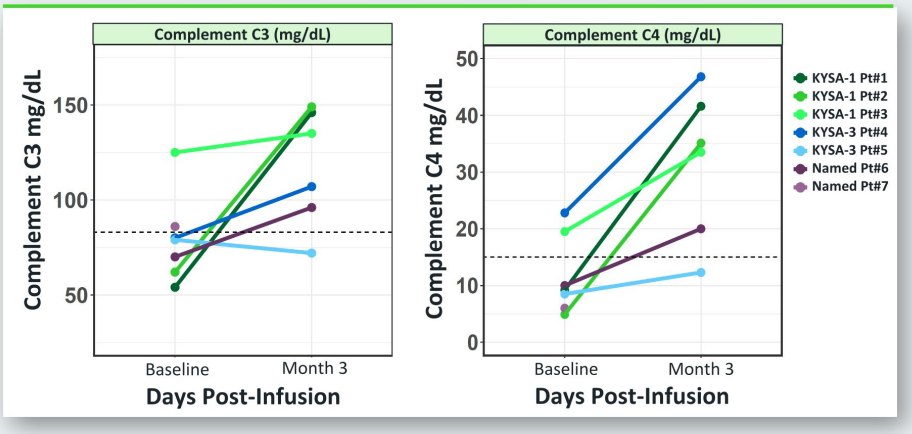
Improvement at 3 Months in Biomarkers and Overall Disease Activity

Reduction in Autoantibodies (RIA)



Normalization of Complement



- Rapid decrease in anti-dsDNA antibodies in all subjects
- Normalization of complement components (C3/C4)
- Overall improvement in clinical disease activity

1. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience.
dsDNA, double-stranded deoxyribonucleic acid; IU, international units.

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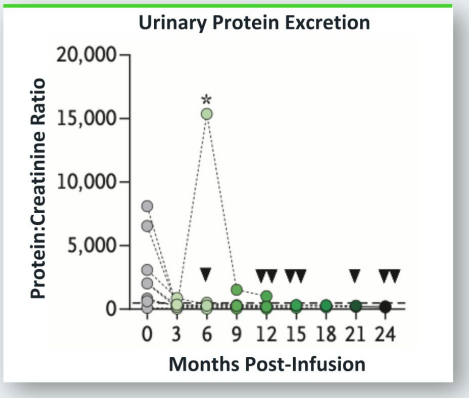
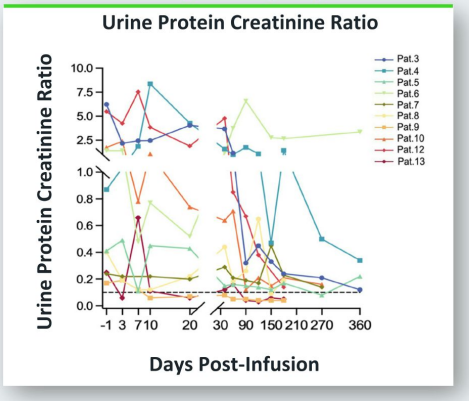
Proteinuria Clinical Trial Experience and Case Reports

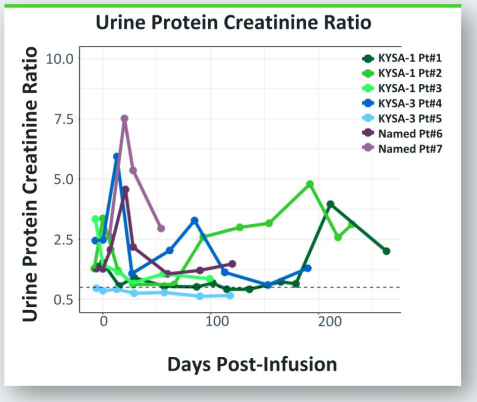
Müller et al.[1] (Erlangen)



Wang et al.[2] (iCell)



KYV-101



- High variability observed in the short term

1. Muller et al. *N Engl J Med*. 2024;390:687-700. 2. Wang et al. *Ann Rheum Dis*. 2024 May 30:ard-2024-225785. 3. Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience.

