MoatRx
Strategy Meets Execution

AXLRx
Accelerating Commercial Consulting.

COMPETITIVE INTELLIGENCE · UNITED STATES

Early Alzheimer's Disease

Kisunla and Leqembi — the category-building decision

Prepared for the Kisunla US commercial team, Eli Lilly

INSIDE THIS BRIEF — 20 pages

01 US Alzheimer's Disease — Market Scale and the Early Treatment Window

02 Five Access Gates Block a Reachable Category

03 Treatment Paradigm — Where Kisunla Fits

04 Leqembi and Kisunla Are Near-Parity — ARIA and SC Are the Two Gaps

05 Lilly's Commercial Machine Is 11x Biogen's — Kisunla Does Not Share It

06 Three Investments Open the Category — Only Lilly Can Fund All Three

07 Kisunla Wins by Building the Category on Four Tracks, Not Fighting for Today's Patients

INDICATION	GEOGRAPHY	BRIEF TYPE	SCOPE	DATE
Early Alzheimer's Disease	United States	Competitive Intelligence	Full	June 2026

SAMPLE BRIEF — AXLRX DEMONSTRATION ONLY

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00 ABOUT THIS BRIEF

Scope, method, and how to read this document.

Read once; reference often.

This competitive intelligence brief answers one commercial question for the Kisunla US commercial team at Eli Lilly: **is the early Alzheimer's disease category too small to invest in, or is it unreached — and what does Lilly's scale buy in a market blocked by diagnosis and access barriers?** Evidence is sourced from live connectors (PubMed, FDA, CMS, SEC EDGAR). All TBV items are in the Assumption Register only.

WHAT THIS BRIEF COVERS

- **Section 01 · US AD Market.** Prevalence, disease-stage distribution, and the anti-amyloid-eligible population — sized from published rates.
- **Section 02 · Access Gates.** The five gates between an early AD patient and treatment, and which ones are movable.
- **Section 03 · Treatment Paradigm.** Where Kisunla® sits in the treatment landscape and its limited-duration differentiator.
- **Section 04 · Competitive Landscape.** Leqembi® vs Kisunla® head-to-head — approval, efficacy, ARIA, SC option.
- **Section 05 · Machine Asymmetry.** Lilly vs Eisai/Biogen commercial scale — SEC EDGAR Q1 2026 verified.
- **Section 06 · Category Levers.** The investments that widen the eligible pool — and who can fund them.
- **Section 07 · Investment Roadmap.** Kisunla's sequenced 4-track 2026-2028 playbook.

WHAT THIS BRIEF IS NOT

- **Not a revenue forecast.** No forward-looking revenue models — strategic framework only.
- **Not a head-to-head clinical comparison.** CLARITY-AD and TRAILBLAZER-ALZ 2 used different populations and primary endpoints. No validated cross-trial comparison exists.
- **Not primary research.** All clinical data from published phase 3 trials. Epidemiology from public databases and peer-reviewed cohorts.

HOW TO READ THIS BRIEF

p. 5	**Strategic Context.** Binding constraint and five team-owned validation questions. Read before presenting externally.
p. 7	**Executive Summary.** The MoatRx read — what this data means for your commercial strategy.
01 →	**Analytical sections.** Work through in order. Each page answers one commercial question.
p. N+1	**Open Items.** Outstanding questions with named owners — use as an action register.

SOURCE BASIS

MoatRx retrieves from 19 live connectors across three source tiers. Full parameter-level audit trail in **Sources Registry**.

● Verified	Confirmed against original source. Peer-reviewed citations and regulatory documents.
● Benchmark	Single credible source (WHO, GBD, grey literature). Use with context; note geography limitations.
● Client validation	Model-derived or proxy data. Flagged in Assumption Register — primary research required before HTA or board-level use.

— CONTENTS

What's inside.

This competitive intelligence is structured in three layers:
framing shell · analytical evidence stack · closing actions.

1 FRAMING SHELL

1.1 **Background** Drug · disease · market 4

1.2 **Strategic Context** Binding constraint · validation 5

1.3 **Assumption Register** Confidence-tiered parameters 6

1.4 **Executive Summary** MoatRx read · findings · actions 7

2 ANALYTICAL EVIDENCE

2.1 **US AD Market** Prevalence · eligible population 9

2.2 **Access Gates** Five gates · what moves 10

2.3 **Treatment Paradigm** Where Kisunla fits 11

2.4 **Competitive Landscape** Leqembi vs Kisunla 12

2.5 **Machine Asymmetry** Lilly vs Eisai / Biogen 13

3 CLOSING ACTION

3.1 **Category Levers** Investments that widen the pool 14

3.2 **Investment Roadmap** 4-track 2026–2028 plan 15

3.3 **Open Items** Primary-research questions 17

3.4 **Strategic Questions** For the commercial team 18

— REFERENCE

— **Sources Registry** Citations · verification status 19

BACKGROUND

Two approved disease-modifying therapies, five access gates, and a diagnosis unlock that arrived in May 2025.

