

Kyverna: Can One Miv-cel Infusion Sustain Function Without Chronic Immunotherapy in Refractory Stiff-Person Syndrome?

INITIATION MODE	CATALYST	EXPECTED BREADTH
Prospective The rolling BLA is not complete; no FDA acceptance or action date has been announced.	FDA action on the miv-cel BLA in SPS Rolling submission begun with the CMC module; completion targeted for the fourth quarter of 2026.	★★★★☆ Against US specialist care for immunotherapy-refractory, antibody-positive SPS. Basis on page 15.

My take

Miv-cel (mivocabtagene autoleucel, formerly KYV-101) is Kyverna's autologous, fully human CD19 CAR T-cell therapy. After cyclophosphamide and fludarabine conditioning, a single infusion targeting about 100 million CAR T cells is designed to deplete CD19-expressing B cells, which are thought to contribute to the GAD65 and glycine-receptor antibody responses found in most patients with stiff-person syndrome (SPS), a rare autoimmune disorder of rigidity, painful spasms and falls with no FDA-approved therapy. In the single-arm KYSA-8 trial, the median within-patient reduction in time to walk 25 feet was 46% at week 16 and 49% at one year among 26 treated patients, and 24 of 26 were off chronic SPS immunotherapy at one year. [S2, S3]

Those are within-person changes in an open-label study, so they show a large, sustained signal rather than a randomized treatment effect, and the regimen carries real toxicity. The catalyst is FDA action on a BLA that is not yet complete. I bind this thesis to one question: whether an approval turns this signal into treatment that US patients actually receive, with measured walking and disability gains sustained and chronic SPS immunotherapy not restarted after B cells return, across a five-year window from the FDA action. The SPS result is not evidence for a broad autoimmune platform. [S10, S11]

Decision question

If FDA approves miv-cel for SPS, will treated US patients keep the walking and disability gains seen in KYSA-8, without restarting chronic SPS immunotherapy, in enough numbers and centers to change how refractory SPS is treated?

Prospective initiation

Kyverna began a rolling BLA, submitted the chemistry, manufacturing and controls module by August 11, 2026, plans to request priority review under its RMAT designation and targets completion of the submission in the fourth quarter of 2026. A 2027 launch is a company aim conditional on approval. No BLA acceptance, action date or approval exists. [S10, S17]

Catalyst-scope firewall

KYSA-6 in myasthenia gravis, the progressive multiple sclerosis program, the terminated lupus nephritis and systemic sclerosis studies, KYV-102 (a separate whole-blood manufacturing product) and Kyverna's financing are context, and none is credited to this catalyst. Events in other companies' CAR T programs are context, not miv-cel observations.

[S11, S21]

CATALYST DEFINITION AND SCOPE

One Infusion, One FDA Decision, One Durability Question

Catalyst field	Locked definition
Event	FDA action on Kyverna's BLA for miv-cel in stiff-person syndrome: an approval or a complete response letter.
Occurrence	Unresolved. Rolling BLA under way with the CMC module submitted; completion targeted for the fourth quarter of 2026; no acceptance or action date announced through October 23, 2026. [S10, S17]
Mechanism (intended)	Leukapheresis ► CAR T manufacture and release ► cyclophosphamide/fludarabine conditioning ► single infusion ► CD19 B-cell depletion ► hypothesized reduction in the antibody response associated with SPS ► less stiffness and fewer spasms ► better measured walking and less disability ► chronic SPS immunotherapy no longer needed.
Primary outcome test	Approval and label scope; disclosed counts of US patients infused commercially; follow-up showing treated patients keep walking and disability gains without restarting chronic SPS immunotherapy, reported with retained numbers; no late safety finding that restricts use. Revenue corroborates only.
Catalyst anchor and terminal	The anchor is the date FDA actually acts. Terminal review falls five years after that date; no action date exists yet, so no terminal date is fixed.

What the record establishes

A registrational, single-arm, open-label Phase 2 trial treated 26 adults and reported statistically significant within-person improvement on its primary walking endpoint at week 16, with follow-up to a median of 12.0 months. FDA has granted miv-cel RMAT and Orphan Drug designations in SPS, and a commercial supply agreement with ElevateBio BaseCamp was signed on July 23, 2026. [S2, S9, S14]

What the record does not establish

No randomized or blinded comparison of miv-cel, peer-reviewed full KYSA-8 paper, public protocol or statistical analysis plan, or participant-level dataset was located. The registry lists 27 enrolled against 26 treated and analyzed, and no source opened explains the difference. No BLA acceptance, label, commercial treatment count, or publicly announced price or coverage policy was located. [S18, S2]

Dated record

Date	Event	Status
Jun. 17, 2024	First KYV-101 SPS case published in PNAS [S24]	Observed
Sep. 25, 2024	KYSA-8 study start (registry) [S18]	Observed
Dec. 15, 2025	Topline primary results; BLA then guided to the first half of 2026 [S9]	Observed
Apr. 21, 2026	Primary analysis at AAN (cutoff Nov. 26, 2025) [S3, S8]	Observed
Jul. 23, 2026	ElevateBio clinical and commercial supply agreement [S14]	Observed
Aug. 11, 2026	Rolling BLA under way; CMC module submitted [S10]	Observed
Oct. 21, 2026	One-year poster presented at MSToronto (data cutoff Jul. 10, 2026); a corrected file created Oct. 22 changed one figure label [S1, S2]	Observed
Fourth quarter 2026	Completion of the rolling BLA [S7, S10]	Company target

MECHANISM

From B-Cell Depletion to Walking Without Chronic Immunotherapy



☒ Established in primary records ☐ Not yet established

Evidence state	What it measures	What it shows, and what it does not
B-cell depletion	Peripheral CD19 B cells after infusion [S2, S3]	That the cells did what they were designed to do; not that symptoms improved because of it
Antibody reduction	GAD65-IgG, median 83% lower at one year in high-titer patients [S2]	A biological change; GAD65 antibodies are associated with SPS but not established as causal or as a validated efficacy surrogate
Walking time	Within-person change in T25FW time, week 16 and one year [S2]	Large, sustained reduction against each patient's own baseline; not a randomized treatment effect
Treatment freedom	Patients off chronic SPS immunotherapy [S2]	Most stayed off IVIg and similar drugs; symptomatic drug use was not reported
Approval and label	FDA decision and labeled population	Regulatory acceptance of benefit and risk; not uptake
Commercial infusions	Patients treated after approval	Adoption; not durability in those patients

Biology boundary

SPS is associated with antibodies against GAD65 or the glycine receptor, and the trial enrolled only antibody-positive patients. Whether these antibodies cause symptoms, and whether lowering them explains benefit, is a hypothesis rather than an established mechanism. CD19 B-cell depletion is the intended effect, and B cells returned in 17 of 26 patients by one year, so whether benefit outlasts B-cell return is the central durability question. Kyverna reports efficacy was maintained with reconstitution, without per-patient data. [S2, S5]

Class considerations

FDA required boxed-warning and class labeling changes for marketed CD19- and BCMA-directed autologous CAR T products after investigating T-cell malignancies, and noted that patients should be monitored lifelong for secondary malignancy. Kyverna's long-term follow-up study is registered for up to 15 years. These are class and study commitments, not observed miv-cel events. [S11, S19]

Why the decision is the right anchor

FDA action decides whether miv-cel may be marketed, and it can be an approval or a complete response letter. Availability then needs both approval and launch, and an approval fixes the labeled population every later measure depends on.

