

Moderna: Can Phase 3 Intismeran Success Convert Personalized mRNA Cancer Therapy Into a Scalable Oncology Franchise?

INITIATION MODE	CATALYST	EXPECTED SIGNIFICANCE
Post-event Phase 3 topline announced August 19, 2026. Detailed results are not yet public.	INTerpath-001 Phase 3 interim success RFS primary and DMFS key secondary endpoints met at a pre-specified interim analysis.	★★★★☆ Potential materiality only. The screen is on page 12.

My take

Merck and Moderna announced on August 19, 2026 that INTerpath-001, a 1,137-patient Phase 3 trial of intismeran autogene plus KEYTRUDA in completely resected stage IIB to IV melanoma, met its primary endpoint of recurrence-free survival and its key secondary endpoint of distant metastasis-free survival at a pre-specified interim analysis. Neither company has released a hazard ratio, an event rate or a survival curve; Moderna has announced that they will be presented on October 24, 2026 as late-breaking abstract LBA1 in an ESMO Presidential Symposium.

I bind this catalyst to the August 19 readout and to the question of whether it becomes a product that reaches each patient in time and produces a separately attributable profit contribution to Moderna. Under the filed agreement Merck holds the commercialization rights, including sales booking, with U.S. co-promotion rights for Moderna, and profits and losses are generally shared equally. Moderna recorded \$97 million of net collaboration expense for the whole intismeran program in Q2 2026, against total 2025 revenue of \$1.9 billion. The clinical signal is established in direction and unknown in size, and every commercial link after it is still open.

Decision question

Can the Phase 3 result, once detailed, carry intismeran through approval and individualized commercial supply to a separately attributable, positive intismeran profit contribution to Moderna, with its accounting basis and relevant costs identified?

Post-event initiation

The topline result was public seven weeks before this evidence date. I open this record before the detailed Phase 3 numbers exist, so the reading bands on page 14 are set ahead of the data, and I make no claim to have anticipated the readout itself.

Catalyst-scope firewall

Moderna's consolidated revenue, respiratory-vaccine results, cost programs and the \$950 million litigation settlement paid in July 2026 are company context. The eight other Phase 2 and 3 intismeran trials are corroboration, and program-wide figures need a melanoma bridge before they count here. I treat none of them as evidence for this catalyst without a disclosed bridge to intismeran in melanoma.

CATALYST DEFINITION AND SCOPE

One Catalyst, One Clinical-to-Commercial Mechanism

Catalyst field	Locked definition
Event	Positive topline result of the Phase 3 INTerpath-001 trial of intismeran autogene plus pembrolizumab in adults with completely resected high-risk cutaneous melanoma, announced August 19, 2026.
Occurrence	Yes. RFS and DMFS improved with statistical significance and clinical meaning at a pre-specified interim analysis. The trial continues to evaluate overall survival.
Mechanism	Phase 3 efficacy ► detailed disclosure ► regulatory filing ► approval ► individualized supply at commercial scale ► Merck-led commercialization ► attributable intismeran profit contribution to Moderna.
Primary outcome test	A separately attributable, positive intismeran profit contribution to Moderna, with the accounting basis and relevant costs identified, held across two comparable quarters. Revenue alone proves sales rather than profit, and no particular statement line must change sign.
Terminal horizon	FY2028 annual review, an author-set adjudication date. Non-conversion by then is graded negative; Unmeasurable is reserved for a launched product whose economics Moderna has not disclosed separately by that review.

What the record establishes

Intismeran autogene is an investigational mRNA medicine made separately for each patient. The patient's tumor and blood are sequenced, up to 34 neoantigens the immune system could learn to recognize are selected, and they are encoded in one mRNA sequence given every three weeks for up to nine doses. It is combined with KEYTRUDA (pembrolizumab), Merck's immunotherapy, which is already approved after surgery for stage IIB, IIC and III melanoma.

INTerpath-001 randomized 1,137 patients, with no prior systemic melanoma therapy beyond surgery, 2:1 in a double-blind, placebo- and active-comparator-controlled design. Under the collaboration, costs and any profits or losses are generally shared equally worldwide; the filed agreement gives Merck the sole right to commercialize, which it defines to include invoicing and sales, subject to Moderna's U.S. co-promotion rights. Some manufacturing provisions are redacted.

What the record does not establish

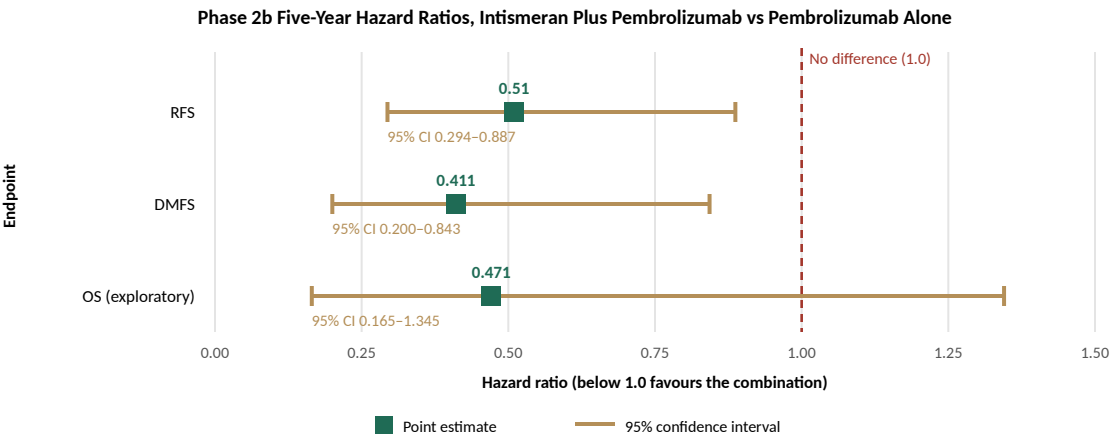
No Phase 3 hazard ratio, absolute event rate, follow-up duration, subgroup result or count of patients who received intismeran was located in the records reviewed through October 5, and no submission date has been announced. Moderna has not disclosed a price, a cost per patient batch, or how its share of commercial results will be presented in its financial statements.

Why this stays a catalyst thesis

The readout is a single, dated, company-confirmed event, and its first graded consequence already has a date: the October 24 presentation. Intismeran already carries its own program-wide collaboration line in Moderna's filings, which gives the economic test a starting instrument. That combination supports a star lock and a terminal horizon, which separates this from an open-ended question about mRNA oncology.