Drug · disease · US market.

THE DRUGS

Leqembi® (lecanemab-irmb, Eisai/Biogen, BLA761269): full FDA approval July 6, 2023. IQLIK® SC autoinjector (BLA761375) added August 29, 2025 for maintenance use. Kisunla® (donanemab-azbt, Eli Lilly, BLA761248): full FDA approval July 2, 2024. Both are IV anti-amyloid monoclonal antibodies indicated for MCI or mild AD dementia with confirmed amyloid-beta pathology. Both require CED registry enrolment for Medicare coverage (CMS NCD 200.3, effective April 7, 2022).

THE DISEASE AND MARKET

- Alzheimer's disease affects approximately 7.2 million US adults aged 65+ (Alzheimer's Association 2025). Anti-amyloid therapy is indicated only in the early stage (MCI or mild AD dementia) with confirmed amyloid — but most diagnosed AD has already progressed past that stage, so the eligible pool is far smaller than prevalence.
- Anti-amyloid drugs modestly slow clinical decline (CDR-SB) in patients with confirmed amyloid. They do not reverse disease. Effect sizes are statistically significant; clinical magnitude is moderate.
- Access requires amyloid confirmation, CED registry participation, ARIA monitoring, and IV infusion capacity — each one narrows the treatable population further.

> **THE FRAMING**
>
> The commercial question is not whether the early AD category is too small to invest in — it is whether to compete for the narrow eligible pool as it stands, or invest upstream to widen it. The pages that follow size the pool, map the gates, compare the two drugs, and weigh the assets each competitor brings to the choice.

STRATEGIC CONTEXT

Five decisions determine whether Kisunla leads or follows early AD category formation.

Client validation questions.

BINDING CONSTRAINT

The early AD category is gated by diagnosis scarcity and access infrastructure — not by demand or drug quality. The blood-test unlock (Lumipulse, May 2025) removed the hardest gate. The binding constraint for Kisunla is whether Lilly invests its machine to open the remaining four gates before Eisai/Biogen build the physician referral relationships by default.

Five questions for the Kisunla commercial team

Q1 **What is Kisunla's internal year-one patient target and the ROI threshold for category-building spend?**

The investment thesis requires a denominator. Internal targets calibrate the scale of blood-dx and PCP investment needed.

Category sizing

Q2 **Is a Kisunla SC formulation in active development — and on what timeline?**

The limited-duration counter-narrative buys time. The go/no-go on SC development is the strategic decision that determines whether limited-duration is a bridge or a destination.

Q3 **Has Lilly initiated blood-test integration discussions with Fujirebio?**

First-mover timing in the blood-test referral channel is material. Eisai has equal incentive. Has Lilly engaged?

Q4 **What share of the Kisunla commercial budget is category-building vs direct HCP promotion?**

The brief argues category-building produces higher ROI than head-to-head detailing for the current unreached population. Does the budget reflect that allocation?

Q5 **Does Kisunla's 24.0% ARIA-E rate create a measurable prescriber preference gap vs Leqembi in APOE4 carriers in community practice?**

APOE4 prevalence is high in early AD. Physician preference data in community practice is the key commercial assumption that no published trial can supply directly.

ASSUMPTION REGISTER

The brief rests on verified anchors — three parameters remain for client validation.

High-confidence base, flagged unknowns.

• High confidence — live-verified this session • Medium — verified rate, US-sited confirmation pending • Low — requires primary

CONFIDENCE	PARAMETER	BASIS	USED IN
• High	US AD dementia prevalence 7.2M	Rajan et al., Alzheimer's & Dementia 2021 (PMID 34043283) — 6.07M (2020), US Census-adjusted; the model AA's 2025 figure derives from. Live-verified.	**Section 01** funnel top
• High	Amyloid-positivity in MCI ~50–65%	Jansen et al., JAMA 2015 (PMID 25988462) — IPD meta-analysis, 3,972 MCI; 27% at 50 → 71% at 90. Live-verified.	**Section 01** funnel
• High	Approvals, efficacy, ARIA-E	FDA BLA761269 / 761375 / 761248; CLARITY-AD (PMID 36449413, ARIA-E 12.6%); TRAILBLAZER-ALZ 2 (PMID 37459141, ARIA-E 24.0%). All live-verified.	**Sections 03–04** comparison
• High	Lilly vs Biogen Q1 2026 revenue	SEC EDGAR 10-Q: LLY $19,799M; BIIB $1,752M. Live-verified from filings.	**Section 05** machine asymmetry
• Medium	AUR eligibility ~13% of presenters	BioFINDER Primary Care (PMID 41865008) applied US Appropriate Use Recommendations: 14.2% lecanemab / 12.8% donanemab. Rate is solid; cohort is Swedish — US-sited confirmation (e.g. Mayo Clinic Study of Aging) would tighten.	**Section 01** eligibility
• Medium	Kisunla® SC formulation timeline	No public Lilly disclosure of an SC programme timeline. Limited-duration counter assumes SC is achievable within the 2026–2028 window.	**Section 07** track 4
• Low	APOE4 prescriber preference gap	No head-to-head prescriber survey in US community practice. Trials report higher ARIA in APOE4 carriers but do not measure real-world prescribing preference.	**Section 04** adoption rate

HOW TO USE THIS REGISTER

The spine is verified: prevalence, amyloid-positivity, approvals, efficacy, ARIA, and competitor revenue are all live-verified peer-reviewed or regulatory sources — the argument does not rest on estimates. **Before board use:** commission a US-sited eligibility read and an APOE4 prescriber-preference survey; confirm the Kisunla SC timeline internally.