TRIAL DESIGN

A 26-Patient Single-Arm Trial in Refractory, Antibody-Positive SPS

How KYSA-8 was run

Design element	KYSA-8 (NCT06588491)
Design	Phase 2, single-arm, open-label, multicenter, registrational; three US sites (University of Colorado, Mayo Clinic Rochester, Thomas Jefferson University) [S18, S2]
Regimen	Planned conditioning: fludarabine 30 mg/m ² /day and cyclophosphamide 300 mg/m ² /day for 3 days, then one infusion at a target of 1×10 ⁸ CAR T cells; administered doses were not itemized in the posters [S5, S2]
Eligibility	Ages 18–75; SPS with high-titer GAD65 or glycine-receptor antibodies; inadequate response to at least one immunotherapy; stiffness index ≥2; bedridden more than 3 months excluded [S18, S5]
Endpoints	Primary: change in timed 25-foot walk (T25FW) at week 16, and safety. Secondary at week 16: modified Rankin scale, distribution-of-stiffness index, Hauser ambulation index, heightened sensitivity scale [S2, S3]
Monitoring	Initial 10-day inpatient period; SPS immunotherapies stopped before conditioning [S3, S2]
Analyses	Primary cutoff Nov. 26, 2025 (median follow-up 6.5 months); one-year cutoff Jul. 10, 2026 (median 12.0 months, range 11.4–12.9, so not every patient had reached 12 months) [S8, S2]
Enrollment	Planned 25 (2025 design abstract); registry actual 27; posters treat and analyze 26 [S5, S18, S2]

Who was treated

Baseline characteristic (n=26)	Value	Baseline characteristic (n=26)	Value
Age, mean (range)	56 (32–73)	Prior IVIg or SClg	26 (100%)
Female	16 (62%)	Prior rituximab / plasmapheresis	4 (15%) / 4 (15%); overlap not reported
Years since diagnosis, median (range)	3.2 (0.6–25.0)	Inadequate response to 1 / ≥2 therapies	17 (65%) / 9 (35%)
Years since symptom onset, median (range)	7.5 (0.8–26.0)	GAD65 antibody positive / high titer	23 (88%) / 21 (81%)
T25FW, median (range)	11.1 s (6.1–89.5)	Glycine-receptor antibody (historical)	3 (12%)
6-minute walk, median (range)	240.5 m (30–490)	Modified Rankin scale, mean (range)	3.6 (2–5)
Walking aid for T25FW	12 (46%): 3 unilateral, 9 bilateral	Stiffness index / sensitivity scale, mean	3.3 / 5.3

Walking-aid counts are read from the poster figure percentages (12%, 35%) and the stated 12 aid users. [S2]

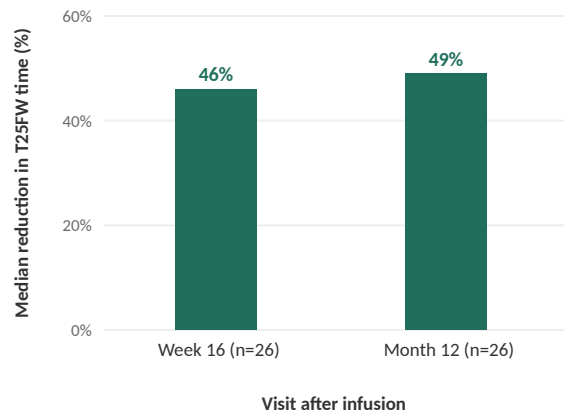
Reading the population

All 26 had received IVIg or SClg and had an inadequate response to at least one immunotherapy, so the result speaks to refractory, antibody-positive SPS in centers able to deliver CAR T, not to all SPS. SPS immunotherapies were stopped before conditioning, although the posters do not state when baseline tests were done relative to withdrawal. [S2]

WALKING OUTCOMES

Walking Time and Aid Use Improved Within Patients and Held at One Year

Primary Endpoint and One-Year Walking Time



Median walking time over 25 feet fell 46% from baseline at week 16 and 49% at one year.

These are medians of each patient's own percentage change; $p = 0.0003$ at week 16 and $p < 0.0001$ at one year test against no change, not against a control. The one-year median time is not derived here from the baseline median, because a median of changes cannot be applied to a median baseline. [S2, S3]

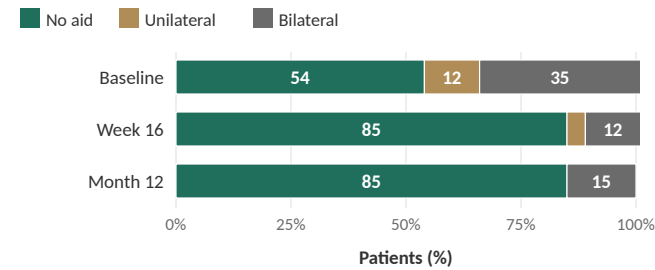
Clinically Meaningful Walking Improvement



21 of 26 patients improved by at least 20% at week 16 and 20 of 26 at one year.

The 20% threshold comes from multiple sclerosis research rather than SPS-specific validation. Kyverna reports that 20 of the 21 week-16 responders kept the response, and about a third walked 25 feet in under 5 seconds at one year. [S2, S7]

Walking Aids Over Time



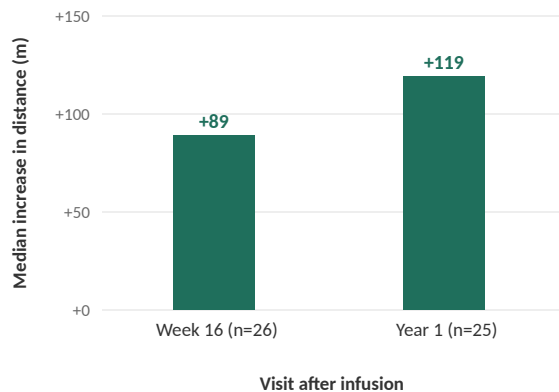
Patients walking without an aid rose from 54% to 85%; 8 of the 12 baseline aid users no longer needed one at week 16 and one year.

The 8 of 12 figure applies to baseline aid users only. At one year 15% of all patients, about 4, still used bilateral aids. [S2]

FUNCTION AND DISABILITY

Broad Within-Patient Gains, With Four in Ten Still Moderately Severely Disabled

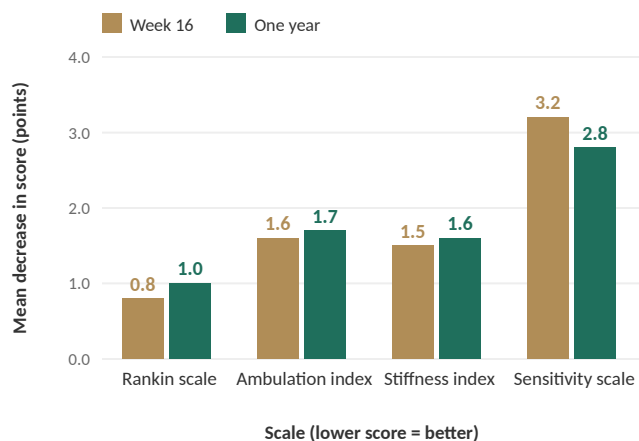
Six-Minute Walk Distance



Median walking distance rose 89 m by week 16 and 119 m by one year, from a baseline median of 240.5 m.

