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Beyond the Headline

How Serious Is Moderna and Merck's Personalized mRNA "Melanoma Vaccine" Breakthrough?

A critical scientific and clinical appraisal of intismeran autogene plus pembrolizumab after the positive Phase III INTerpath-001 readout

José M. López, BSc, MD, PhD, LLD (C)

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Evidence status. This article incorporates the positive Phase III top-line announcement issued by Moderna and Merck on 19 August 2026. Full numerical INTerpath-001 efficacy and safety data had not yet been presented or peer reviewed at the time of writing.

Abstract

On 19 August 2026, Moderna and Merck announced that the Phase III INTerpath-001 trial of intismeran autogene (formerly mRNA-4157/V940) plus pembrolizumab had met its primary endpoint of recurrence-free survival and a key secondary endpoint of distant metastasis-free survival in patients with completely resected stage IIB-IV cutaneous melanoma. The announcement is clinically consequential: it is the first positive Phase III readout for an individualized neoantigen therapy and for an mRNA-based cancer therapy, and it follows a randomized Phase IIb programme whose benefit has remained evident through five years of follow-up. Yet the public phrase "melanoma vaccine" can obscure as much as it reveals. Intismeran is not a prophylactic vaccine for healthy people, nor has it been shown to cure established metastatic melanoma as a stand-alone therapy. It is an individualized therapeutic immunotherapy manufactured from the mutational profile of a patient's tumour and evaluated, in this pivotal study, as an addition to established PD-1 blockade after complete surgical resection. This article examines the biological rationale, trial architecture, statistical strength, regulatory relevance, manufacturing implications and major unresolved questions. The current evidence justifies taking the Moderna-Merck programme very seriously. It does not yet justify claims that an mRNA vaccine has "cured melanoma." The more defensible conclusion is also the more important one: individualized, computationally selected neoantigens delivered through mRNA have now crossed the threshold from plausible precision-immunology concept to positive Phase III oncology strategy.

Keywords: *melanoma; intismeran autogene; mRNA-4157; V940; individualized neoantigen therapy; pembrolizumab; cancer vaccine; immunotherapy; precision oncology; INTerpath-001*

KEY POINTS

- The Phase III result is genuinely important: INTerpath-001 is a large, randomized, double-blind, active-comparator trial, not an uncontrolled proof-of-concept study.
- The term "vaccine" is scientifically valid only if understood as a therapeutic, individualized cancer vaccine; the intervention does not prevent melanoma in healthy people.
- The Phase III press release confirms that RFS and DMFS endpoints were met, but the hazard ratios, absolute benefits, subgroup data and mature overall-survival results remain undisclosed.
- If the detailed dataset confirms a substantial absolute benefit with acceptable toxicity, the result may mark a transition from precision drug selection toward patient-specific drug creation.

1. Why this announcement deserves attention-and restraint

Cancer-vaccine headlines have appeared for decades, often at stages of development where enthusiasm was driven more by biological possibility than by definitive clinical evidence. The Moderna-Merck announcement is different. On 19 August 2026, the companies reported that a prespecified interim analysis of INTerpath-001 had met both its primary endpoint of recurrence-free survival (RFS) and a key secondary endpoint of distant metastasis-free survival (DMFS). The study enrolled 1,137 patients with completely resected stage IIB, IIC, III or IV cutaneous melanoma and compared intismeran plus pembrolizumab with pembrolizumab plus placebo in a randomized, double-blind, active-comparator design (Moderna & Merck, 2026).

That is the evidentiary context in which the word breakthrough should be judged. This is no longer a mouse experiment, a first-in-human immunogenicity study or a small uncontrolled series. It is a positive pivotal trial against an established immunotherapy. At the same time, the detailed Phase III dataset has not yet been disclosed. The sponsors have not publicly reported the RFS or DMFS hazard ratios, absolute event rates, confidence intervals, landmark survival estimates, stage-specific effects, complete adverse-event profile or mature overall-survival analysis. The correct response is therefore neither dismissal nor celebration without qualification. It is disciplined attention.

> *A positive Phase III trial is a major evidentiary event. A positive Phase III press release is not yet the same thing as a fully assessable Phase III dataset.*

2. Is it really a "vaccine"? Yes-but not in the ordinary preventive sense

The terminology is one of the main sources of public confusion. A vaccine need not be prophylactic. The National Cancer Institute classifies cancer treatment vaccines as immunotherapies intended to help the immune system recognize and destroy malignant cells in people who already have cancer (National Cancer Institute, n.d.). Under that definition, describing intismeran as a therapeutic cancer vaccine is scientifically legitimate.