EXECUTIVE SUMMARY

The anti-amyloid-eligible pool is a fraction of prevalence — compete for it, or invest upstream to widen it.

Kisunla's category choice.

MOATRX READ

Having Alzheimer's is not the same as being treatable. Of patients who present with cognitive symptoms, only about one in eight is anti-amyloid-eligible once stage, amyloid status, and safety criteria are applied. Kisunla's choice is whether to compete for that narrow pool against a first-mover, or invest upstream — in diagnosis and referral — to widen it, where Lilly's commercial scale is the decisive asset.

7.2M

US ADULTS WITH AD DEMENTIA

Rajan 2021 · AA 2025 · PMID 34043283

~13%

OF SYMPTOM PRESENTERS ARE ELIGIBLE

US AUR criteria · BioFINDER · PMID 41865008

+11.4 pp

KISUNLA ARIA-E GAP VS LEQEMBI

24.0% vs 12.6% · PMID 37459141 / 36449413

KEY FINDINGS

01 The eligible pool is a fraction of prevalence.

7.2M US adults have AD dementia (Rajan, PMID 34043283), but only the early-stage, amyloid-positive, safety-eligible subset qualifies — roughly 13% of those who present with cognitive symptoms under US Appropriate Use Recommendations (BioFINDER, PMID 41865008).

02 Upstream gates decide the pool size.

Stage recognition and amyloid confirmation gate the most patients and sit furthest upstream — so investment there widens the pool, while coverage and site-of-care (shared, structural) mainly shape throughput.

03 Near-parity efficacy — ARIA and SC are the two gaps.

CLARITY-AD (PMID 36449413): ~27% CDR-SB slowing, ARIA-E 12.6%. TRAILBLAZER-ALZ 2 (PMID 37459141): ~36% slowing low/med tau, ARIA-E 24.0%. Leqembi holds lower ARIA and the IQLIK SC option. Not head-to-head comparable.

04 Lilly's commercial scale is the decisive asset.

LLY Q1 2026 revenue $19.8B vs BIIB $1.75B (SEC EDGAR). Kisunla is backed by a diversified machine that can fund diagnosis, access, and awareness in parallel; Leqembi's co-promoters must prioritise.

ACTION SEQUENCE

NOW T+0

Initiate Fujirebio blood-test partnership.

Contact Fujirebio on Kisunla-specific blood-test access programme integration and PCP ordering protocol development.

90 DAYS T+90 d

Launch PCP awareness and referral programme.

MCI screening tools, Alzheimer's Association partnership, specialist referral protocols for blood-test-positive patients.

6 MONTHS T+6 mo

Commit on SC programme vs limited-duration positioning.

Internal decision: accelerate SC formulation or invest fully in the limited-duration differentiation narrative as the durable IQLIK counter.

SEQUENCING PRINCIPLE

Blood-dx and PCP pathways first — awareness without access creates demand the system cannot absorb. SC answer runs in parallel. Getting the sequence wrong means referrals the system cannot convert.

II

EVIDENCE

The analytical stack.

Sections 01–07 · evidence, scenarios, and decision framework.