The one-year value comes from 25 patients. Kyverna compares the gain with a 20 m minimally important change taken from multiple sclerosis literature. [S2, S6]

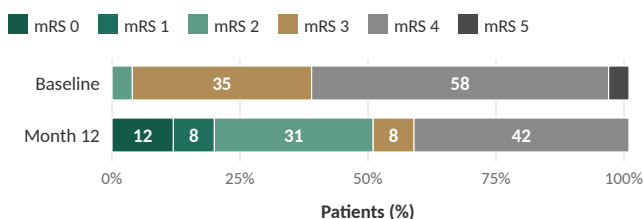
Disability, Ambulation, Stiffness and Sensitivity



Mean scores improved on all four scales at both visits; three changed little between week 16 and one year, and the sensitivity score improved less at one year.

Signed mean changes, week 16 then one year: Rankin -0.8 to -1.0; ambulation -1.6 to -1.7; stiffness -1.5 to -1.6; sensitivity -3.2 to -2.8 (one-year $p \leq 0.0003$, within-person). [S2, S8]

Disability Level Before and After



At one year 13 of 26 patients (50%) were at Rankin 0-2, against 1 of 26 at baseline, while 11 of 26 (42%) remained at Rankin 4.

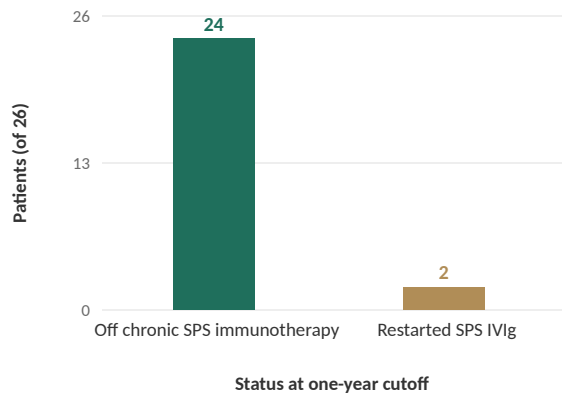
Bar labels are the poster's rounded percentages; counts are the only whole numbers of 26 consistent with them (12%, 8% and 31% give 3, 2 and 8). Rankin 4 means moderately severe disability, unable to walk or attend to bodily needs without help.

[S2]

DURABILITY

Most Patients Stayed Off Chronic Immunotherapy, With B Cells Returning in Two-Thirds

Freedom From Chronic SPS Immunotherapy



24 of 26 patients remained off chronic SPS immunotherapy at one year; two restarted IVIg after month 8, one despite continued benefit.

A separate patient received replacement IVIg for low antibody levels; whether that patient overlaps with these counts is not stated, so the numbers are not combined. Use of symptomatic drugs such as benzodiazepines and baclofen was not reported. [S2]

Durability evidence at one year

Measure	Observation	Limit
Walking responders	20/26 at one year; 20 of 21 week-16 responders sustained [S2, S7]	Median follow-up 12.0 months; range 11.4–12.9
B-cell return	Reconstitution in 17/26 (65%) by one year [S2]	No per-patient timing against clinical status
Antibodies	GAD65-IgG median –83% in patients with ≥20 nM at baseline [S2]	Not a validated functional surrogate
IVIg restarts	2/26 after month 8 [S2]	Reasons stated for one patient only
Longer follow-up	Long-term study registered to 2041; SPS walking measured to year 4 [S19]	No results yet

Earlier evidence for persistence

The poster cites initial SPS and myasthenia gravis patients treated outside the trial with benefit beyond 24 months without chronic immunotherapy, and published compassionate-use cases describe walking gains within three to six months. These are single cases or small series with different follow-up, so they support plausibility rather than a durability rate. [S2, S24]

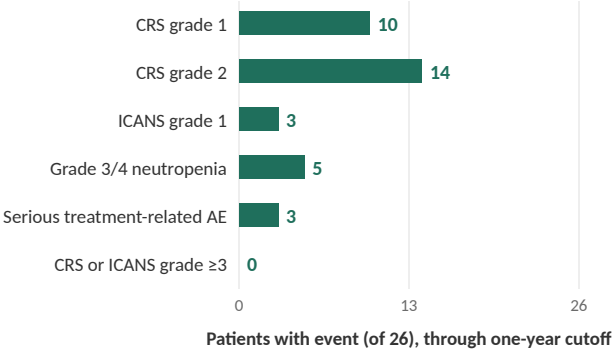
What would show durability

Two things matter: whether patients whose B cells have returned keep their walking and disability gains, and how many restart IVIg or other chronic immunotherapy over the following years. Both need per-cohort reporting with retained numbers and elapsed time since infusion.

SAFETY

No High-Grade CRS or Neurotoxicity, but Real Toxicity in 26 Patients

Treatment-Related Adverse Events



Cytokine release syndrome occurred in 24 of 26 patients, all grade 1 or 2, and three patients had serious treatment-related events.

Grade 3/4 neutropenia occurred in 5 patients; 4 resolved after a median of 121.5 days and one had residual grade 1 neutropenia at study end. No immune-effector hemophagocytic syndrome was seen. [S2]

Severe events behind the grades

Event	Detail
Grade 4 localized neck edema	Managed with elective intubation, antibiotics, high-dose corticosteroids, tocilizumab, anakinra and siltuximab; resolved within 9 days [S3]
Prolonged inpatient monitoring	Two low-grade events with hospital monitoring beyond the initial 10-day inpatient period, counted as serious per protocol; in one, a grade 2 peritonsillar abscess with grade 1 CRS extended the initial inpatient monitoring [S3, S2]
Late re-expansion	One patient had CAR T re-expansion at month 9 with grade 3 neutropenia (G-CSF) and grade 2 low antibody levels (IVIg), resolving by month 12 [S2]
Neutropenia count	Four cases in April, five in October: one early transient case found in data cleaning, not a new late case [S2, S3]
Common events at week 16	Fatigue 54%, diarrhea 38%, headache 31% [S3]

Primary analysis versus one year

Measure (n=26)	April 2026 (cutoff Nov. 26, 2025)	October 2026 (cutoff Jul. 10, 2026)
Grade 3/4 neutropenia	4; 3 resolved (median 85 days), 1 ongoing [S3]	5; 4 resolved (median 121.5 days), 1 residual grade 1 [S2]
Serious treatment-related AEs	3 [S3]	3; no new serious infections [S2]
High-grade CRS or ICANS; IEC-HS	None; none	None; none

Reading the safety record

No high-grade CRS or neurotoxicity does not mean no severe toxicity: the regimen requires chemotherapy conditioning, an initial inpatient stay, and produced a grade 4 airway event and prolonged neutropenia. Twenty-six patients followed for about a year cannot exclude rarer or later harms, including the class malignancy risk that FDA labels for marketed CAR T products. [S2, S3, S11]