What would be misleading is to allow the familiar infectious-disease meaning of the word to migrate into this context. Intismeran is not being administered to healthy populations to prevent melanoma from arising. The patients in INTerpath-001 had already developed melanoma and had undergone complete surgical resection. The therapeutic goal is adjuvant: to reduce the probability that microscopic residual disease will later produce local, regional or distant recurrence.

The distinction becomes even more important when media language moves from "vaccine" to "melanoma vaccine that prevents cancer" or "vaccine that cures melanoma." Neither statement accurately describes the present evidence. The trial asks whether adding an individualized neoantigen therapy to pembrolizumab after

surgery improves outcomes compared with pembrolizumab alone. It does not establish population-level prevention, nor does it establish that intismeran alone eradicates established metastatic disease.

3. What Intismeran autogene actually does

Intismeran autogene, previously designated mRNA-4157 or V940, is an individualized mRNA-based neoantigen therapy. A tumour sample and normal comparator material are used to identify somatic mutations that are specific to an individual patient's cancer. Computational methods then prioritize candidate neoantigens—mutated peptides predicted to be processed, presented by the patient's HLA molecules and capable of eliciting therapeutically useful T-cell responses. A patient-specific synthetic mRNA product is manufactured to encode up to 34 selected neoantigens (Khattak et al., 2026; Moderna & Merck, 2026).

After intramuscular administration, the encoded sequences are translated and enter normal antigen-processing and presentation pathways. The intended consequence is not a nonspecific stimulation of immunity but a repertoire of T cells directed against molecular features that distinguish the patient's tumour from normal tissue. This is a biologically elegant target-selection strategy because true mutation-derived neoantigens are tumour-specific and should, in principle, carry a lower risk of central immune tolerance than shared self-antigens.

Pembrolizumab contributes a complementary mechanism. By blocking PD-1 signalling, it reduces an inhibitory pathway that can restrain antitumour T-cell function. The therapeutic logic is therefore combinatorial: the individualized mRNA product seeks to broaden or create tumour-specific immune recognition, while checkpoint blockade seeks to preserve the activity of those lymphocytes in the face of inhibitory signalling. Mechanistic analyses now provide direct support for that model. Five-year translational work from KEYNOTE-942 demonstrated increased T-cell receptor clonality and novel clonotype expansion, while separate 2026 analyses showed durable, polyclonal neoantigen-specific T-cell responses directed against vaccine-encoded targets (Khattak et al., 2026; Sullivan et al., 2026).

4. Why melanoma was a rational disease in which to test the concept

Melanoma is unusually well suited to the first rigorous tests of individualized neoantigen vaccination. Cutaneous melanoma frequently carries a high burden of ultraviolet-associated somatic mutations, thereby increasing the potential universe of tumour-specific neoantigens. It is also one of the malignancies in which immune checkpoint blockade has already demonstrated that endogenous antitumour immunity can be clinically powerful when inhibitory pathways are removed.

This matters when interpreting the broader significance of the result. A successful Phase III trial in melanoma validates an important therapeutic principle, but it does not automatically validate the same magnitude of benefit in every solid tumour. Cancers differ in mutational burden, antigen-presentation competence, immune-cell infiltration, stromal architecture, clonal heterogeneity and the degree of immunosuppression within their microenvironment. Melanoma is a particularly favourable proving ground. The real test of platform generalizability will come from other tumour types.

The scientific roots of the approach also predate the current Moderna-Merck programme. In 2017, independent early studies demonstrated that personal neoantigen vaccination—using peptide or RNA approaches—could generate broad patient-specific T-cell responses in melanoma (Ott et al., 2017; Sahin et al., 2017). Those studies established feasibility and immunogenicity. The significance of INTerpath-001 is that the field has now moved from first-in-human biological proof to a positive randomized Phase III strategy.

5. The Phase IIb evidence: why it was promising, but not sufficient on its own

The pivotal Phase III programme was built on KEYNOTE-942, a randomized, open-label Phase IIb trial involving 157 patients with completely resected high-risk stage IIIB-IV cutaneous melanoma. Patients were allocated 2:1 to receive intismeran plus pembrolizumab or pembrolizumab alone (Weber et al., 2024). At the primary analysis, recurrence or death had occurred in 22.4% of the combination group and 40.0% of the pembrolizumab-alone group. The estimated 18-month RFS rates were 78.6% and 62.2%, respectively.