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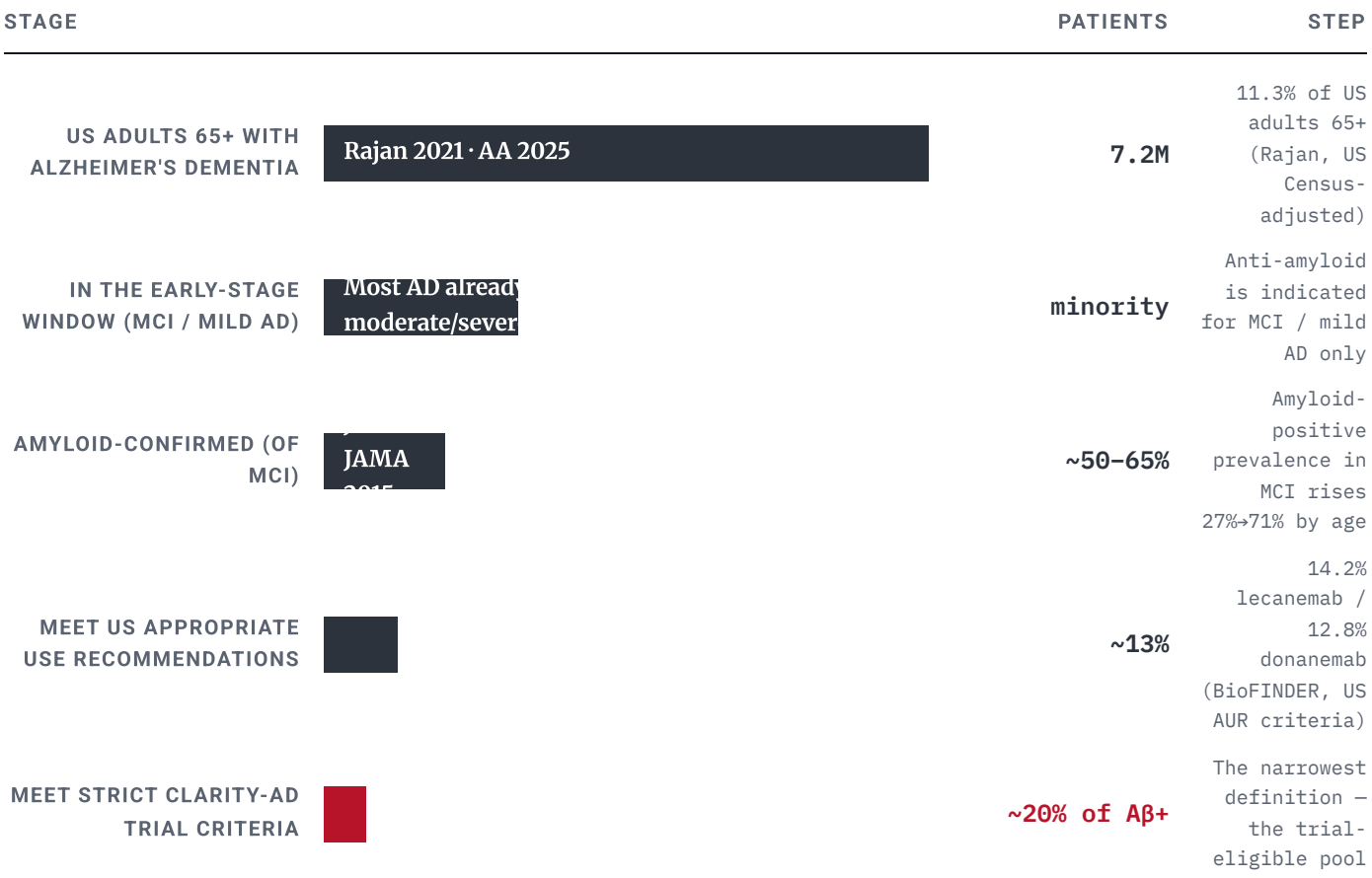
01 US ALZHEIMER'S DISEASE — PREVALENCE AND THE ANTI-AMYLOID-ELIGIBLE POPULATION

7.2 million Americans have Alzheimer's dementia — anti-amyloid eligibility narrows to a small, well-defined fraction.

Four gates, each with a published rate.

FROM PREVALENCE TO THE ELIGIBLE POOL — EVERY STEP CARRIES A PUBLISHED RATE



Stages draw on different denominators — prevalence, MCI, and cognitive-symptom presenters — so bar widths are illustrative of the multiplicative narrowing, not a single cumulative rate; each step's rate is sourced. Prevalence: Rajan 2021 (PMID 34043283), basis for AA 2025. Amyloid-positivity: Jansen 2015 (PMID 25988462). AUR eligibility: BioFINDER (PMID 41865008). Trial-strict: Cogfrail (PMID 41634843).

Prevalence is large; the anti-amyloid-eligible pool is a small, well-defined fraction of it — and that is before diagnosis, coverage, and site-of-care are even attempted. The commercial choice follows directly: compete for the narrow eligible pool as it stands today, or work upstream to widen it. Section 02 maps the gates that decide which patients ever reach eligibility.

02 FIVE ACCESS GATES BLOCK A REACHABLE CATEGORY

Five gates stand between an early AD patient and treatment — each removes patients.

Where the eligible population is lost.