REPORTED BENCHMARK

The Phase 2b Benchmark Phase 3 Will Be Read Against



In this descriptive five-year update, Phase 2b RFS and DMFS intervals stay below 1.0, while the exploratory overall-survival interval crosses it.

Phase 2b measure	Reported value	Treatment
Recurrence-free survival	HR 0.51 (95% CI 0.294–0.887), a 49% lower hazard of recurrence or death	Benchmark, primary endpoint
Five-year RFS, Kaplan–Meier estimate	68.8% (95% CI 56.3–78.3) vs 49.1% (33.3–63.0)	Abstract 9500; JCO paper uses a 4-year landmark
Distant metastasis-free survival	HR 0.411 (95% CI 0.200–0.843), a 59% lower hazard	Benchmark, key secondary endpoint
Overall survival	HR 0.471 (95% CI 0.165–1.345)	Exploratory trend only
Follow-up	Median 60.3 months (range 50.5–76.4)	Descriptive analysis, no alpha allocated
Safety	Intismeran-related grade 3: 11 of 104 treated (10.6%); none grade 4–5; 104 of 107 randomized were treated	Tolerability benchmark

Sources: [2], [3], [4].

What a hazard ratio measures

At 0.51 the estimated hazard of recurrence or death was 49% lower with the combination; however, that does not mean 49 points fewer events or 49% fewer patients with an event. The absolute picture comes from the five-year Kaplan–Meier estimates, a 19.7-point difference by my subtraction, with RFS measured from the first pembrolizumab dose and counting new primary melanoma.

Why the survival trend does not count

The overall-survival interval runs from 0.165 to 1.345, consistent with no difference at all, so I record it as a trend and give it no weight.

REPORTED BENCHMARK • CONTINUED

Phase 2b and Phase 3 Are Different Experiments

Design element	Phase 2b KEYNOTE-942	Phase 3 INTERpath-001
Patients	157	1,137
Disease stage	Adults, resected cutaneous stage IIIB to IV	Adults, completely resected cutaneous stage IIB to IV; no prior systemic therapy beyond surgery
Blinding	Open-label	Double-blind, placebo- and active-comparator-controlled
Intismeran dosing	1 mg every three weeks, up to nine doses	1 mg every three weeks, up to nine doses
Pembrolizumab dosing	200 mg every three weeks, up to 18 doses	400 mg every six weeks, up to nine cycles
Follow-up at reported analysis	Median 60.3 months	Interim analysis; not yet disclosed
RFS hazard ratio	0.51	Not yet disclosed; due October 24, 2026
RFS clock	From first pembrolizumab dose; includes new primary melanoma	From randomization; investigator-assessed recurrence or death from any cause, per Aug. 19 release

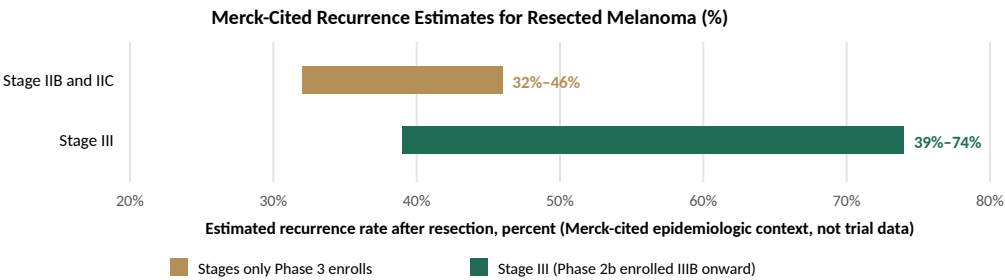
Sources: [2], [3], [6], [1]; Phase 3 RFS clock per [1].

How I read the benchmark

I print 0.51 and the 19.7-point gap as historical benchmarks and decline to use them as forecasts. Phase 3 has a broader stage mix, reads at an interim with shorter follow-up, and is double-blind, although none of these mechanically sets the direction of its hazard ratio. Any absolute-benefit comparison also needs matched time points and the actual control-arm risk, which only the October 24 data can supply.

What October 24 has to disclose

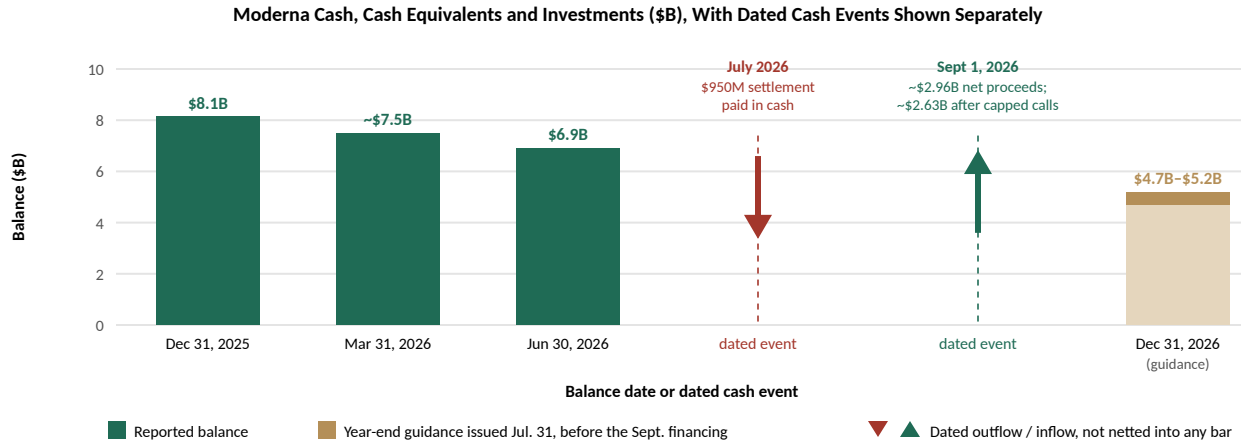
The scheduled presentation needs to show the RFS and DMFS hazard ratios with intervals, absolute event rates in each arm, median follow-up, results by stage, grade 3 or higher adverse events, and, among patients randomized to the combination, how many received a first dose and how many completed treatment. That last figure is a scale-up test of the Phase 2b supply record.



The ranges overlap, so stage mix alone does not settle the absolute benefit; Phase 3's actual control-arm risk will.

COMPANY BASELINE

Moderna Enters the Catalyst Loss-Making and Newly Funded



Cash, cash equivalents and investments fell about \$1.2 billion in H1 2026, to \$6.910 billion, and the July guidance predates the September financing; the July payment and September proceeds are dated events, not a recomputed balance.