COMPARATOR PROBLEM

A Large Signal Without a Control Arm

Question	What the record shows	Implication
Is there a control?	No. KYSA-8 is single-arm and open-label; every patient knew they received CAR T ^[S18]	Improvement cannot be separated from expectation, regression to the mean or co-interventions
Were raters blinded?	Not stated in the posters or registry	Effort-dependent walking tests are open to bias without blinding
Is there an external comparison?	A retrospective natural-history study of 153 eligible patients from 188 records at two centers, using walking tests from routine care ^[S4]	Different population (56% had prior immunotherapy) and data collection; not a control
How large is placebo response in SPS?	In a 24-patient rituximab RCT, quality of life improved early in both arms and the primary endpoint was negative ^[S23]	Placebo effects are real in SPS
What randomized evidence exists?	IVIg improved stiffness and sensitivity scores in a 16-patient randomized crossover trial ^[S22]	The only positive randomized SPS immunotherapy evidence located
Are the thresholds SPS-validated?	20% T25FW and 20 m 6MWT thresholds derive from MS literature ^[S2]	Responder rates depend on borrowed definitions

What the natural-history study adds

In routine care at Johns Hopkins and the University of Colorado, walking-aid use rose 73% over time and Rankin scores did not improve, and Kyverna reports that most patients showed minimal or no walking improvement. That supports the view that SPS rarely improves on its own. However, patients, timing and measurement differ from KYSA-8, so it frames the unmet need rather than providing a treatment comparison. ^[S4, S8]

Why the signal still matters

The within-patient changes are consistent across walking, disability, stiffness and sensitivity scales, sustained at one year in most patients, and accompanied by B-cell depletion and antibody falls. That concordant persistence is encouraging. However, without a control group or rater-blinding detail, the treatment-specific share of the change cannot be estimated, and differences in design rule out comparing its size with earlier IVIg or rituximab trials. ^[S2]

What a randomized test could look like

Kedrion's Phase 3 IVIg trial (randomized, quadruple-masked, n=38, T25FW at week 24; not yet recruiting as of October 23, with a November 2026 estimated start) and Jefferson's efgartigimod crossover trial (n=26, recruiting) will measure placebo-condition walking changes in SPS, which will help frame open-label results. ^[S25]

ECOSYSTEM AND ROLES

Who Makes, Supplies, Licenses and Funds Miv-cel

Party	Role in this catalyst	Status in the record
Kyverna Therapeutics	Developer, KYSA-8 sponsor and BLA applicant	Rolling BLA under way [S10]
ElevateBio BaseCamp	Clinical and commercial manufacturing, release and testing of miv-cel	Supply agreement Jul. 23, 2026; five-year initial term; minimum orders in specified years or after approval; quantities and prices redacted [S14, S11]
Minaris Advanced Therapies	Cell manufacturing, release and testing (Philadelphia)	Master services agreement, March 2022 [S11]
Oxford Biomedica (UK)	Lentiviral vector process development; intended vector supplier	Licence and supply agreement, September 2023 [S11]
National Institutes of Health	Licensor of anti-CD19 CAR patents for autoimmune use	Exclusive worldwide; low single-digit royalties; autologous approval benchmark royalties totaling \$5.7M minimum [S11]
Oxford Finance LLC (lender, not Oxford Biomedica)	Collateral agent and lender	Up to \$150M facility; \$25M drawn [S15, S11]
Trial centers	University of Colorado, Mayo Clinic Rochester, Thomas Jefferson University	KYSA-8 sites [S18]
FDA	Regulator	RMAT and Orphan Drug designations in SPS [S9]
CAR T treatment centers and payers	Delivery and coverage	No commercial center list or coverage policy announced [S10]

Supply chain unknowns

Turnaround from collection to infusion, release failures and capacity were not disclosed in any filing opened, and the ElevateBio agreement redacts quantities and prices. Kyverna's October investor deck, inspected by the packet reviewer but blocked to me (HTTP 403), states manufacturing success above 98%; its denominator, cutoff, definition of success and reproducibility are unknown, so it is a company claim, not an established release rate. For a product made individually from each patient's cells, every failed batch delays treatment. [S14]

Licences and obligations

Kyverna's licence with Kite was terminated in October 2025, with \$3.8M still owed by December 31, 2026 in cash or stock. Its Intellia agreement covers a separate allogeneic product (KYV-201), not miv-cel supply, and KYV-102 is a separate whole-blood product with its own IND. [S11]

Commercial build

Kyverna had 134 full-time employees at December 31, 2025, and by August 2026 reported hiring commercial leadership, a Chief Commercial Officer and Chief Financial Officer, commercial site activation and payer engagement. [S12, S10]

DELIVERY AND ACCESS

The Trial Pathway Is Known; Commercial Delivery Gaps Remain

The delivery funnel to track

Step	What has to happen	Disclosed status
Diagnosis	Antibody-positive SPS confirmed by a specialist	Sponsor estimate of about 6,000 diagnosed US patients
Label eligibility	Patient matches the approved population	No label exists
Fitness for conditioning	Able to tolerate chemotherapy and CAR T	Trial excluded those bedridden over 3 months; age 18–75
Center readiness	Contracted, trained and activated CAR T center	Company targets about 10 centers initially (October deck; inspected by the packet reviewer, not by the author, HTTP 403); none announced as active
Payer approval	Coverage for an autoimmune CAR T	No policy announced
Collection and manufacture	Leukapheresis, manufacture, release	Not in filings; October deck claims over 98% success (denominator, cutoff and definition unknown)
Infusion and monitoring	Conditioning, infusion, inpatient monitoring	Trial used an initial 10-day inpatient stay
Durable outcome	Function maintained without restarting SPS immunotherapy	One-year trial data only

Population estimates, labeled as sponsor figures

Measure	Value	Basis
US patients diagnosed with SPS	About 6,000	Kyverna 10-K, epidemiology and claims data [S12]
Of whom treated with off-label immunotherapy	2,000–2,500	Kyverna 10-K [S12]
Treating-physician survey, willingness to use	85% of 20 physicians	October deck; inspected by the packet reviewer, not by the author (HTTP 403)
Price positioning	Premium to oncology CAR T list prices	October deck aspiration; inspected by the packet reviewer, not by the author (HTTP 403); no publicly announced price located

Coverage

Medicare's national coverage determination for CAR T covers autologous treatment for cancer and is silent on autoimmune use, which leaves the Medicare pathway for an SPS approval undefined rather than excluded. Commercial payers' current SPS policies concern IVIg and similar off-label therapy, and no miv-cel coverage policy has been located. [S26]

What cannot be inferred

Diagnosed and immunotherapy-treated patient estimates are not eligible or paying patients, the prevalent pool is finite rather than recurring, and no price, net revenue, uptake rate or center count is projected here.