5

GATES FROM FIRST SYMPTOM TO FIRST DOSE

Each one removes patients

Apr 2022

CED COVERAGE RESTRICTION IN FORCE

CMS NCD 200.3 — registry required

IV + MRI

EVERY PATIENT, EVERY CYCLE

Infusion + ARIA monitoring burden

EACH GATE IS A CONVERSION LOSS — AND EACH IS MOVABLE TO A DIFFERENT DEGREE

GATE 1 — STAGE RECOGNITION	PCPs rarely identify MCI at the point of earliest symptoms. Without referral, patients are not evaluated for anti-amyloid therapy until disease has progressed past the early-stage indication.
GATE 2 — AMYLOID CONFIRMATION	Amyloid-beta pathology must be confirmed before initiation — historically via PET (~$3,000+, specialist-only) or CSF lumbar puncture. A plasma test (Fujirebio Lumipulse®, FDA K242706, May 2025) now offers a less invasive route, though PET/CSF remain the references for borderline results.
GATE 3 — SAFETY SCREENING	ARIA risk stratification, APOE4 genotyping, and anticoagulant review exclude a meaningful share of otherwise-eligible patients. Kisunla® ARIA-E 24.0% vs Leqembi® 12.6% shapes selection in APOE4 carriers.
GATE 4 — CED REGISTRY COMPLIANCE	Medicare covers both drugs only under Coverage with Evidence Development (CMS NCD 200.3, Apr 2022). The clinician must enrol the patient in a CMS-approved registry; treatment outside an approved study or NIH trial is nationally non-covered.
GATE 5 — SITE-OF-CARE CAPACITY	Both drugs require IV infusion and periodic MRI for ARIA. Infusion-center capacity and neurologist access cap throughput, especially outside major academic centres.

WHICH GATES MOVE

Gates 1 and 2 sit furthest upstream, so they gate the most patients — and both are addressable through diagnosis-pathway and referral investment. Gates 3–5 (safety, coverage, site-of-care) are structural and shared by both competitors; they shape selection and throughput but are harder to move unilaterally.

The upstream gates — recognition and confirmation — decide how many patients ever reach eligibility, so they are where commercial investment changes the size of the pool rather than the share of it. Section 03 places Kisunla in the treatment landscape for the patients who do clear the gates.

03 TREATMENT PARADIGM — WHERE KISUNLA FITS

Kisunla is the second disease-modifying therapy for early AD — limited-duration dosing is its differentiator.

Stop when amyloid clears.

ANTI-AMYLOID THERAPY SITS AT THE FRONT OF THE CASCADE — KISUNLA® AND LEQEMBI® ARE THE ONLY DISEASE-MODIFYING OPTIONS

TREATMENT TYPE	AGENTS	STAGE INDICATED	KEY PROFILE
Symptomatic — AChEI	Donepezil, rivastigmine, galantamine	All stages	Cognitive symptom management; do not slow disease
Symptomatic — NMDA antagonist	Memantine	Moderate-severe	Add-on to AChEI; do not slow disease
Disease-modifying — anti-amyloid	Leqembi® (lecanemab, Eisai/Biogen)	MCI / mild AD + amyloid confirmed	Ongoing IV treatment; SC maintenance (IQLIK®, Aug 2025)
Disease-modifying — anti-amyloid	Kisunla® (donanemab, Eli Lilly)	MCI / mild AD + amyloid confirmed	**Limited-duration: treatment stops when amyloid cleared**

Symptomatic agents manage cognition at all stages; disease-modifying anti-amyloid mAbs slow progression in early stages only. Both require confirmed amyloid before initiation.

KISUNLA'S DIFFERENTIATOR

Limited-duration dosing is Kisunla's primary commercial differentiator. Patients who clear amyloid stop treatment — a defined endpoint vs an ongoing therapy. This positions Kisunla as a finite course, not a lifelong commitment, and is Lilly's primary narrative counter to Leqembi's IQLIK® SC maintenance.

The treatment landscape has two disease-modifying options and Kisunla is the newer, with the only finite-course profile. Section 04 compares the two drugs on the five dimensions that matter to a commercial head: approval, efficacy, ARIA risk, dosing, and site-of-care options.

04 LEQEMBI AND KISUNLA — NEAR-PARITY EFFICACY, TWO STRUCTURAL GAPS

Leqembi and Kisunla are near-parity on efficacy — ARIA and SC are the two gaps.

No head-to-head data available.

13 mo
LEQEMBI® FIRST-MOVER LEAD
Jul 2023 vs Jul 2024 approval

~2x
KISUNLA® ARIA-E RATE
24.0% vs 12.6% — Leqembi edge

IV only
KISUNLA® SITE-OF-CARE GAP
vs Leqembi IQLIK® SC autoinjector

FIVE-ATTRIBUTE HEAD-TO-HEAD — ORIENTATION ONLY

ATTRIBUTE	LEQEMBI® (LECANEMAB)	KISUNLA® (DONANEMAB)
FDA approval	Jul 6, 2023 · BLA761269	Jul 2, 2024 · BLA761248
CDR-SB efficacy signal	~27% slowing vs placebo at 18 mo · CLARITY-AD (PMID 36449413) · primary endpoint	~36% slowing vs placebo at 18 mo · TRAILBLAZER-ALZ 2 (PMID 37459141) · secondary endpoint, low/med tau — not directly comparable
ARIA-E rate	12.6% · lower risk; supports SC maintenance safety profile	24.0% · higher; FDA-revised titration protocol for APOE4 carriers
Dosing	IV every 2 weeks (initiation); IQLIK® SC once-weekly at-home maintenance (BLA761375, Aug 2025)	IV monthly; **no SC option**
Treatment duration	Ongoing	Limited-duration — stop when amyloid cleared

No head-to-head trial exists. CLARITY-AD and TRAILBLAZER-ALZ 2 used different populations, primary endpoints, and tau enrichment — direct efficacy comparison is not valid.