The hazard ratio for recurrence or death was 0.561 (95% CI, 0.309-1.017). DMFS produced a stronger signal, with a hazard ratio of 0.347 (95% CI, 0.145-0.828) (Weber et al., 2024). These are clinically interesting effects. But the RFS result also illustrates why statistical literacy matters. The two-sided P value was approximately .053 and the 95% confidence interval marginally crossed 1.0. The study met its prespecified statistical framework, but the result was not the kind of large, conventional confirmatory dataset from which a new standard of care should be declared without replication.

There were additional limitations. The control arm contained only 50 patients, and the study was open label. None of this rendered KEYNOTE-942 uninformative. It simply placed the trial in the category it belonged in: a strong randomized Phase II signal that required a larger, blinded Phase III confirmation. INTerpath-001 was therefore not a ceremonial exercise. It addressed precisely the residual uncertainty that remained after KEYNOTE-942.

6. Five-year follow-up materially strengthened the case

By June 2026, the maturation of KEYNOTE-942 had become one of the most persuasive elements of the development story. At a median planned follow-up of 60.3 months, the RFS hazard ratio remained 0.510 (95% CI, 0.294-0.887) and the DMFS hazard ratio was 0.411 (95% CI, 0.200-0.843). The exploratory overall-survival analysis favoured the combination numerically, with HR 0.471, but its confidence interval was wide (95% CI, 0.165-1.345), reflecting the small number of deaths and preventing a definitive survival claim (Khattak et al., 2026).

Durability matters in adjuvant immunotherapy. A transient early separation of recurrence curves can be clinically interesting yet ultimately disappointing if the benefit erodes with time. The five-year data did not show that pattern. Instead, the clinical signal remained evident long after treatment had ended. That persistence substantially increased the prior probability that a larger confirmatory trial would reproduce a real biological effect.

Table 1. Evolution of the evidence before and after the Phase III announcement

Evidence layer	Study / source	Main finding	Interpretive weight
Biological feasibility	Ott et al.; Sahin et al. (2017)	Personalized neoantigen vaccination can induce patient-specific T-cell responses in melanoma.	Strong proof of concept; not efficacy confirmation.
Randomized Phase IIb	KEYNOTE-942 (2024)	RFS HR 0.561; DMFS HR 0.347 versus pembrolizumab alone.	Compelling signal, but small and open label.
Long-term durability	KEYNOTE-942 5-year update (2026)	RFS HR 0.510; DMFS HR 0.411; OS trend not conclusive.	Strengthens biological and clinical credibility.
Confirmatory Phase III	INTerpath-001 top-line (19 Aug 2026)	Primary RFS and key DMFS endpoints met at prespecified interim analysis.	Pivotal positive result; detailed magnitude still unavailable.

7. INTerpath-001 changes the evidentiary level

INTerpath-001 is the trial that changes the status of the programme. ClinicalTrials.gov describes it as a Phase III, randomized, double-blind, placebo- and active-comparator-controlled study of adjuvant intismeran plus pembrolizumab versus placebo plus pembrolizumab in high-risk resected melanoma (ClinicalTrials.gov, 2025). The sponsor's 19 August 2026 announcement states that the final enrolled population reached 1,137 patients, randomized 2:1 after complete surgical resection (Moderna & Merck, 2026).

The primary endpoint is RFS. Key secondary endpoints include DMFS, overall survival, safety, tolerability and quality of life. Crucially, pembrolizumab is not a weak comparator. It is an established adjuvant treatment in resected melanoma, supported by Phase III evidence including KEYNOTE-716 in stage IIB/IIC disease (Luke et al., 2024). This raises the clinical bar: the relevant question is not whether intismeran is better than no adjuvant therapy, but whether it adds benefit beyond active PD-1 blockade.

According to the top-line release, the prespecified interim analysis demonstrated statistically significant and clinically meaningful improvements in both RFS and DMFS, with no new safety signals reported. The study will continue to evaluate other key secondary endpoints, including overall survival (Moderna & Merck, 2026). If the complete analysis is consistent with the headline, this is exactly the kind of confirmatory evidence that the field needed.