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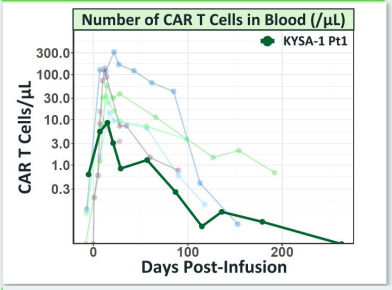
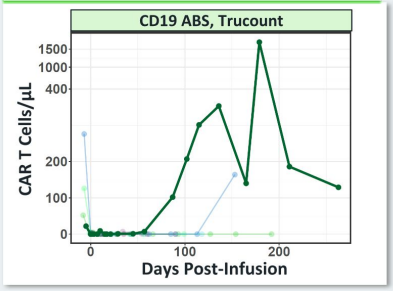
Short-Term Disease Control in One Patient With Lupus Nephritis

Low CAR expansion at 50M cells



Early return of B cells at 50M cells



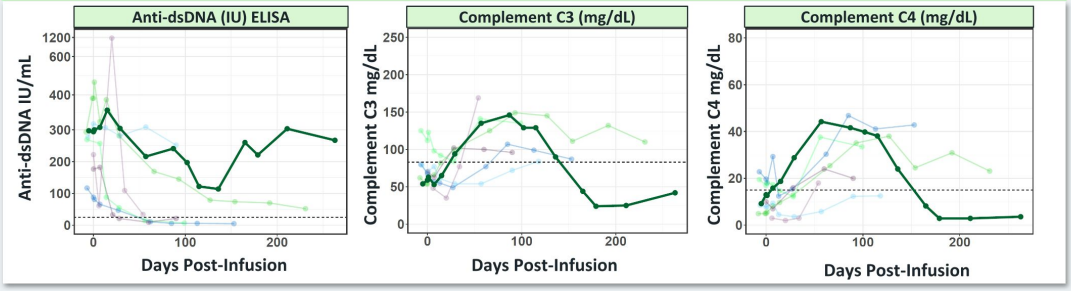
Promising safety profile

Initial disease response

Disease recurrence after 5 months

- Patient with high BMI and treated with 50M cells
- Low CAR exposure associated with initial response but disease recurrence

Initial improvements in biomarkers and disease activity followed by recurrence of disease after 5 months



BMI, body mass index; CAR, chimeric antigen receptor; ITP, immunothrombocytopenia.