Measure	Current reading	Treatment
Revenue, FY2025	\$1.9 billion, down 40% year over year	Reported fact
Net loss, FY2025	\$2.8 billion, against \$3.6 billion in FY2024	Reported fact
R&D expense, H1 2026	\$1,300 million, against \$1,556 million in H1 2025	Reported fact, six months
Operating cash use, H1 2026	\$1,156 million, against \$1,956 million in H1 2025	Reported fact; excludes July payment
Litigation settlement, \$950 million	Accrued at June 30 and paid in cash in July 2026; \$884 million H1 cost of sales, including amortization; \$66 million license intangible remaining at June 30	Reported fact, 10-Q Note 12, MD&A
July 31 year-end cash guidance	\$4.7–5.2 billion, excluding further credit-facility draws; issued before the September financing	Company guidance
0% convertible notes due 2032	\$3.0 billion principal, closed Sept. 1, 2026; ~\$2,957.3 million net, less \$328.8 million for capped calls, leaving ~\$2,628.5 million before other uses	Reported fact, Form 8-K

Sources: [8], [10], [11], [14].

What the baseline means for this catalyst

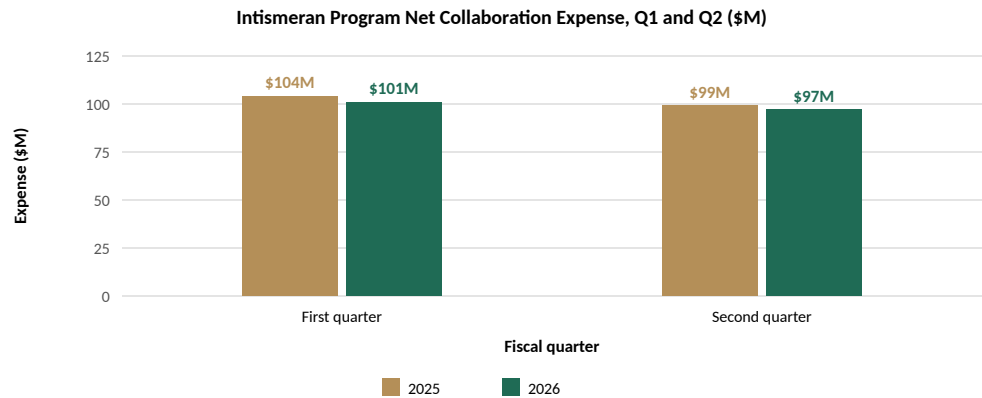
Moderna's revenue still comes mostly from respiratory vaccines, and that base fell 40% in 2025. The September financing changes how much runway Moderna has to fund a launch: it says the remaining proceeds may be used for general corporate purposes, which may include investing in the growth of its oncology business and repaying debt. I do not build a new year-end cash figure, because Moderna has not updated its guidance on a post-financing basis.

Timing sensitivity, hypothetical

The lower H1 2026 cash use partly reflects timing. In the operating cash-flow reconciliation, accrued liabilities were a \$475 million source of cash in H1 2026 against a \$395 million use in H1 2025, while the balance itself rose \$523 million, to \$1,909 million, including the \$950 million settlement accrued at June 30 and paid in July. Had the \$950 million been paid within the half, and assuming the entire payment were classified as operating cash flow, H1 2026 operating cash use would have been about \$2.1 billion against \$1.956 billion; part of the payment bought a license intangible, and its actual classification awaits later filings. That figure is a hypothetical timing sensitivity, not a reported result or a normalized comparison, and it carries no inference about commercial or intismeran performance.

CATALYST BASELINE

The Intismeran Line Moderna Already Reports



Moderna's recognized net collaboration expense for the whole intismeran program, after Merck's reimbursement, was close to \$100 million in each of these quarters.

Intismeran measure	Current reading	Treatment
Net collaboration expense, Q2 2026, whole program	\$97 million (Q2 2025: \$99 million)	Reported fact, 10-Q Note 5; not melanoma alone
Net collaboration expense, H1 2026, whole program	\$198 million (H1 2025: \$203 million)	Reported fact, 10-Q Note 5; not melanoma alone
Net capital-expenditure cost recovery	\$1 million in Q2 2026; \$2 million in H1 2026	Reported fact; kept separate from operating expense
H1 expense against H1 R&D expense	~15.2%	Author calculation: \$198M / \$1,300M; scale reference only
Profit and cost split	Generally equal worldwide, subject to certain exceptions	Reported fact
Roles	Moderna leads manufacture and Merck most trials in development; Merck commercializes and books sales, with Moderna U.S. co-promotion	Reported fact; 10-Q Note 5 and filed agreement
Moderna's financial presentation	How its share of commercial results will appear	Not disclosed

Sources: [8], [9], [16].

Why this line is the starting instrument

Moderna accounts for the program under ASC 808 and reports two program-wide figures, net collaboration expense and a separate capex cost recovery. Both cover every intismeran trial and are recognized amounts rather than cash spending or a run rate. Because Merck books sales, Moderna's share will most likely arrive through a collaboration line, although its presentation is not disclosed. Conversion therefore means a separately attributable, positive contribution with basis and costs identified across two comparable quarters, and program-wide figures count only with a melanoma bridge.

MECHANISM

From a Positive Readout to Moderna's Income Statement



Only the first stage has passed its stated evidence test.

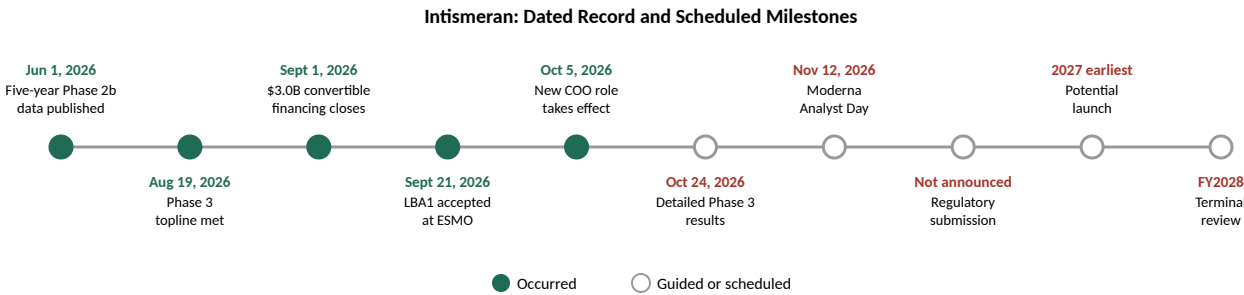
Where the mechanism currently stands

The topline result is established. Every later stage either has a scheduled date with no content yet, as with October 24, or has no date at all. Moderna said in January 2026 that positive data could support a launch as early as 2027, which is an aspiration rather than a promised approval date.