8. What the Phase III announcement proves-and what it does not yet allow us to quantify

There is a temptation, after a positive Phase III announcement, to treat the remaining numerical details as secondary. In oncology they are not. A therapy can meet a statistical endpoint and still offer a modest absolute clinical gain; conversely, an apparently similar hazard ratio can be highly consequential in a population with substantial baseline risk. The magnitude of benefit determines whether a result is merely positive or genuinely practice changing.

As of 20 August 2026, Moderna and Merck have not publicly reported the Phase III hazard ratios for RFS or DMFS, the corresponding confidence intervals, numbers of events, landmark survival estimates, absolute risk reductions or number needed to treat. Nor do we yet have detailed efficacy according to stage, BRAF status, PD-L1 expression, tumour mutational burden, circulating tumour DNA or other potential biomarkers. The companies have said that the data will be presented at an international medical meeting and shared with regulators (Moderna & Merck, 2026).

This distinction should shape responsible scientific communication. We can say that INTerpath-001 is a positive Phase III trial because the prespecified endpoints were reported as met. We cannot yet independently judge the exact magnitude, consistency or clinical efficiency of that benefit. The phrase "clinically meaningful" currently comes from the sponsors; it will become independently assessable only when the numerical dataset is available.

9. Relative risk, absolute benefit and the danger of headline mathematics

Cancer-treatment communication often compresses hazard ratios into phrases such as "reduces recurrence by 50%." Such shorthand can be useful, but it is easily misread as meaning that half of patients are cured or that recurrence is prevented in one of every two treated patients. A hazard ratio is a relative time-to-event measure. It does not directly equal an absolute risk reduction, and it is not a cure fraction.

This is especially relevant in INTerpath-001 because the trial spans stage IIB through completely resected stage IV melanoma. Baseline recurrence risks differ substantially across this spectrum. The same relative

hazard reduction can therefore translate into very different absolute gains. For clinicians, patients and payers, the forthcoming stage-specific absolute event rates may be at least as important as the headline hazard ratio.

10. Overall survival remains the hardest unanswered clinical question

RFS is a clinically meaningful and accepted endpoint in adjuvant melanoma, and DMFS has particular importance because distant relapse often represents the transition to life-threatening systemic disease. Nevertheless, overall survival remains the most definitive outcome. INTerpath-001 is continuing in order to assess it, which means that an OS benefit has not yet been established (Moderna & Merck, 2026).

The five-year KEYNOTE-942 analysis offers an encouraging direction of travel, but not proof. Its OS hazard ratio of 0.471 was accompanied by a wide 95% confidence interval from 0.165 to 1.345 (Khattak et al., 2026). That interval comfortably includes no survival advantage. Statements that the new regimen has already been proven to “save lives” or extend overall survival would therefore run ahead of the evidence. Such an effect is plausible; it is not yet demonstrated.

11. Safety and the special ethics of adjuvant therapy

The risk-benefit calculation after complete tumour resection is different from that in uncontrolled metastatic disease. Patients may have no radiographically detectable cancer and some would never recur even without additional therapy. Adjuvant treatment therefore exposes an entire risk population to toxicity in order to prevent future events in a subset. The greater the baseline cure rate, the more carefully incremental toxicity and absolute benefit must be weighed.

In the earlier KEYNOTE-942 programme, treatment-related grade 3 or higher adverse events at approximately three years were reported in 25% of patients receiving the combination and 20% receiving pembrolizumab alone. Common events attributed to the mRNA product included fatigue, injection-site pain and chills (Moderna & Merck, 2023c). The five-year analysis continued to describe the safety profile as manageable without new safety signals (Khattak et al., 2026). The Phase III top-line release likewise reports no new safety signals, but complete event tables, discontinuation rates and immune-mediated toxicity data remain necessary before the benefit-risk balance can be judged in individual stage groups.

This is also why the combination should not be discussed as if the mRNA component exists in isolation. INTerpath-001 tests intismeran plus pembrolizumab. Pembrolizumab can itself cause serious, occasionally life-threatening immune-mediated toxicities. The clinical proposition is therefore the incremental benefit and incremental burden of the combination over PD-1 blockade alone.