COMPETITION AND CURRENT CARE

No Approved Therapy, and Lower-Intensity Rivals Seeking Controlled Evidence

Product or approach (sponsor)	Role	Evidence or status	Relevance
Benzodiazepines, baclofen and other symptomatic drugs	Symptomatic	Off-label standard care	Continue alongside any immunotherapy; KYSA-8 did not report changes
IVIg (multiple manufacturers)	Chronic immunotherapy	Off-label; 16-patient randomized crossover positive [S22]	All KYSA-8 patients had already received IVIg or SClg
Kedrion IVIg 10%	Randomized Phase 3	NCT07552987: n=38, T25FW at week 24; not yet recruiting; start Nov. 2026, primary completion Jan. 2028 (estimates) [S25]	Could produce the first randomized SPS walking result
Rituximab (off-label)	B-cell depletion	24-patient RCT negative on primary endpoint [S23]	Antibody-based B-cell depletion has not shown benefit in a trial
Efgartigimod PH20 SC (investigator study)	Antibody-lowering (FcRn)	NCT07860021: Jefferson, crossover RCT, n=26, recruiting; primary completion Dec. 31, 2027 (estimate) [S25]	No registrational sponsor program verified
CTX112 (CRISPR Therapeutics)	Allogeneic CD19 CAR T	NCT07804004: Phase 1/2 across neuro-autoimmune diseases including SPS; not yet recruiting [S25]	Off-the-shelf alternative, early
Prula-cel (Adicet)	Allogeneic anti-CD20 CAR T made from gamma-delta T cells	NCT06375993: Phase 1 including an SPS cohort [S25]	Early; no SPS data inspected
Autologous stem-cell transplant	Immune reset	NCT00716066: Phase 2 in neuro-autoimmune disease, active not recruiting [S25]	Intensive; limited SPS evidence

What competition means here

No efficacy ranking is drawn because no trial compares these products directly and their populations, designs and endpoints differ. Miv-cel's proposed difference is a one-time treatment that stops chronic immunotherapy, traded against conditioning chemotherapy, inpatient monitoring and CAR T risks. IVIg already has randomized SPS evidence from a small crossover trial, and a positive larger randomized IVIg or efgartigimod trial would add to the controlled evidence behind a lower-intensity option. [S2, S25]

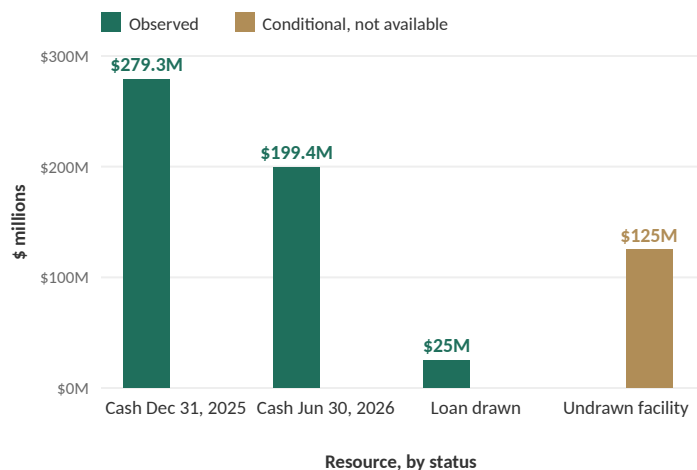
Class context

FDA has required boxed-warning and class labeling changes for marketed CD19- and BCMA-directed autologous CAR T products over T-cell malignancy, with lifelong monitoring. That is class labeling context, not a miv-cel observation, although it shapes how regulators, centers and payers view autoimmune CAR T. [S11, S29]

RESOURCES

Funded Cash and Conditional Debt, Shown Apart

Kyverna Resources, Kept Separate by Status



Cash and securities fell from \$279.3M to \$199.4M in the first half of 2026; \$125M of the loan facility is undrawn and conditional.

The undrawn amount includes \$15M of Term A available to December 31, 2026, conditional Term B and C loans and a discretionary Term D, so it is not added to cash. [S13, S11, S15]

Measure (first half unless stated)	2025	2026	Label
Net cash used in operating activities [S11]	\$76.9M	\$81.9M	Reported fact
Net loss [S11]	\$86.7M	\$78.0M	Reported fact
Research and development [S11]	\$73.2M	\$54.9M	Reported fact
General and administrative [S11]	\$18.6M	\$26.1M	Reported fact
Shares outstanding (Dec 31, 2025 / Jun 30, 2026 / Aug 3, 2026) [S11]	60.39M	61.57M / 61.84M	Reported fact
December 2025 offering: 13.3M shares at \$7.50, about \$100M gross [S16]	—	—	Reported fact
At-the-market sales, June 2026 / remaining capacity [S11]	—	\$3.6M / \$96.3M	Reported fact
Loan terms: SOFR-based, 8.75% floor, effective rate 10.8% at Jun 30; matures Oct. 2030; secured by substantially all assets including IP; revenue covenant from Q2 2027 with exceptions [S15, S11]	—	Terms	Reported fact
Runway into 2028, including loan availability [S10]	—	Guidance	Company statement

Why resources matter to the catalyst

Completing the BLA, preparing centers and building supply all precede revenue, and the loan's minimum-revenue covenant begins with the quarter ending June 30, 2027, subject to cash and market-capitalization exceptions. The \$300M shelf registration is capacity to issue securities, not cash. [S15, S11]

COUNTEREVIDENCE

Reasons the Signal May Not Become Durable Routine Care

Alternative	Why it remains plausible	What would confirm it
The effect is smaller than it looks	Open-label walking tests without stated rater blinding; immunotherapy withdrawal before treatment; placebo effects seen in SPS [S23, S2]	A randomized SPS trial showing large placebo-arm walking gains
Benefit fades as B cells return	B cells returned in 17/26 by one year; 2 restarted IVIg [S2]	Rising IVIg restarts or walking decline in long-term follow-up
FDA asks for more evidence	Single-arm registrational design; Kyverna's 10-K notes FDA may find the trial insufficient [S12]	Refusal to file, complete response letter, or a randomized-trial requirement
Toxicity limits use	Conditioning chemotherapy; CRS in 92%; a grade 4 airway event; prolonged neutropenia [S2, S3]	Restrictive label, REMS, or late safety findings
Delivery is slow or narrow	No publicly announced center list, price or coverage located; individual manufacturing	Few infusions and long waits in the first launch year
Lower-intensity options gain evidence	Kedron IVIg Phase 3 (not yet recruiting; November 2026 estimated start) and efgartigimod crossover trial (recruiting) [S25]	Positive randomized results before or soon after launch
Timelines slip further	BLA guidance moved from the first half of 2026 to fourth-quarter completion [S9, S10]	BLA completion beyond 2026 or a refusal to file

How I weigh the alternatives

The first two decide whether the thesis question can be answered in the patient's favor, because they concern whether the signal is real and lasting. Regulatory and toxicity risks decide whether the question gets tested at all. Delivery limits decide how many patients the answer reaches.