Why manufacturing is the gating stage

Every patient needs a medicine that does not exist until their tumor has been sequenced, so a therapy that works in a trial can still fail commercially if patients cannot receive it in time or each batch costs more than payers reimburse.

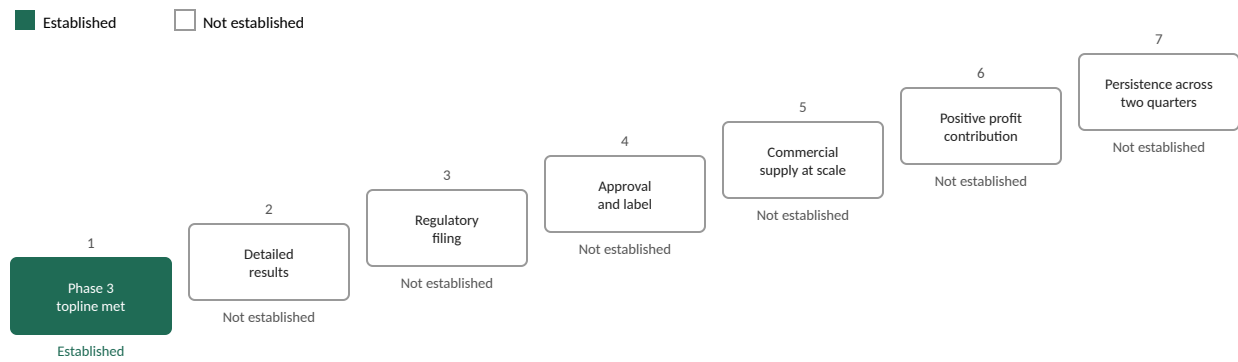
Mechanism stage	What is disclosed today	What would advance the stage
Phase 3 topline	RFS and DMFS met at a pre-specified interim analysis	Already complete
Detailed results	Scheduled for October 24, 2026	Hazard ratios, event rates, follow-up, subgroups, dosing completeness
Regulatory filing	Companies will engage regulators; no date	A dated submission or acceptance
Approval and label	Nothing	Approval with label scope by stage
Commercial manufacturing	Marlborough facility supplying clinical batches since September 2025	Disclosed turnaround, success rate and capacity at commercial volume
Moderna profit contribution	Program-wide net expense of \$97 million in Q2 2026	A separately attributable, positive contribution with costs identified



Five dated events have already shaped the record, although every milestone that could produce revenue still lies ahead; the 2027 launch is a company aspiration and FY2028 is my own adjudication date.

MECHANISM • CONTINUED

Catalyst-to-Commercial-Impact Chain



Stage	Required evidence	Current reading	Does not pass
1. Phase 3 topline	Pre-specified endpoints met with significance	Established: August 19, 2026, interim	Company language without endpoints
2. Detailed results	Hazard ratios, event rates, follow-up, stage subgroups, safety	Not established: due October 24	Relative benefit without absolute rates
3. Regulatory filing	A dated submission or acceptance by FDA or EMA	Not established: no date announced	Statements of intent to engage regulators
4. Approval and label	Approval with label scope	Not established	Priority designations
5. Commercial supply	Turnaround, success rate and capacity at commercial volume	Not established: clinical supply only	Facility existence or automation claims
6. Profit contribution	Separately attributable positive contribution to Moderna, basis and costs identified	Not established: program-wide net expense	Revenue alone; program-wide totals without a melanoma bridge
7. Persistence	Stage 6 repeated across two comparable quarters	Not testable before launch	One favorable quarter

Substitution control

Each unestablished stage has a nearby figure that would appear to fill it. Phase 2b hazard ratios would appear to fill stage two, the Marlborough facility stage five, Moderna’s narrowing consolidated loss stage six, and two good company quarters stage seven. Some are relevant evidence, but none is sufficient for the particular stage it would appear to fill, so I decline all four as substitutes.

MANUFACTURING LANE

The Product Is Also a Supply Chain



Phase 2b rates come from different populations and are not multiplied into one yield; tissue, release and dosing metrics at commercial scale were not located.

Supply-chain item	Reading	Evidence class
Design success, Phase 2b	84.3% (156 of 185 patients whose tumor tissue was assessed)	Reported fact, JCO publication
Manufacturing success, Phase 2b	>99% (104 of 105 combination-arm patients with a successful design)	Reported fact, JCO publication
Whole process time	About six weeks from adequate tumor and blood sample submission to delivery at a clinical site, in trials	Company-authored operational paper, JCO Oncology Advances, 2026
Turnaround trend	>15% improvement in turnaround time in 2025 versus the 2024 average, measured from sample receipt at Personalis through delivery at site; absolute averages not disclosed	Company statement, 2026 proxy
Dedicated facility	Marlborough, Massachusetts; supplying clinical batches since September 2025	Company statement
Operations leadership	Juan Andres named to a newly created COO role effective Oct. 5, 2026; Chief Technical Operations and Quality Officer to retire	Reported fact, Form 8-K
Cost per patient batch and commercial capacity	Not located in the records reviewed	Unknown
External benchmark: BioNTech	30–40 days from sequence identification to released product, and a separate historical target under 28 days	BioNTech 20-F for 2023; different clocks and years

Sources: [2], [5], [12], [13], [25].

Where Phase 2b lost patients

Phase 2b design attrition was 15.7% (29 of 185), so observed attrition was concentrated before downstream manufacturing, although the record does not identify the cause of each unsuccessful design. Commercial turnaround, cost, release testing and capacity remain unproven. The operational paper strengthens the evidence of clinical feasibility, although not of commercial volume or unit cost, and I do not apply the proxy's percentage to it to invent a day count. BioNTech's dated figures are not a speed ranking or evidence of its current performance.

What Moderna's leadership change does and does not show

The 8-K ties the new COO role to the company's increasing scale, and Mr. Andres previously led the build-out of Moderna's manufacturing network. I record it as organizational preparation, although not as evidence of supply performance, and the technical operations head's retirement is a transition risk.