12. Regulatory significance: encouraging, not equivalent to approval

The programme has already received unusually strong regulatory attention. The US Food and Drug Administration granted Breakthrough Therapy Designation to mRNA-4157/V940 plus pembrolizumab in February 2023, and the European Medicines Agency subsequently granted access to the PRIME scheme (Moderna & Merck, 2023a, 2023b). These designations matter because they facilitate interaction with regulators and are reserved for programmes showing sufficient early promise in serious disease.

They should not be misrepresented as prior endorsements of efficacy. The FDA itself states that Breakthrough Therapy Designation is intended to expedite development and review when preliminary clinical evidence suggests a substantial improvement over available therapy on a clinically significant endpoint (U.S. Food and Drug Administration, n.d.). It is not marketing authorization. As of this article’s evidence cut-off, intismeran remains investigational; Moderna and Merck have said that they intend to discuss filing submissions with regulators following the Phase III result (Moderna & Merck, 2026).

13. The manufacturing model may be as disruptive as the biology

The pharmaceutical challenge is easy to underestimate because the injection itself looks familiar. Intismeran is not manufactured as millions of identical doses from a single fixed sequence. Each patient requires a tumour sample, genomic and transcriptomic analysis, mutation calling, computational neoantigen ranking, selection of a patient-specific set of targets, synthesis of the individualized mRNA construct, formulation, quality control, release and delivery back to the treating centre.

This creates something close to an N-of-1 manufacturing paradigm inside industrial GMP. Conventional drug development seeks reproducibility by producing the same medicinal product for every eligible patient. Individualized neoantigen therapy seeks reproducibility of a process whose output is deliberately different for every patient. The regulatory object therefore becomes partly the product and partly the validated platform that repeatedly creates unique products.

If the clinical benefit is substantial, this will create demanding questions for health systems: acceptable turnaround time, sequencing and bioinformatics infrastructure, tumour-sample adequacy, manufacturing failure rates, chain of identity, batch release, cross-border logistics, cost, reimbursement and equity of access. A therapy can be scientifically transformative yet operationally constrained if individualized production cannot be scaled with sufficient speed and reliability.

14. The quiet centrality of computation-and why this is more than an mRNA story

mRNA is the visible technological brand, but the deeper platform is a genomics-to-algorithm-to-manufacturing pipeline. Neoantigen selection is an inference problem. Not every nonsynonymous mutation produces a stable peptide; not every peptide is processed; not every processed peptide binds the patient's HLA molecules; not every HLA-bound peptide is displayed in sufficient quantity; and not every displayed neoantigen generates a therapeutically useful T-cell response. The quality of target selection therefore depends on computational biology as much as on synthetic RNA chemistry.

For that reason, a successful Phase III programme would validate more than a delivery vehicle. It would validate the proposition that individualized tumour sequencing, algorithmic antigen prioritization and rapid manufacturing can be integrated reliably enough to generate a reproducible clinical benefit. In a broader history of precision oncology, this represents a subtle but important shift. Traditional precision medicine often asks which existing drug best matches a patient's tumour. Individualized neoantigen therapy asks whether the medicinal product itself can be created around the patient's tumour.

> *The conceptual transition is from precision drug selection to precision drug creation.*

15. Does this validate mRNA cancer therapy in general? Only in a qualified sense

It is reasonable to describe INTerpath-001 as the first positive Phase III validation of an mRNA-based cancer therapy, as Moderna and Merck do. It would be less accurate to conclude that "mRNA works against cancer" in a generic sense. mRNA is an information-delivery modality, not an efficacy guarantee. The encoded biological instruction, disease context, target selection, formulation, dose, immune environment and combination partner determine the therapeutic result.

The defensible inference is narrower and more powerful: a patient-specific mRNA construct encoding computationally selected tumour neoantigens, administered in the adjuvant setting and combined with PD-1 blockade, can apparently improve clinically relevant outcomes in resected high-risk cutaneous melanoma.

Whether the same platform can deliver comparable value in tumours with lower mutational burden or more immunosuppressive microenvironments remains an empirical question.

16. Is the word “breakthrough” justified?

Biomedical journalism routinely labels early findings as breakthroughs, which has diluted the term. Here, however, there is a defensible case for using it carefully. The evidence now consists of biologically coherent mechanism, randomized Phase II efficacy, durable five-year follow-up, mechanistic T-cell data and a positive, large, blinded Phase III trial against active standard therapy. That is qualitatively different from a preclinical or early-phase announcement.