THE TWO GAPS

Leqembi holds two structural edges on the molecule: lower ARIA burden (12.6% vs 24.0%) and IQLIK SC maintenance. Kisunla holds monthly dosing frequency and limited-duration dosing. On efficacy alone, the drugs are near-parity — the commercial outcome will be decided by access infrastructure, machine scale, and which narrative lands with physicians.

Competing on the molecule is a losing strategy for both sides — the data is too close and the ARIA gap cuts against Kisunla in high-risk patients. The question Section 05 answers: which company has the scale to compete on the dimensions that actually decide the category — access, awareness, and infrastructure.

05 LILLY'S COMMERCIAL MACHINE IS 11X BIOGEN'S — KISUNLA DOES NOT SHARE IT

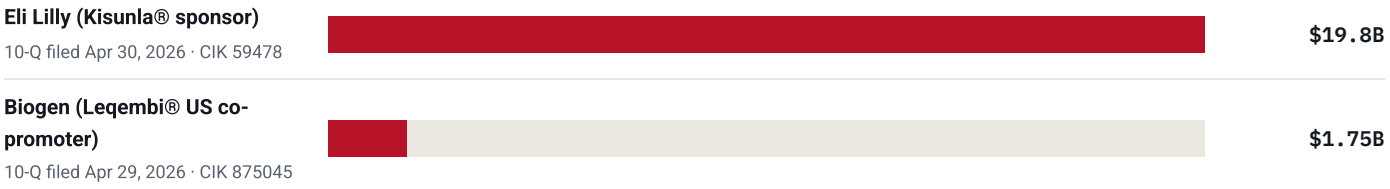
Lilly's commercial machine is 11x Biogen's — and Kisunla does not share the machine it competes against.

SEC EDGAR Q1 2026 · verified.

THE MACHINES BEHIND THE DRUGS ARE NOT COMPARABLE

Kisunla is one asset in Lilly's diversified portfolio alongside Mounjaro, Zepbound, Verzenio, and a deep pipeline. Leqembi is a franchise-defining bet for both Eisai and Biogen — with Biogen carrying reputational damage from Aduhelm's restricted CMS coverage. Kisunla benefits from the full Lilly commercial machine. Leqembi does not.

Q1 2026 TOTAL REVENUE — COMMERCIAL SCALE PROXY (SEC EDGAR, VERIFIED)



Total company Q1 2026 revenue as proxy for available investment capacity. Both figures verified via SEC EDGAR 10-Q filings. Eisai (Leqembi primary partner) is Tokyo-listed; not available via SEC EDGAR. 11.3x = $19.8B / $1.75B (derived from verified SEC figures).

A

Lilly — the machine Kisunla rides

DIVERSIFIED

Mounjaro and Zepbound cardiometabolic engine, Verzenio oncology, and a deep pipeline fund a vast US commercial and field organisation. Kisunla is one asset in the portfolio — Lilly can finance blood-dx, awareness, access, and SC development in parallel without betting the company on AD.

B

Eisai + Biogen — a franchise bet

CONCENTRATED

Two mid-caps co-promoting a single franchise-defining product. Biogen carries the Aduhelm credibility scar with payers and physicians. Limited capacity to fund category-building infrastructure alone — the slow Leqembi ramp reflects it.

What 11x buys: Lilly can fund blood-test partnerships, PCP education, CED streamlining, infusion-site expansion, and SC development simultaneously — Eisai and Biogen must choose. The machine asymmetry is Kisunla's structural advantage, not the molecule, and it decides whether the category-building infrastructure gets funded. Section 06 names the three investments that convert that scale into category leadership.

06 CATEGORY LEVERS — THREE INVESTMENTS THAT OPEN THE MARKET

Three investments determine who owns early AD — not the molecule.

Blood-dx · PCP pathways · SC parity.

NPV 97%

LUMIPULSE BLOOD TEST ACCURACY

FDA K242706 · May 2025 · PCP-orderable

PPV 93%

DIAGNOSTIC SPECIFICITY

First scalable confirmation without specialist

+11.4 pp

KISUNLA ARIA-E GAP VS LEQEMBI

24.0% vs 12.6% · shapes APOE4 monitoring investment

Aug 2025

LEQEMBI IQLIK® SC APPROVED

BLA761375 · Kisunla IV-only · actionable gap

LEVER 1 — BLOOD-BASED DIAGNOSIS ROLLOUT	Partner with Fujirebio (Lumipulse K242706, cleared May 2025) to embed plasma amyloid testing in primary care ordering workflows. Fund PCP education and referral protocols. This lever unlocks volume upstream of every other gate — a patient who cannot be confirmed cannot start therapy regardless of coverage or site capacity. **First-mover earns the PCP referral relationship before Eisai can respond.**
LEVER 2 — PCP AWARENESS AND REFERRAL PATHWAYS	Most early AD patients present first to primary care. A PCP who does not recognise MCI as actionable does not order a blood test and does not refer. MCI screening tools, Alzheimer's Association partnerships, and structured referral protocols drive the top of the funnel before any downstream investment pays off.
LEVER 3 — SC PARITY ANSWER	Leqembi IQLIK® (Aug 2025) creates a maintenance convenience advantage and frees infusion slots for new Leqembi patients. Kisunla's two-part response: (a) accelerate SC formulation development, and (b) in the interim, position limited-duration dosing — **'a finite course with a defined endpoint'** — as the value differentiator against ongoing therapy.