COUNTEREVIDENCE

A Positive Interim Readout Leaves the Commercial Risks Open

Alternative	Why it remains plausible	What would confirm it
Smaller Phase 3 effect	Phase 3 has a broader stage mix and reads at an interim	RFS hazard ratio well above the Phase 2b range on October 24
Survival does not follow	The Phase 2b survival interval crosses 1.0	Overall survival failing to separate as the trial matures
Upstream attrition	Phase 2b design success was 84.3% of patients whose tumor tissue was assessed	A material share of patients randomized to the combination never receiving intismeran
Economics fail	Price, cost per batch and Moderna's financial presentation are undisclosed	No positive attributable contribution after launch
Narrow adoption	Up to nine injections over about six months on top of up to a year of KEYTRUDA	Uptake concentrated in academic centers
Regulatory narrowing	An interim readout may draw requests for more mature data	Label restricted by stage, or a request for survival data before review
Off-the-shelf alternatives win	KEYTRUDA and Opdivo need no patient-specific sequencing or manufacture	Prescribers reserving intismeran for the highest-risk stages
Platform risk	Autogene cevumeran missed its PFS endpoint in previously untreated advanced melanoma	Weak or inconsistent results in intismeran's other tumor types

The commercial burden intismeran has to clear

Patients with resected melanoma already have two approved, off-the-shelf PD-1 drugs, KEYTRUDA and Bristol Myers Squibb's Opdivo, neither of which requires patient-specific tumor sequencing or individualized manufacture. Intismeran therefore has to show added absolute benefit large enough to justify sequencing, an individualized batch and up to nine more injections, and also whatever price premium follows. The comparator page that follows sets out each alternative and what it can and cannot tell us.

Confounders I keep separate

Respiratory-vaccine demand, the \$950 million July 2026 settlement, the September financing, cost programs and other launches all move Moderna's results, so I read this catalyst only through intismeran-specific lines.

Platform-risk note

On August 28, 2026 BioNTech announced termination of its Phase 2 of autogene cevumeran monotherapy against watchful waiting in resected ctDNA-positive colorectal cancer, after a futility boundary in October 2025 and a later numerical overall-survival imbalance, with no new safety signal. A numerical imbalance does not establish drug-caused harm, and the wider program, including a pancreatic trial, continues, so I treat this as platform-development risk rather than a like-for-like comparator.

COMPARATOR CONTROL

Intismeran Must Beat an Existing Adjuvant Standard While Proving the Personalized Platform

Measure	Intismeran + KEYTRUDA	KEYTRUDA alone	Opdivo	Autogene cevumeran
Role here	The catalyst	Randomized control and incumbent standard	Approved commercial alternative	Individualized mRNA platform comparator
Setting	Resected stage IIB–IV melanoma (Phase 3)	Adjuvant label: resected stage IIB, IIC and III	Adjuvant label: resected stage IIB, IIC, III and IV	Untreated advanced melanoma; other tumors
Development stage	Phase 3 positive topline; hazard ratios due Oct. 24	Approved	Approved	No positive registrational result
Key efficacy evidence ¹	Phase 2b, stage IIB–IV: RFS HR 0.51 (0.29–0.89); 5-year RFS 68.8% vs 49.1%	KEYNOTE-716, stage IIB/IIC, first interim: RFS HR 0.65 (0.46–0.92) vs placebo; median follow-up 14.4 months	CheckMate-76K, stage IIB/IIC: RFS HR 0.42 (0.30–0.59); 12-month RFS 89.0% vs 79.4%; minimum follow-up 7.8 months	IMCODE001 Phase 2 with pembrolizumab: primary PFS endpoint missed
Treatment burden (adult IV schedules) ²	Sequencing, then up to 9 individualized injections every 3 weeks plus pembrolizumab 400 mg every 6 weeks, up to 9 cycles	200 mg every 3 weeks or 400 mg every 6 weeks, up to 12 months	240 mg every 2 weeks or 480 mg every 4 weeks, up to 1 year	Patient-specific sequencing and manufacture
Individualized manufacture	Yes, up to 34 neoantigens	No	No	Yes

¹ Different trials, populations, analysis versions, follow-up and controls, so these are not ranked, none is a hurdle for intismeran, and none is projected across either drug's broader label. ² Subcutaneous formulations of both PD-1 drugs are also approved; INTERpath-001 studied the IV regimen shown.

Clinical alignment

KEYTRUDA is the randomized control in INTERpath-001, so it remains the cleanest measure of what intismeran adds, whereas KEYNOTE-716 is context only.

Commercial difference

Opdivo gives resected melanoma another effective PD-1 option, and the only one labeled for stage IV, without patient-specific sequencing or individualized manufacture. That makes the absolute benefit by stage, rather than the pooled hazard ratio, the number that will decide uptake.

Platform counterevidence

Despite inducing neoantigen-specific immune responses, autogene cevumeran missed its primary PFS endpoint with pembrolizumab in previously untreated advanced melanoma, which is why I keep intismeran's other eight trials as corroboration rather than evidence.

EXPECTED SIGNIFICANCE

A Four-Star Catalyst for a Narrowing Company

Expected-significance lock

★★★★☆ I hold four stars. Moderna generated \$1.9 billion of revenue in 2025, almost all of it from respiratory vaccines, and that base fell 40%. It has built a dedicated facility for intismeran, recorded \$198 million of program-wide net collaboration expense in H1 2026, and names oncology as a major long-term value driver. A launched adjuvant melanoma therapy, even at a generally equal share, would sit against that small base. I stop short of five because the bound object is one indication. Company-defining reach would require the approach to work across tumor types, which is outside this catalyst's binding.

Dimension	Lock-time evidence	Reading
Revenue reach	FY2025 revenue of \$1.9 billion, down 40%	A launched product could be large against this base
Cost and capacity	Dedicated facility; \$198 million of program-wide net collaboration expense in H1 2026	Material commitment
Strategic relevance	Oncology named as a major long-term value driver; new COO role	Central to the growth plan
Breadth beyond melanoma	Nine Phase 2 and 3 trials across four tumor types	Excluded by scope

Scale bridge

Measure	Reading	Basis
H1 2026 program-wide net collaboration expense against H1 2026 R&D expense	~15.2%	Author calculation: \$198M / \$1,300M
Estimated new U.S. melanoma cases, 2026	~112,000, all stages	Epidemiological ceiling cited in the August 19 release; the resected stage IIB-IV subset is smaller and not disclosed

What four stars does not mean

The lock does not assume a strong October 24 result, approval in 2027, or attractive economics, and it does not treat 112,000 cases as the addressable market. It records how much of Moderna's business a fully realized catalyst could touch.

What would move the lock

The lock moves only if the catalyst object is redefined, for instance if the binding scope widens beyond melanoma. The October 24 data and every later result inform the outcome grade and leave four stars where they sit.