Current challenges at October 23, 2026

Challenge	Current status
Controlled evidence	No controlled miv-cel evidence in SPS; historical IVIg and rituximab RCTs exist; KYSA-6 in myasthenia gravis is randomized but tests a different disease
Regulatory timing	BLA incomplete; no acceptance or action date
Data transparency	No peer-reviewed full paper, protocol, statistical plan or participant-level data; 27 enrolled versus 26 treated unexplained
Delivery	No publicly announced price, coverage policy or activated commercial center located
Platform scope	Two lupus nephritis studies and one systemic sclerosis study terminated by sponsor decision [S21]

EXPECTED BREADTH

A Four-Star Forecast for Refractory SPS Care

Expected breadth



Four stars, forecast against one ecosystem: US specialist care for immunotherapy-refractory, antibody-positive stiff-person syndrome, covering the neuroimmunology and CAR T centers, infusion providers and payers that treat these patients. If the catalyst is fully realized, an approved one-time therapy would become the first FDA-approved SPS treatment and would give eligible patients an alternative to indefinite off-label IVIg, after a trial in which measured walking time improved, and 8 of 12 baseline walking-aid users no longer needed an aid for the timed test. I stop short of five because the regimen's intensity, center access and fitness requirements will keep many patients on current care, because 42% of trial patients remained at Rankin 4 at one year, and because lower-intensity therapies are seeking randomized evidence. [S2, S12]

Why the change would be broad within this ecosystem

Kyverna estimates about 6,000 diagnosed US patients, of whom 2,000–2,500 receive off-label immunotherapy; how many would meet a label and be fit for conditioning is unknown, so the estimate is a judgment about the potential change in care rather than a count of eligible patients. For those who are treated, the change would be one of kind rather than dose: a single course in place of recurring IVIg, after which 24 of 26 trial patients were off chronic SPS immunotherapy at one year. [S12, S2]

Why it would not be complete

Symptomatic drugs, physical therapy and specialist follow-up would continue, and the trial excluded patients bedridden for more than three months and those over 75. IVIg already has small randomized SPS evidence, Kedrion's Phase 3 IVIg trial is due to start, an efgartigimod crossover trial is recruiting and allogeneic CAR T programs are entering the disease, so the reference treatment could be contested even after an approval. [S18, S22, S25]

Historical and forward context

Kyverna says miv-cel could become the first approved CAR T therapy for an autoimmune disease, and I located no approved autoimmune CAR T. The BLA submission is targeted for completion in the fourth quarter of 2026, with FDA acceptance and action dates unknown, so the estimate is set now and does not move with those milestones. [S6, S10]

What four stars does not mean

Stars estimate how much of this one ecosystem a fully realized catalyst would reach. They make no statement about approval odds, durability or uptake, and they do not move with disclosure quality.

Realized Depth

Realized Depth is reserved for outcomes that actually occur after the FDA action, such as approval, commercial infusions and durable function in treated patients. No post-approval catalyst outcome has occurred, so no Realized Depth is recorded and no outcome grade is issued.

ADMISSIBILITY AND HORIZON

A Measurable Test, Anchored on an FDA Action Not Yet Scheduled

Dimension	Reading	Reason
Attribution feasibility	High	A single lead product with SPS as its first indication; revenue and infusion counts attributable if disclosed
Future measurability	Conditional	Product-level counts and long-term outcomes depend on Kyverna disclosure; follow-up study runs to 2041
Disclosure risk	Moderate to high	No peer-reviewed full paper or protocol located; key details sit in posters and releases
Reversibility	Low for patients; moderate for the program	Conditioning and CAR T cannot be undone; a label or supply action could pause use
Catalyst anchor	Date of FDA action	Not yet scheduled; a complete response letter is an occurrence with a negative result
Terminal horizon	Five years after the actual action date	No date fixed until FDA acts

What counts as durable function off chronic SPS immunotherapy

Treated patients keep measured walking and disability gains without restarting chronic SPS immunotherapy. A pass needs approval with a label covering the studied population, disclosed commercial treatment counts, and follow-up of named cohorts that reports retained numbers, walking measures and chronic SPS immunotherapy status together, rescue treatment, attrition and elapsed time since infusion, through a horizon measured from the actual FDA action. Replacement IVIg for low antibody levels is tracked as a separate category. The evidence required is qualitative and joint: walking and disability measures together with chronic SPS immunotherapy status, by named cohort, with the treated denominator, retention, rescue treatment and follow-up time since infusion, plus commercial infusion counts, activated centers and payer access where disclosed. Missing items are recorded as missing; no numerical threshold is preset, low disclosure is a tracking gap rather than failure, and revenue alone cannot pass the test.

Sponsor targets versus observations

Statement	Type
BLA completion Q4 2026; priority review request; 2027 launch if approved [S10, S7]	Company targets
Runway into 2028 [S10]	Company guidance
About 6,000 diagnosed; 2,000–2,500 on off-label immunotherapy [S12]	Company estimate
About 10 initial centers; over 98% manufacturing success; 85% of 20 physicians willing (October deck; reviewer-inspected, HTTP 403 to author)	Company statements
KYSA-8 efficacy, safety, cash balances, loan draw [S2, S11]	Observations

Admissibility verdict

The catalyst is admissible, although the action date is not yet set and durability measurement depends on Kyverna publishing follow-up with denominators.

TRACKING STANDARD

Falsifiers and Failure Conditions

Test	Metric and source	Condition	Window	Missing-data behavior
Submission	Kyverna filings	Kyverna completes the submission	Company target Q4 2026	Delay recorded against target
FDA filing	Kyverna filings	Accepted or refused; date unknown	No target set	Record when disclosed
FDA action	FDA letter; 8-K	Approval with a label covering the studied population	When scheduled	Action date sets the terminal
Centers	Company disclosures	Targeted vs contracted vs trained vs activated vs first-infused, kept separate	From launch	Unreported stages are gaps
Infusions	Commercial US patients infused (if disclosed)	Rising counts across consecutive quarters	From launch	Not located is not absence
Price and coverage	List and net price; payer policies; denials	Coverage without blanket exclusion	First two launch years	Unknown price stays unknown
Manufacturing	Failure and redo rates; turnaround distribution	Disclosed with denominators	From launch	Unnamed metrics not inferred
Durability	Long-term follow-up; post-approval reports	Named cohort with retained n, walking measures and chronic SPS immunotherapy status, rescue and attrition	Five years after FDA action	Unreported periods are gaps
Safety	Label updates; FDA communications; filings	No late signal that restricts use	Five years after FDA action	Class events recorded separately

Period integrity and absence of evidence

Within-person trial changes are never compared with real-world counts or other trials' arms, durability figures carry their denominator and cutoff, and Kyverna results in other diseases neither confirm nor contradict this catalyst. A missing figure is recorded as not located, and an inaccessible document as inaccessible.

Falsifiers

The thesis fails if	Evidence that would show it
FDA does not approve, or requires a randomized trial first	Refusal to file, complete response letter or published FDA feedback
Cohort follow-up shows walking or disability gains lost, or chronic SPS immunotherapy restarted, in a substantial share of the treated denominator	Named-cohort reports with treated n, retention, rescue and time since infusion
A late safety signal restricts use	Boxed warning changes, REMS or regulatory action
Approval does not translate into treatment	Disclosed commercial infusion counts, activated centers and payer coverage remain minimal in the first two launch years; undisclosed counts are recorded as a gap, not as zero

NEXT MEASUREMENT

What I Will Check Before and After the FDA Decision

Occasion	Timing	What gets reopened
Kyverna third-quarter 2026 report and 10-Q	Expected November 2026; date not announced in filings through Oct. 23	BLA status, loan draws, ATM use, ElevateBio agreement exhibit
Completion of the rolling BLA	Fourth quarter 2026 (company target)	Submission date; priority review request
FDA filing decision	After completion; not scheduled	Acceptance, review timeline, advisory committee plans
FDA action	Not scheduled	Occurrence, label scope, monitoring requirements
Kedrion IVIg Phase 3 start	November 2026 (registry estimate)	Controlled SPS evidence timeline
Peer-reviewed KYSA-8 publication	Not announced	Protocol, blinding, symptomatic drugs, per-patient data