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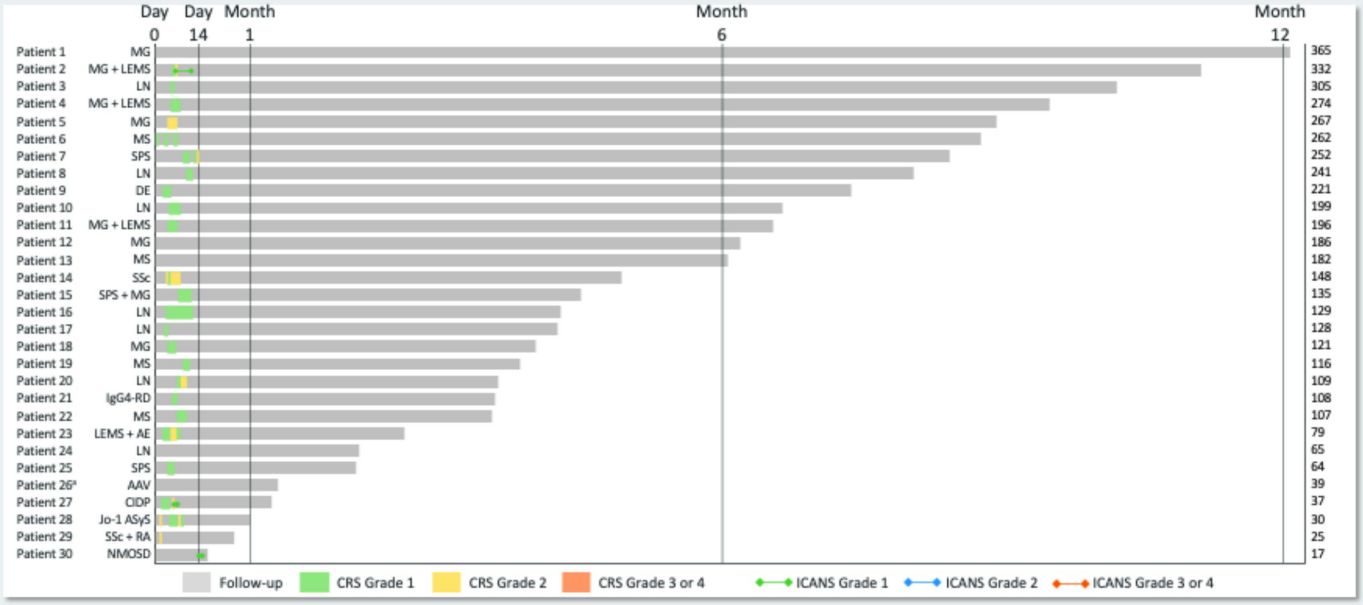
Safety: CAR T Cell-Related Safety Events, If Encountered, Are Readily Manageable

No ≥ Grade 3 CRS or ICANS Observed



[a]Adverse events report pending. Note: Time from infusion as of May 29, 2024 (days). Internal data from KYSA-1, KYSA-3, and investigator-reported named patient experience.

AAV, ANCA-associated vasculitis; AE, autoimmune encephalitis; ASyS, antisynthetase syndrome; CIDP, chronic inflammatory demyelinating polyradiculoneuropathy; CRS, cytokine release syndrome; DE, DAGLA encephalitis; ICANS, immune effector cell-associated neurotoxicity syndrome; IgG4-RD, immunoglobulin G4-related disease; LEMS, Lambert-Eaton myasthenic syndrome; LN, lupus nephritis; MG, myasthenia gravis; MS, multiple sclerosis; RA, rheumatoid arthritis; SSc, systemic sclerosis; SPS, stiff person syndrome.

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Published Case Reports – *Neuron*
KYV-101 in Myasthenia Gravis

Neuron

Case Study

Treatment of concomitant myasthenia gravis and Lambert-Eaton myasthenic syndrome with autologous CD19-targeted CAR T cells

Highlights

- Anti-CD19 CAR T cell therapy led to clinical recovery in two cases of MG and LEMS
- Patients regained full mobility, with ongoing recovery 4- and 6-months post infusion
- Deep B cell depletion and normalization of pathogenic autoantibodies was observed
- Application of anti-CD19 CAR T cells was safe, with manageable side effects

Authors

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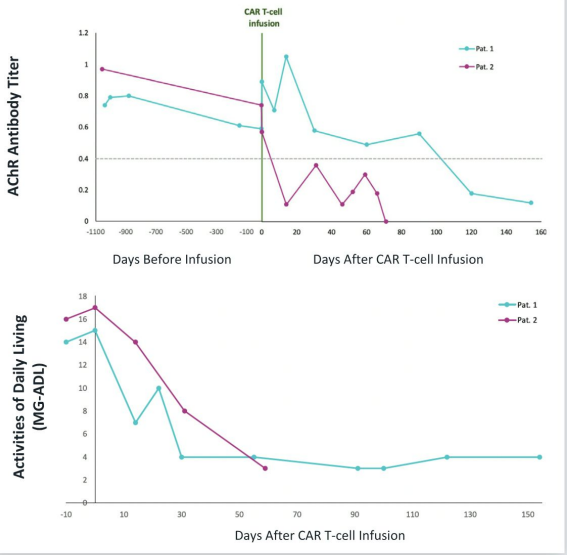
Impact on Autoantibodies and MG-ADL disease score



AChR, acetylcholine receptor; CAR, chimeric antigen receptor; LEMS, Lambert-Eaton myasthenic syndrome; MG, myasthenia gravis; MG-ADL, MG activities of daily living scale.