ADMISSIBILITY AND HORIZON

A Clean Catalyst Date, a Commercial Test Years Away

Dimension	Reading	Reason
Attribution feasibility	High	A single product with its own program-wide collaboration line; melanoma economics need a bridge
Future measurability	Conditional	Depends on whether Moderna discloses its share of intismeran results, and a melanoma bridge, after launch
Disclosure risk	Moderate to high	Phase 2b supply metrics exist; commercial turnaround, cost and accounting route do not
Reversibility	Moderate	Survival data, label scope or post-marketing findings could still narrow use
Terminal horizon	FY2028	Non-conversion graded; Unmeasurable only if launched economics are undisclosed by then

Persistence lock

Two consecutive comparable quarters after launch are required before I call the commercial outcome durable. One quarter of profit contribution, or one strong presentation, does not establish persistence.

Terminal rule

The terminal review is the FY2028 cycle, my own adjudication date, and does not move. My decisions at that review are fixed now: no filing, approval or launch is graded negative; a launch with disclosed losses is graded negative on economics; one comparable quarter leaves persistence not established; program-wide results without a melanoma bridge are not attributable and do not pass; and Unmeasurable applies only to a launched product whose economics Moderna has not disclosed by the review. Later tracking notes may record subsequent evidence but do not overwrite the terminal grade.

Label	Meaning in this thesis
Reported fact	Directly stated in an SEC filing, a peer-reviewed publication or a cited company record, with the original definition and period preserved
Company statement	A management statement recorded with its original scope and qualifiers
Author calculation	Reproducible arithmetic from disclosed inputs, labeled and period-bound
Unknown / Unmeasurable	Required evidence is absent, and no proxy is substituted for it

Why measurability is conditional

The filed agreement gives Merck the commercialization role, including sales booking, so Moderna's share would most likely reach it through a collaboration line rather than product revenue, although the eventual presentation is not disclosed. That route is measurable if disclosed separately with a melanoma bridge; however, folding intismeran into a broader oncology or collaboration total would leave the economic stage unattributable from Moderna's filings alone.

TRACKING STANDARD

Falsifiers and Failure Conditions

Test	Metric and source	Condition	Window	Missing-data behavior
Effect size	Phase 3 RFS and DMFS hazard ratios and absolute rates, ESMO LBA1	Read against the Phase 2b benchmarks	October 24, 2026	If withheld, stage 2 stays not established
Supply at scale	Among patients randomized to the combination: first-dose receipt, completion; design yield	Disclosed and close to Phase 2b performance	October 24 onward	Silence is a disclosure gap and does not count as failure
Regulatory path	Dated FDA or EMA submission or acceptance	Submission disclosed	Through the FY2028 review	Statements of intent do not satisfy it
Commercial supply	Turnaround, success rate, capacity	Disclosed at commercial volume	Through launch	Facility claims do not substitute
Economics	Separately attributable positive profit contribution, basis and costs identified	Across two comparable quarters	Through FY2028	Revenue alone or consolidated trends do not substitute

Scenario interpretation bands, set before the data

Band	RFS hazard ratio (point estimate)	How I will read it
Close to Phase 2b	0.65 or lower	Relative effect in the Phase 2b range despite a broader stage mix
Smaller	Above 0.65 to 0.80	Stage-level absolute benefit becomes the deciding evidence
Modest	Above 0.80	Absolute benefit has to justify treatment burden and cost on its own

These bands are my own reading aids, written down before the data so the interpretation cannot drift. They are not regulatory, statistical or clinical thresholds, and none of them determines label scope, which will depend on absolute benefit by stage, DMFS, safety, data maturity and the regulator's view.

Interpretation rule

A strong Moderna quarter does not confirm intismeran, and a weak one does not contradict it. Every update keeps the clinical layer, the supply layer, the intismeran economic line and Moderna's consolidated results separate. Clinical figures carry their follow-up period, and hazard ratios from different follow-up lengths are compared side by side without being subtracted.

NEXT MEASUREMENT

What the Next Disclosures Have to Show

Occasion	Timing	What gets reopened
ESMO 2026, LBA1 (scheduled 10:30 a.m. EDT per Moderna), and Moderna webcast (1:00 p.m. EDT)	October 24, 2026	Hazard ratios, event rates, follow-up, stage subgroups, safety, dosing completeness
Q3 2026 results and conference call; Form 10-Q	November 6, 2026, call 8:00 a.m. ET; 10-Q date not announced	Program-wide collaboration line; launch-readiness spending
Moderna Analyst Day	November 12, 2026	Launch plan, manufacturing capacity, turnaround and cost
Regulatory submission or acceptance	Not announced	Filing date, review designation, requested indication by stage
Approval decision	Not announced	Label scope and any manufacturing conditions
Potential launch	Company: as early as 2027, if Phase 3 data are positive	Launch readiness against the approval sequence
FY2028 results	Estimated early 2029	Terminal adjudication

Horizon derivation

Occurrence on August 19, 2026 is followed by detailed results on October 24, a filing with no announced date, an undated approval decision, followed by a potential launch Moderna has said could occur as early as 2027, a first full launch quarter, and two comparable commercial quarters. That places the initial outcome grade at the FY2028 annual review, my own adjudication date rather than a company commitment. A slower path is graded at that review and does not extend it.

Known forward confounders

Respiratory-vaccine seasonality, the July 2026 litigation payment, the September 2026 convertible financing, cost-reduction programs, other product launches and any change in how Moderna presents collaboration accounting each need to be separated before a future period is read.

What would change the direction

The reading strengthens if the RFS hazard ratio lands close to the Phase 2b range with consistent benefit in stage IIB and IIC, if dosing completeness is disclosed and high, and if a dated submission follows. It weakens if the hazard ratio lands well above the Phase 2b range with small stage IIB and IIC benefit, if a material share of patients randomized to the combination never received intismeran, or if no positive attributable contribution appears after launch.

Measurement discipline at each reopen

Every update preserves Merck's and Moderna's own metric labels, records whether a manufacturing metric is newly disclosed or still not located, and treats any new indication as corroboration.