Baseline values to measure against

Measure	Baseline at initiation
Median within-person reduction in T25FW time	46% at week 16; 49% at one year (n=26)
At least 20% T25FW improvement	21/26 at week 16; 20/26 at one year
Baseline aid users walking without aid	8/12 at week 16 and one year
Off chronic SPS immunotherapy at one year	24/26
B-cell reconstitution by one year	17/26
Commercial US infusions; price; coverage	None before approval; not disclosed; not disclosed

Data still needed for an independent reading

Item	Why it matters
Protocol and statistical analysis plan	Endpoint definitions, missing-data handling and rater blinding
Symptomatic medication changes	Benzodiazepine or baclofen changes could affect walking tests
Per-patient B-cell and clinical timelines	Tests whether benefit outlasts B-cell return
Enrollment disposition (27 vs 26)	Whether one enrolled patient was not treated, and why

Oct. 22–23 additions captured

A corrected file of the October 21 poster, created October 22 (clinical cutoff unchanged at July 10), changed one figure label, the week-4 six-minute-walk count from 26 to 25. Registry records for Kedrion's IVIg trial and CRISPR's CTX112 trial show last updates on October 22. A Bristol Myers Squibb release dated October 23 on zola-cel in multiple sclerosis was supplied in the owner packet but could not be opened (HTTP 403) and concerns a different product. [S1, S2, S25, S28]

STANDARDS AND DISCLOSURES

How to Read This Thesis

Term	Definition
Stiff-person syndrome (SPS)	A rare autoimmune neurological disorder causing rigidity, painful spasms and falls
GAD65 and glycine-receptor antibodies	Autoantibodies associated with SPS; trial entry required one of them
CD19 CAR T	A patient's T cells engineered to recognize CD19 on B cells and remove them
Conditioning (Cy/Flu)	Cyclophosphamide and fludarabine chemotherapy given before CAR T
CRS and ICANS	Cytokine release syndrome and immune-effector neurotoxicity, graded 1 (mild) to 4
T25FW	Timed 25-foot walk, in seconds; lower is better
6MWT	Distance walked in six minutes
Modified Rankin scale	Disability from 0 (none) to 6 (death); 4 means unable to walk or self-care without help
Within-person change	Each patient compared with their own baseline, without a control group
BLA; RMAT	Biologics license application; FDA Regenerative Medicine Advanced Therapy designation

Evidence label	Meaning in this thesis
Reported fact	Directly stated in a filing, registry, poster, peer-reviewed paper or cited company release, with its period preserved
Company statement or estimate	A sponsor expectation or assumption, such as BLA timing or patient estimates
Author calculation	Reproducible arithmetic from disclosed inputs
Author inference	A reading the record supports but does not state, always labeled

Comparator and breadth boundaries

No cross-trial ranking is drawn. Expected breadth on page 15 estimates reach within US refractory SPS care; admissibility on page 16 decides whether the outcome can be graded.

Citations and access

Bracketed codes such as [S2] point to the source register on pages 20 and 21. Sources supplied by the owner that I could not open are marked as such, and no figure from them is presented as verified. This document is not a recommendation, rating, price target or medical advice.

PRIMARY SOURCES

Source Register

#	Document	Published	Access	Supports
S1	Piquet AL et al. One-year analysis of KYSA-8, poster P0364, MSToronto 2026 (original file). https://kyverna.wpenginpowered.com/wp-content/uploads/2026/10/KYSA_8_1Y_MSToronto_2026_Poster_Final__with_QR_Code.pdf	Presented Oct. 21, 2026; cutoff Jul. 10, 2026	Opened; superseded by S2	Original one-year figures
S2	Same poster, corrected file (week-4 6MWT n changed from 26 to 25). https://kyverna.wpenginpowered.com/wp-content/uploads/2026/10/KYSA_8_1Y_MSToronto_2026_Poster_Final_Corrected.pdf	Presented Oct. 21, 2026; cutoff Jul. 10, 2026; corrected file created Oct. 22	Opened; figures read visually	All one-year efficacy and safety
S3	Piquet AL et al. KYSA-8 primary analysis poster, AAN 2026. https://kyverna.wpenginpowered.com/wp-content/uploads/2026/04/KYSA_8_PA_AAN_2026_Poster_Final.pdf	Apr. 2026 (file Apr. 20)	Opened	Inpatient period, severe events, common AEs
S4	Newsome SD et al. Natural history of T25FW in SPS, AAN 2026 poster. https://kyverna.wpenginpowered.com/wp-content/uploads/2026/04/T25FW_in_SPS_AAN_2026_Poster_Final.pdf	Apr. 2026	Opened	Retrospective 153 of 188
S5	Piquet AL et al. Design of KYSA-8, AAN 2025 abstract (doi 10.1212/WNL.0000000000210669). https://index.mirasmart.com/AAN2025/PDFfiles/AAN2025-002925.html	2025	Opened	Planned regimen, n=25
S6	Kyverna release: full one-year registrational data at MS Toronto (GlobeNewswire). https://www.globenewswire.com/news-release/2026/10/21/3385400/0/en/kyverna-therapeutics-presents-full-one-year-registrational-data-set-demonstrating-sustained-clinical-benefit-of-miv-cel-in-stiff-person-syndrome-at-ms-toronto.html	Oct. 21, 2026	Opened (web reader)	6MWT, statements
S7	Kyverna Form 8-K Ex. 99.1: one-year topline, SPS and gMG. https://www.sec.gov/Archives/edgar/data/1994702/000119312526400062/kytx-ex99_1.htm	Sep. 24, 2026	Opened	Responders sustained; BLA Q4 2026
S8	Kyverna Form 8-K Ex. 99.1: AAN primary analysis. https://www.sec.gov/Archives/edgar/data/1994702/000119312526167512/kytx-ex99_1.htm	Apr. 21, 2026	Opened	Week-16 secondary changes; cutoff
S9	Kyverna Form 8-K Ex. 99.1: KYSA-8 topline. https://www.sec.gov/Archives/edgar/data/1994702/000119312525318377/d285116dex991.htm	Dec. 15, 2025	Opened	BLA 1H 2026 guidance; RMAT, ODD
S10	Kyverna Form 8-K Ex. 99.1: Q2 2026 results. https://www.sec.gov/Archives/edgar/data/1994702/000119312526344572/kytx-ex99_1.htm	Aug. 11, 2026	Opened	Rolling BLA, CMC module, runway
S11	Kyverna Form 10-Q, quarter ended June 30, 2026. https://www.sec.gov/Archives/edgar/data/1994702/000119312526344607/kytx-20260630.htm	Filed Aug. 11, 2026	Opened	Financials, partners, licences, risks
S12	Kyverna Form 10-K, fiscal 2025. https://www.sec.gov/Archives/edgar/data/1994702/000119312526126242/kytx-20251231.htm	Filed Mar. 26, 2026	Opened	Prevalence estimate, employees, FDA risk
S13	Kyverna Form 8-K Ex. 99.1: Q4 and full-year 2025 results. https://www.sec.gov/Archives/edgar/data/1994702/000119312526126216/kytx-ex99_1.htm	Mar. 26, 2026	Opened	Dec. 31, 2025 cash
S14	Kyverna Form 8-K: ElevateBio clinical and commercial supply agreement. https://www.sec.gov/Archives/edgar/data/1994702/000119312526316916/kytx-20260723.htm	Jul. 27, 2026 (agreement Jul. 23)	Opened	Supply terms