1. Motte J, et al. *Neuron* 2024;112:1–7.

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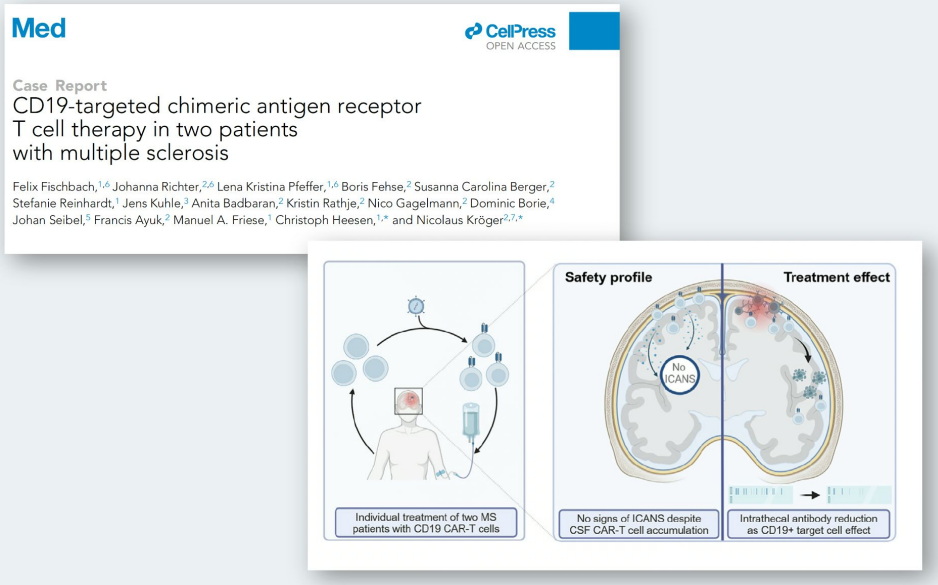
Published Case Reports – *MED*
KYV-101 in Multiple Sclerosis


Med

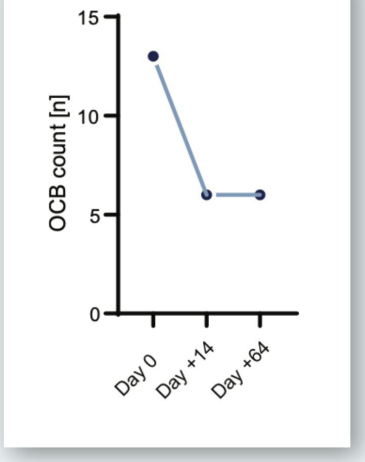
CellPress
OPEN ACCESS

Case Report

CD19-targeted chimeric antigen receptor T cell therapy in two patients with multiple sclerosis

Felix Fischbach,[1,6] Johanna Richter,[2,6] Lena Kristina Pfeffer,[1,6] Boris Fehse,[2] Susanna Carolina Berger,[2] Stefanie Reinhardt,[1] Jens Kuhle,[3] Anita Badbaran,[2] Kristin Rathje,[2] Nico Gagelmann,[2] Dominic Borie,[4] Johan Seibel,[5] Francis Ayuk,[2] Manuel A. Friese,[1] Christoph Heesen,[1,*] and Nicolaus Kröger[2,7,*]

Evidence of Biologic Activity by Demonstrated Decrease in OCBs



CAR, chimeric antigen receptor; CSF, cerebrospinal fluid; ICANS, immune effector cell-associated neurotoxicity syndrome; MS, multiple sclerosis; OCB, oligoclonal band.