Developments after the October 5 evidence date, dated through October 14, 2026

- **October 7, 2026.** Tempus announced an expanded multi-year collaboration with Moderna and Merck, building on work begun last year, to support preparation for potential commercialization: timely collection and transfer of tumor tissue and blood samples, and, subject to regulatory approvals, sequencing services for intismeran design and manufacture. Financial terms were not disclosed. It is operational preparation, although it adds no efficacy, cost, capacity or launch-date evidence [27].
- **October 13, 2026.** Merck confirmed LBA1 in Presidential Symposium I as the first presentation of INTERpath-001 data, without numerical results, and set its own oncology investor event for October 26, 7:30 p.m. CET / 2:30 p.m. ET [28]. Moderna separately announced third-quarter 2026 results and an 8:00 a.m. ET call for Friday, November 6, 2026; it gave no Form 10-Q filing date [29].
- No numerical Phase 3 efficacy, regulatory submission date or approval date was located in the records reviewed through October 14, 2026, and the October 5 baseline readings above are unchanged.

STANDARDS AND DISCLOSURES

How to Read This Thesis

Term	Definition
Recurrence-free survival (RFS)	Time to recurrence, new primary melanoma (in KEYNOTE-942) or death; clocks differ by trial
Distant metastasis-free survival (DMFS)	Time to distant metastasis or death
Hazard ratio	The relative instantaneous event rate between arms; 0.51 means a 49% lower hazard, not 49% fewer patients with an event
Adjuvant	Treatment given after surgery has removed all visible cancer
ASC 808	The accounting standard for collaborations in which partners share risks and rewards
Neoantigen	A protein fragment created by a tumor mutation that the immune system can learn to recognize
Individualized neoantigen therapy	A medicine designed and manufactured for one patient from that patient's tumor sequence
Established	A dated, company-confirmed disclosure verified against a primary source
PD-1 inhibitor	An off-the-shelf antibody, such as KEYTRUDA or Opdivo, that releases a brake on the immune system

Period and basis

Balance-sheet figures are point-in-time, and quarterly and six-month figures are never combined into one ratio.

Non-GAAP and metric boundary

This thesis uses no non-GAAP measures. The program-wide intismeran net collaboration expense is a GAAP figure reported in Moderna's 10-Q notes.

Comparator boundary

KEYTRUDA, the trial's control arm, is the clinical comparator, while Opdivo is a commercial alternative and autogene cevumeran a platform comparator; each is used only for the question its evidence answers, and hazard ratios from different trials are never ranked.

Significance and admissibility boundary

Expected significance, locked on page 12, measures potential materiality if the mechanism converts, while attribution, measurability and disclosure risk, tracked on page 13, decide whether the outcome can be graded.

Research posture

This document tracks a catalyst and a mechanism and is not a recommendation, a rating or a price target. It was prepared independently, without compensation from, or engagement by, Moderna, Merck or any other party named here, and no position is held in any security named in it.

PRIMARY SOURCES

Source Register

#	Document	Use in this thesis
1	Merck and Moderna, joint release on Phase 3 INTERpath-001 topline results, Aug. 19, 2026. news.modernatx.com/merck-and-moderna-announce-phase-3-interpath-001-trial-of-intismeran-p...	Catalyst, interim status, design, dosing, RFS definition, incidence estimate.
2	Khattak A, Carlino MS, Meniawy T, et al., 5-year update of KEYNOTE-942, Journal of Clinical Oncology, 2026. ascopubs.org/doi/10.1200/JCO-26-00835	Descriptive analysis, hazard ratios, safety, design and manufacturing yields.
3	Carlino MS, et al., KEYNOTE-942 5-year update, ASCO 2026 abstract 9500. ascopubs.org/doi/10.1200/JCO.2026.44.16_suppl.9500	Five-year Kaplan–Meier RFS estimates and intervals.
4	Moderna and Merck, five-year KEYNOTE-942 data at ASCO 2026, Jun. 1, 2026. www.merck.com/news/moderna-and-merck-present-5-year-data-for-intismeran-autogene-in-combi...	Follow-up and safety summary.
5	Intismeran Autogene Therapy: An End-to-End Pathway From Tumor Tissue to Individualized Neoantigen Treatment, JCO Oncology Advances, 2026. ascopubs.org/doi/10.1200/OA-25-00206	About six weeks from sample submission to site delivery; one mRNA sequence, up to 34 neoantigens.
6	ClinicalTrials.gov, NCT05933577 (INTERpath-001). clinicaltrials.gov/study/NCT05933577	Phase 3 eligibility and prior-treatment exclusions.
7	Moderna, ESMO 2026 late-breaking data release, Sept. 21, 2026 (via Newswire). www.newswire.com/news/moderna-announces-late-breaking-data-to-be-presented-at-esmo-congre...	Scheduled LBA1 time and investor webcast.
8	Moderna, Inc., Form 10-Q for the quarter ended June 30, 2026, Notes 5, 9 and 12. www.sec.gov/Archives/edgar/data/1682852/000168285226000150/mrna-20260630.htm	Program-wide net collaboration expense; capex cost recovery; cash and investments; operating cash flow, accrued liabilities and settlement allocation.
9	Moderna, Inc., Form 10-Q for the quarter ended March 31, 2026. www.sec.gov/Archives/edgar/data/1682852/000168285226000060/mrna-20260331.htm	Q1 net collaboration expense; development-phase roles.
10	Moderna, Inc., Q2 2026 results, Form 8-K Exhibit 99.1, Jul. 31, 2026. www.sec.gov/Archives/edgar/data/1682852/000168285226000147/exhibit9912026q2pressrelea.htm	Results, July 2026 framework, \$950M July settlement payment, Analyst Day.
11	Moderna, Inc., Form 8-K, 0.00% Convertible Senior Notes due 2032, Sept. 1, 2026. www.sec.gov/Archives/edgar/data/1682852/000119312526378505/d108896d8k.htm	\$3.0B financing, net proceeds and capped calls.
12	Moderna, Inc., Form 8-K, appointment of Chief Operating Officer, Sept. 30, 2026. www.sec.gov/Archives/edgar/data/1682852/000119312526408289/d18337d8k.htm	New COO role; technical operations retirement.
13	Moderna, Inc., 2026 Proxy Statement. www.sec.gov/Archives/edgar/data/1682852/000130817926000081/mrna-courtesy-pdf.pdf	Turnaround improvement above 15% and its clock (p. 55, note 3).
14	Moderna, Inc., Form 10-K for fiscal year 2025. www.sec.gov/Archives/edgar/data/1682852/000168285226000033/mrna-20251231.htm	FY2025 revenue decline and drivers.
15	Moderna, 2025 Shareholder Letter, Form 8-K Exhibit 99.1, Jan. 5, 2026. www.sec.gov/Archives/edgar/data/1682852/000168285226000003/exhibit991-01052026lettert.htm	Marlborough, conditional launch aspiration, oncology strategy.