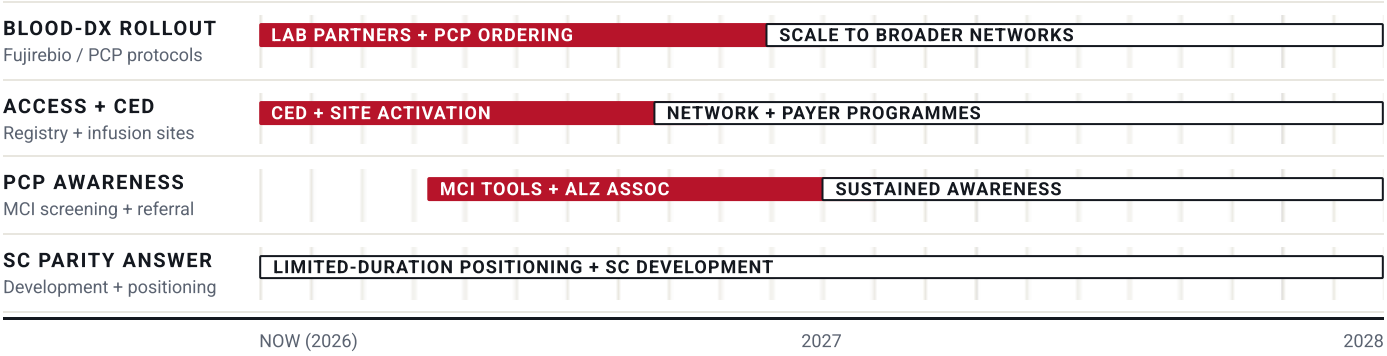
All three levers require coordinated investment that only Lilly's machine can fund simultaneously. The diagnostic infrastructure analogue applies: the company that builds the referral pathway before competitors earns a structural advantage when the category opens at scale. Lilly can build all three tracks in parallel. Section 07 sequences them into the roadmap.

07 KISUNLA'S 2026-2028 INVESTMENT ROADMAP

Kisunla wins by building the category on four tracks — not competing for today's treated population.

2026-2028 · diagnosis · access · awareness · SC.

SEQUENCING PRINCIPLE: DIAGNOSIS BEFORE AWARENESS; ACCESS AND SC RUN IN PARALLEL



Blood-dx and access infrastructure run first — awareness without access creates demand the system cannot absorb; SC parity runs in parallel as a defensive move. Timing indicative; SC development timeline requires internal confirmation.

START NOW — THE THREE Q1 2026 MOVES

1. Open Fujirebio (Lumipulse) partnership talks for Kisunla blood-test access integration before Eisai moves first. **2.** Make the SC formulation go/no-go decision — it sets whether limited-duration is a bridge or the permanent position. **3.** Reset the commercial budget split toward category-building (blood-dx, PCP pathways) over head-to-head HCP detailing.

The 2026-2028 window is Kisunla's to lead or cede. Fund all four tracks using the machine advantage and Kisunla builds the referral pathways, diagnostic infrastructure, and access network that define the market leader when early AD opens at scale. Compete molecule-for-molecule and the machine advantage is never deployed — and the category opens for someone else.

ACTION

III

From evidence to decision.

Outstanding questions, owner-assigned actions, and the next engagement.

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○ OPEN ITEMS

Primary research items that secondary sources cannot resolve.

These items require direct primary research or internal Lilly data before the brief can inform final commercial planning.

01 **Early treatment uptake (ATU) studies — physician and patient perception.**

What do neurologists and PCPs report about early AD treatment intent, barriers to initiation, and perceptions of Kisunla vs Leqembi? Qualitative ATU with both audiences is the highest-priority primary research need.

OWNER → LILLY MEDICAL AFFAIRS / MARKET RESEARCH

02 **Kisunla SC formulation development status and timeline.**

Is a Kisunla SC programme active? What is the Phase 1/2 timeline? The answer determines whether limited-duration positioning is a bridge to SC or the permanent differentiator strategy.

OWNER → LILLY R&D / CMO

03 **Blood-test integration engagement with Fujirebio — has Lilly initiated?**

First-mover timing in the PCP blood-test referral channel is material. Eisai has equal incentive to move here. Status of any existing Lilly-Fujirebio commercial discussions.

OWNER → LILLY MARKET ACCESS

04 **Confirmed Leqembi FY2025 treated patient count (Eisai investor relations).**

The brief uses Eisai press-release figures for the category size. Actual treated patient count from Eisai IR would sharpen the baseline.