PRIMARY SOURCES

Source Register, Continued

#	Document	Published	Access	Supports
S15	Kyverna Forms 8-K: Oxford Finance loan and amendment. https://www.sec.gov/Archives/edgar/data/1994702/000119312525261719/kytx-20251102.htm https://www.sec.gov/Archives/edgar/data/1994702/000119312526298979/kytx-20260708.htm	Nov. 3, 2025; Jul. 9, 2026	Opened	Facility terms
S16	Kyverna Form 8-K: \$100M underwritten offering. https://www.sec.gov/Archives/edgar/data/1994702/000121390025123033/ea0270041-8k_kyverna.htm	Dec. 18, 2025	Opened	Offering
S17	Kyverna release: MSToronto presentations (GlobeNewswire copy). https://finviz.com/news/399768/kyverna-therapeutics-to-present-positive-data-in-stiff-person-syndrome-and-progressive-multiple-sclerosis-at-mstoronto2026	Oct. 7, 2026	Opened (web reader)	BLA completion this quarter
S18	ClinicalTrials.gov NCT06588491 (KYSA-8), updated Jul. 24, 2026. https://clinicaltrials.gov/study/NCT06588491	Accessed Oct. 23, 2026	Opened (API)	Design, sites, enrollment 27
S19	ClinicalTrials.gov NCT07403188 (long-term follow-up). https://clinicaltrials.gov/study/NCT07403188	Accessed Oct. 23, 2026	Opened (API)	15-year follow-up
S20	ClinicalTrials.gov NCT06193889 (KYSA-6, gMG). https://clinicaltrials.gov/study/NCT06193889	Accessed Oct. 23, 2026	Opened (API)	Context only
S21	ClinicalTrials.gov NCT05938725, NCT06342960 (lupus nephritis), NCT06400303 (systemic sclerosis), updated Aug. 31, 2026. https://clinicaltrials.gov/study/NCT05938725 https://clinicaltrials.gov/study/NCT06342960 https://clinicaltrials.gov/study/NCT06400303	Accessed Oct. 23, 2026	Opened (API)	Terminations
S22	Dalakas MC et al. High-dose IVIg for stiff-person syndrome. <i>N Engl J Med</i> 2001;345:1870–1876. https://pubmed.ncbi.nlm.nih.gov/11756577/	Dec. 2001	Abstract	Randomized crossover
S23	Dalakas MC et al. Rituximab in SPS, double-blind RCT. <i>Ann Neurol</i> 2017;82:271–277. https://pubmed.ncbi.nlm.nih.gov/28749549/	Aug. 2017	Abstract	Negative RCT
S24	Faissner S et al. <i>PNAS</i> 2024;121:e2403227121; case report <i>Neurol Neuroimmunol Neuroinflamm</i> 2025. https://pubmed.ncbi.nlm.nih.gov/38885382/ https://pubmed.ncbi.nlm.nih.gov/41052399/	Jun. 2024; Oct. 2025	Abstract	Compassionate-use cases
S25	ClinicalTrials.gov NCT07552987 (Kedrion IVIg), NCT07860021 (efgartigimod), NCT07804004 (CTX112), NCT06375993 (prula-cel), NCT00716066 (transplant). https://clinicaltrials.gov/study/NCT07552987 https://clinicaltrials.gov/study/NCT07860021 https://clinicaltrials.gov/study/NCT07804004 https://clinicaltrials.gov/study/NCT06375993 https://clinicaltrials.gov/study/NCT00716066	Accessed Oct. 23, 2026	Opened (API), statuses rechecked Oct. 23	Competitor status
S26	CMS National Coverage Determination 110.24, CAR T-cell therapy. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=374	Effective Aug. 7, 2019	Opened (web reader)	Coverage scope
S27	Hobart J et al. <i>Neurology</i> 2013 (T25FW threshold); Oosterveer DM et al. <i>Mult Scler Relat Disord</i> 2022 (6MWT threshold).	Cited in S2	Not opened; cited by poster	Threshold origin
S28	Owner-packet sources not opened by the author: Kyverna October 2026 investor deck (inspected by the packet reviewer); BMS zola-cel MSToronto release (Oct. 23, 2026). https://ir.kyvernax.com/static-files/a0b5b1a8-87cc-4647-a743-2221fd11a895	Oct. 2026	HTTP 403 to author; not independently verified	Labeled context only
S29	FDA: Yescarta prescribing information; boxed warning and section 5.7. https://www.fda.gov/media/108377/download	Jul. 2026	Opened (PDF)	Class label

DISCLOSURES

Bottom Line and Investment-Risk Disclosure

Bottom line

In 26 patients with refractory, antibody-positive stiff-person syndrome, one miv-cel infusion was followed by a median 49% within-patient reduction in 25-foot walk time at one year, with 24 of 26 off chronic SPS immunotherapy. The study had no control arm, the regimen carries real toxicity and the BLA is not yet complete. The open question is whether an approval turns that signal into durable function without chronic SPS immunotherapy for patients in routine US care. Four stars records how much of refractory SPS care a fully realized result would reach, and nothing about which way it will go.

[S2, S10]

Next measurement

Kyverna's third-quarter report, then completion and FDA acceptance of the BLA. I will check the FDA decision as soon as it is public, then label scope, commercial infusions and the first long-term follow-up disclosures, recording each against this baseline.

What would move my reading

Signals that would strengthen it	Signals that would weaken it
BLA accepted with priority review and an approval with a broad refractory-SPS label	Refusal to file, complete response letter or a randomized-trial requirement
Long-term follow-up showing gains kept after B-cell return, with retained numbers	Rising IVIg restarts or walking decline
Activated centers and disclosed commercial infusions	No publicly announced price or coverage after launch (a tracking gap), and no disclosed infusions
Peer-reviewed full KYSA-8 report with protocol detail	Late safety signals or restrictive labeling

Source hierarchy and completeness

Facts about miv-cel come from Kyverna's SEC filings, trial registry records, conference posters and releases; competitor facts come from registries and published trials. The register supports the reported summaries used here; it is not exhaustive, because no protocol, statistical plan, peer-reviewed full paper or participant-level dataset was available, and two owner-supplied documents could not be opened (HTTP 403).

Grading and terminal rule

No outcome grade is issued and no Realized Depth is recorded until outcomes occur. Expected breadth is four stars against US specialist care for immunotherapy-refractory, antibody-positive SPS. Terminal review falls five years after the actual FDA action date.

Investment-risk disclosure. Independent research for informational and educational purposes. Not personalized investment advice, an offer, a solicitation, a recommendation, a rating, a price target, a stock prediction, an expected-security-return analysis or medical advice. Investing involves risk, including possible loss of principal. Figures are drawn from the primary sources listed on pages 20 and 21 and are current as of the evidence date printed on page 1.