The correct formulation is therefore not “a vaccine has cured melanoma.” It is that personalized mRNA neoantigen therapy has achieved a landmark Phase III validation in the adjuvant treatment of resected high-risk melanoma. Whether that result is large enough to change practice broadly will depend on the numerical dataset. Whether it is historically transformative will depend on generalization across tumour types and on the feasibility of delivering individualized products at health-system scale.

Table 2. Claims that are justified today—and claims that are not

Supported by the current evidence	Not established by the current evidence
INTerpath-001 is a positive Phase III adjuvant melanoma trial.	That the regimen prevents melanoma from developing in healthy people.
Adding intismeran to pembrolizumab improved RFS and DMFS at a prespecified interim analysis.	That intismeran alone produces the Phase III benefit.
Intismeran is legitimately described as an individualized therapeutic cancer vaccine / neoantigen therapy.	That established metastatic melanoma is cured by the vaccine.
The approach has a coherent mechanism and demonstrated neoantigen-specific T-cell activity.	That overall survival is already improved.
Five-year Phase IIb data show durable RFS and DMFS benefit.	That the same efficacy will occur across other cancer types.

17. What the full Phase III presentation must answer

The forthcoming scientific presentation should be judged less by the adjectives used to describe the trial than by a relatively short set of quantitative questions. The RFS and DMFS hazard ratios and confidence intervals will establish effect size and precision. Absolute recurrence rates and landmark survival estimates will determine clinical magnitude. Stage-specific results will show whether the benefit is consistent from stage IIB through resected stage IV disease. Detailed toxicity and treatment-discontinuation data will define the incremental burden of adding the individualized therapy.

Other questions are more technological than statistical but no less important: what proportion of enrolled patients successfully received a manufactured individualized product; how long production took; how often tumour material was inadequate; whether delays affected treatment initiation; and whether specific molecular or immunological biomarkers identify groups with larger or smaller benefit. Quality-of-life data and eventually health-economic analyses will matter greatly in a therapy that combines checkpoint inhibition with bespoke manufacturing.

And finally there is overall survival. RFS and DMFS can support regulatory and clinical decisions, but mature OS will determine whether prevention of recurrence translates into a demonstrable extension of life in an era where patients who relapse may receive multiple effective salvage treatments.

18. Conclusion

The Moderna-Merck announcement should be taken seriously—very seriously. It is supported by a coherent biological mechanism, randomized Phase II evidence, durable five-year follow-up, direct mechanistic evidence of neoantigen-specific T-cell responses and now a positive, large, double-blind Phase III trial. That combination distinguishes INTerpath-001 from the long history of "cancer vaccine" headlines built on preliminary evidence.

Scientific seriousness, however, requires resisting exaggeration in both directions. Dismissing the result because the word vaccine sounds promotional would be intellectually careless. Declaring melanoma cured by an mRNA vaccine would be equally careless. The evidence supports a more precise conclusion: intismeran autogene appears to represent the first successful Phase III validation of a patient-specific mRNA neoantigen strategy capable of adding clinically relevant antitumour activity to established PD-1 immunotherapy after complete resection of high-risk cutaneous melanoma.

The magnitude of that benefit, its absolute value across disease stages, its impact on overall survival, its full safety profile and the practicality of individualized manufacturing remain to be established from the complete dataset and subsequent regulatory review. Those are not minor caveats; they are the questions that determine how a positive trial becomes a treatment standard.

If the full INTerpath-001 results show a substantial absolute reduction in recurrence and distant metastasis with acceptable toxicity—and if comparable principles subsequently reproduce in biologically distinct cancers—the historical importance of this programme will extend well beyond melanoma. The deeper achievement would be the demonstration that an individual tumour can be sequenced, computationally interpreted and converted into a bespoke medicinal product quickly and reliably enough to change clinical outcomes. That would represent not simply another successful immunotherapy, but a new industrial architecture for precision oncology.

Author note and evidence boundary

This is an independent critical appraisal of publicly available scientific, regulatory and corporate information. It is not a clinical-practice guideline and does not replace individual medical decision-making. The evidence cut-off is 20 August 2026. At that date, the detailed numerical results of the Phase III INTerpath-001 interim analysis had been announced but had not yet been presented in full at a scientific meeting or published in a peer-reviewed manuscript. Conclusions concerning exact effect size, subgroup consistency, detailed safety and overall survival should be updated when the full dataset becomes available.

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