1. Fischbach F, et al. *Med*. 2024;22:S2666-6340(24)00114-4.

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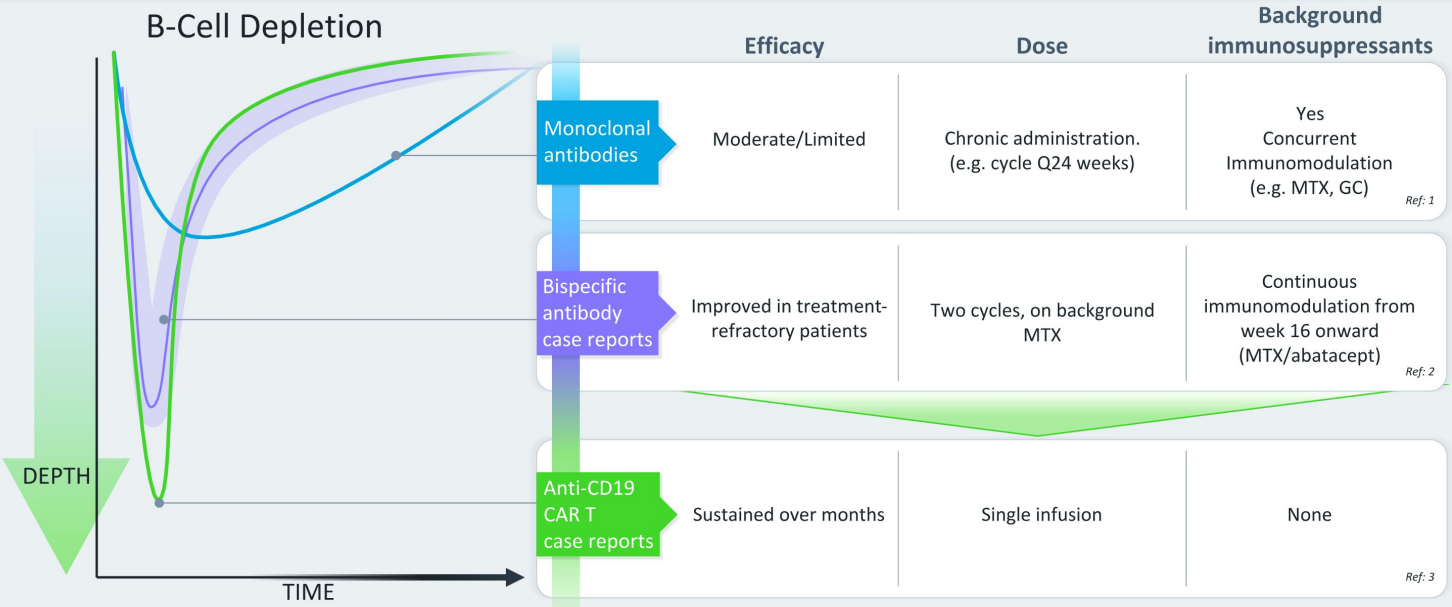
CAR T-Cell Therapy May Allow Complete Disease Control in a Treatment-Free Setting (*Immune Reset*)



Note: Bispecific antibody experience in autoimmunity and anti-CD19 CAR T in autoimmunity based on published case reports rather than clinical trials.
CAR, chimeric antigen receptor; GC, glucocorticoids; MTX, methotrexate, Q24, every 24.
1. RITUXAN® (rituximab) USPI, Biogen and Genentech USA, Inc. 2021. 2. Bucci L, et al. *Nat Med*. 2024;Apr 26. 3. Müller F, et al. *N Engl J Med*. 2024;390:687-700.