PRIMARY SOURCES • CONTINUED

Source Register, Comparators, Benchmarks and Dated Developments

#	Document	Use in this thesis
16	Moderna and Merck, Amended and Restated mRNA Cancer Vaccine Collaboration and License Agreement, S-1 Exhibit 10.5, 2018. www.sec.gov/Archives/edgar/data/1682852/000119312518323562/d577473dex105.htm	Merck commercialization and sales booking; Moderna U.S. co-promotion (\$\$1.66, 2.1(f), 8).
17	Bristol Myers Squibb, FDA approval of Opdivo for completely resected stage IIB or IIC melanoma, Oct. 13, 2023. news.bms.com/news/corporate-financial/2023/U.S.-Food-and-Drug-Administration-Approves-Opd...	IIB–IV adjuvant label.
18	Kirkwood J, et al., CheckMate 76K primary results, Nature Medicine, 2023. pmc.ncbi.nlm.nih.gov/articles/PMC10667090	HR 0.42 (0.30–0.59); 12-month RFS 89.0% vs 79.4%; follow-up.
19	U.S. FDA, OPDIVO prescribing information, 2026. www.accessdata.fda.gov/drugsatfda_docs/label/2026/125554s138lbl.pdf	Adjuvant melanoma adult IV dosing.
20	U.S. FDA, KEYTRUDA supplemental approval letter, BLA 125514/S-112, Dec. 3, 2021. www.accessdata.fda.gov/drugsatfda_docs/applletter/2021/125514Orig1s112ltr.pdf	Adjuvant stage IIB or IIC approval and indication.
21	Luke JJ, et al., KEYNOTE-716, The Lancet, 2022;399:1718–1729. doi.org/10.1016/S0140-6736(22)00562-1	Median follow-up 14.4 months at first interim.
22	U.S. FDA, KEYTRUDA prescribing information, June 2025. www.accessdata.fda.gov/drugsatfda_docs/label/2025/125514s180lbl.pdf	Adjuvant melanoma label and adult IV dosing; KEYNOTE-716 first-interim RFS hazard ratio (\$14.1, Table 61).
23	Merck, FDA approval of KEYTRUDA for resected stage IIB or IIC melanoma, Dec. 2021. www.merck.com/news/fda-approves-mercks-keytruda-pembrolizumab-as-adjuvant-treatment-for-a...	Merck-cited recurrence estimates by stage.
24	BioNTech SE, Annual Report on Form 20-F for 2025. www.sec.gov/Archives/edgar/data/1776985/000177698526000017/bntx-20251231.htm	IMCODE001 primary PFS endpoint missed.
25	BioNTech SE, Annual Report on Form 20-F for 2023, filed Mar. 2024. www.sec.gov/Archives/edgar/data/1776985/000177698524000027/bntx-20231231.htm	30–40-day turnaround; historical under-28-day target.
26	BioNTech SE, Form 6-K and Exhibit 99.1, Aug. 28, 2026. www.sec.gov/Archives/edgar/data/1776985/000177698526000061/a991260828_bntxxrcxenxfn.htm	Colorectal Phase 2 termination announcement.
27	Tempus, expanded multi-year collaboration with Moderna and Merck, Oct. 7, 2026. investors.tempus.com/node/10796/pdf	Sample collection and transfer; sequencing subject to approvals; terms undisclosed.
28	Merck, ESMO 2026 preview, Oct. 13, 2026. www.merck.com/news/merck-showcases-first-time-pivotal-phase-3-results-from-oncology-pipel...	LBA1 first presentation; Merck investor event Oct. 26.
29	Moderna, to report third quarter 2026 financial results on Friday, November 6, 2026, Oct. 13, 2026. www.accessnewswire.com/newsroom/en/healthcare-and-pharmaceutical/moderna-to-report-third-...	Q3 results and call date; no 10-Q filing date given.

Source hierarchy and completeness

Filed and contractual facts come from Moderna's SEC filings, clinical facts from the joint releases, JCO publications and the ASCO abstract, and comparator facts from FDA documents, peer-reviewed papers and company records; every link is clickable. Detailed numerical Phase 3 efficacy results, commercial manufacturing cost and launch economics were not located in the records reviewed through October 5, 2026, nor in the dated developments reviewed through October 14, 2026.

DISCLOSURES

Bottom Line and Investment-Risk Disclosure

Bottom line

Merck and Moderna reported on August 19, 2026 that a 1,137-patient Phase 3 trial met its primary and key secondary endpoints at an interim analysis. Positive Phase 3 topline results are public; detailed numerical results are scheduled for October 24.

The supply chain is better measured than it first appears: in Phase 2b, design succeeded for 156 of 185 patients whose tumor tissue was assessed and manufacturing for 104 of 105 successful designs. The open questions are whether that holds at Phase 3 scale, whether regulators approve, and whether Merck's commercialization produces a separately attributable, positive profit contribution to Moderna. Four stars records how much of a \$1.9 billion, shrinking revenue base that could touch. It records nothing about whether it will.

Next measurement

October 24, 2026: detailed INTERpath-001 results scheduled at ESMO 2026 (LBA1, Presidential Symposium, 10:30 a.m. EDT per Moderna) and Moderna's investor webcast at 1:00 p.m. EDT. I will record the results against the benchmarks and interpretation bands the same day and publish a dated tracking note against this baseline.

What would move my reading

Signals that would strengthen it	Signals that would weaken it
Phase 3 hazard ratios close to the Phase 2b range, with consistent stage IIB and IIC benefit	Benefit concentrated in stage III and IV only
High dosing completeness and low design attrition in Phase 3	A material share of patients never receiving their product
A dated submission and a positive attributable contribution after launch	No filing by the FY2028 review, or economics folded into broader totals

Grading and terminal rule

No outcome grade is issued here, and four stars stays locked. The terminal review is the FY2028 cycle and does not move. Non-conversion by then is graded negative, Unmeasurable applies only to a launched product with economics undisclosed by that review, and later tracking does not overwrite the grade.

Record dating

This thesis carries an October 5, 2026 evidence date, with later developments through October 14, 2026 dated separately on page 15, and a twenty-nine-source register. Each reopen listed on page 15 produces a dated tracking note against this baseline, and the October 5 baseline readings are not edited.

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, or an expected-security-return analysis. Investing involves risk, including possible loss of principal. Figures are drawn from the primary sources listed on pages 17 and 18 and are current as of the evidence date printed on page 1. Clinical results from an interim analysis may differ from final results.