OWNER → LILLY COMPETITIVE INTELLIGENCE

→ STRATEGIC QUESTIONS

Positioning, investment, and commercial strategy questions for the Kisunla launch team.

These questions require internal commercial judgement and cannot be answered from secondary research.

01 **What is Kisunla's brand positioning against the limited-duration vs ongoing-therapy narrative — and how much are we investing to make it visible?**

Limited-duration is Kisunla's differentiator. Brand strategy, messaging investment, and conference / KOL advocacy must be explicitly funded to make it land with neurologists and PCPs.

02 **What is the salesforce deployment model for Kisunla — specialist-focused neurology MSL or broad PCP reach?**

The blood-test unlock suggests PCP reach is now as important as specialist engagement. Salesforce sizing, MSL investment, and channel mix need to reflect the new diagnosis pathway.

03 **What conference and publication strategy is Lilly deploying to build Kisunla's clinical credibility ahead of IQLIK comparison?**

ARIA data, APOE4 subgroup analyses, real-world outcomes, and limited-duration endpoint data should be the active publication pipeline. Which congresses and journals are prioritised?

04 **What is the patient advocacy and Alzheimer's Association engagement strategy for Kisunla?**

Category-building requires upstream awareness. Lilly's partnership with Alzheimer's Association on MCI recognition and early referral is a direct lever on Gate 1 (stage recognition) — is it funded at the required scale?

SOURCES REGISTRY

Sources and verification status.

Every claim maps to a source row.

All sources underpinning claims in this competitive intelligence are listed below with verification status and section mapping. TBV items require live verification before client presentation.

#	AUTHORS / ORGANISATION	TITLE / PUBLICATION	REFERENCE	STATUS	SECTION
1	**van Dyck CH, Swanson CJ, Aisen P et al.**	Lecanemab in Early Alzheimer's Disease (CLARITY-AD). N Engl J Med. 2022;388(1):9-21.	PMID 36449413 · DOI 10.1056/NEJMoa2212948	Verified	03 04
2	**Sims JR, Zimmer JA, Evans CD et al.**	Donanemab in Early Symptomatic Alzheimer Disease: TRAILBLAZER-ALZ 2 RCT. JAMA. 2023;330(6):512-527.	PMID 37459141 · DOI 10.1001/jama.2023.13239	Verified	03 04
3	**FDA Drugs@FDA**	Leqembi (lecanemab-irmb) BLA761269, approval Jul 6 2023; IQLIK SC BLA761375, approval Aug 29 2025.	FDA BLA761269 / BLA761375	Verified	03 04
4	**FDA Drugs@FDA**	Kisunla (donanemab-azbt) BLA761248, approval Jul 2 2024.	FDA BLA761248	Verified	03 04
5	**FDA 510(k) Premarket Notifications**	Lumipulse G pTau217/beta-Amyloid 1-42 Plasma Ratio (Fujirebio Diagnostics). Cleared May 16, 2025.	FDA K242706	Verified	02 06
6	**Centers for Medicare and Medicaid Services**	NCD 200.3: Monoclonal Antibodies Directed Against Amyloid for the Treatment of AD. CED effective April 7, 2022.	CMS NCD 200.3	Verified	01 02
7	**Eli Lilly and Company**	Form 10-Q filed April 30, 2026 (CIK 59478). Q1 2026 Revenue: $19,799,000,000.	SEC EDGAR 0000059478-26-000045	Verified	05
8	**Biogen Inc.**	Form 10-Q filed April 29, 2026 (CIK 875045). Q1 2026 Revenue: $1,752,300,000.	SEC EDGAR 0000875045-26-000045	Verified	05
9	**Rajan KB, Weuve J, Barnes LL et al.**	Population estimate of people with clinical AD and mild cognitive impairment in the United States (2020-2060). Alzheimer's & Dementia. 2021;17(12):1966-1975. (Basis for AA 2025 7.2M figure.)	PMID 34043283 · DOI 10.1002/alz.12362	Verified	01
10	**Jansen WJ, Ossenkoppele R, Knol DL et al.**	Prevalence of cerebral amyloid pathology in persons without dementia: a meta-analysis. JAMA. 2015;313(19):1924-1938.	PMID 25988462 · DOI 10.1001/jama.2015.4668	Verified	01
11	**Borgström Bolmsjö B, Barbosa Djärf J, et al.**	Eligibility for amyloid targeting therapies among primary care patients with cognitive symptoms (BioFINDER Primary Care). Alzheimer's Res Ther. 2026;18(1). Applied US Appropriate Use Recommendations.	PMID 41865008 · DOI 10.1186/s13195-026-02019-2	Verified	01
12	**Bellelli F, Delrieu J, et al.**	Lecanemab eligibility under CLARITY-AD vs US/French Appropriate Use Recommendations (Cogfrail). Alzheimer's Res Ther. 2026;18(1).	PMID 41634843 · DOI 10.1186/s13195-026-01966-0	Verified	01

STATUS KEY Verified Benchmark Client validation TBV = to be verified live before client use

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