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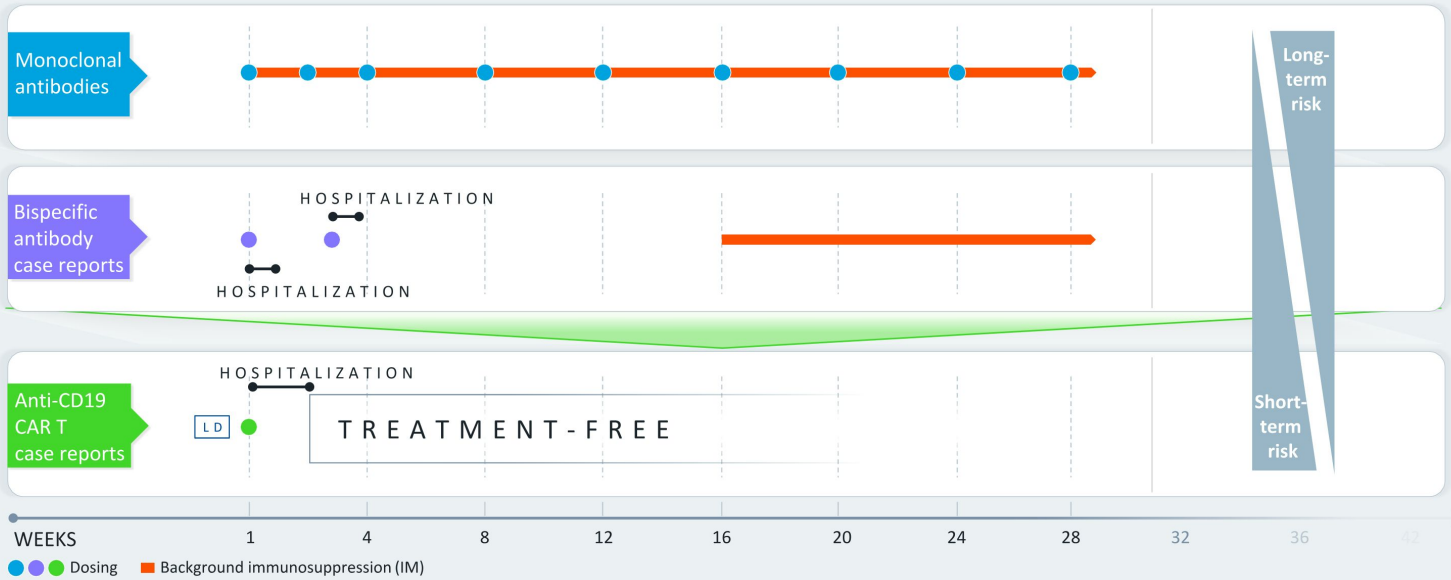
Conceptual Considerations for Various B-Cell Targeting Approaches Favor CAR T-Cell Therapy (*Immune Reset*)



Note: Bispecific antibody experience in autoimmunity and anti-CD19 CAR T in autoimmunity based on published case reports rather than clinical trials; bispecific antibody experience adapted from Bucci L, et al. *Nat Med*. 2024;Apr 26.; anti-CD19 CAR T LD and hospitalization estimated from unpublished KYSA study protocols and internal data. Anti-CD19 CAR T treatment-free duration experience adapted from published case reports, including Müller F, et al. *N Engl J Med.* 2024;390:687-700. Monoclonal experience modeled on intravenous BENLYSTA (belimumab) Prescribing Information 2024. GlaxoSmithKline.
CAR, chimeric antigen receptor; LD, lymphodepletion.

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Conclusions

- Over 50 patients have received the KYV-101 CAR construct
- The 30-patient experience in autoimmune diseases shows a promising safety profile, expected CAR T-cell expansion, and effective B-cell depletion
- There is reduction in autoantibodies and overall improvement of disease activity in the setting of immunosuppressant withdrawal
- The first patient treated has DIFR after 1 year
- These data support advancing a broad clinical trial program across a range of rheumatic and neurologic autoimmune diseases

CAR, chimeric antigen receptor; DIFR, durable immunomodulator-free response; LN, lupus nephritis.

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