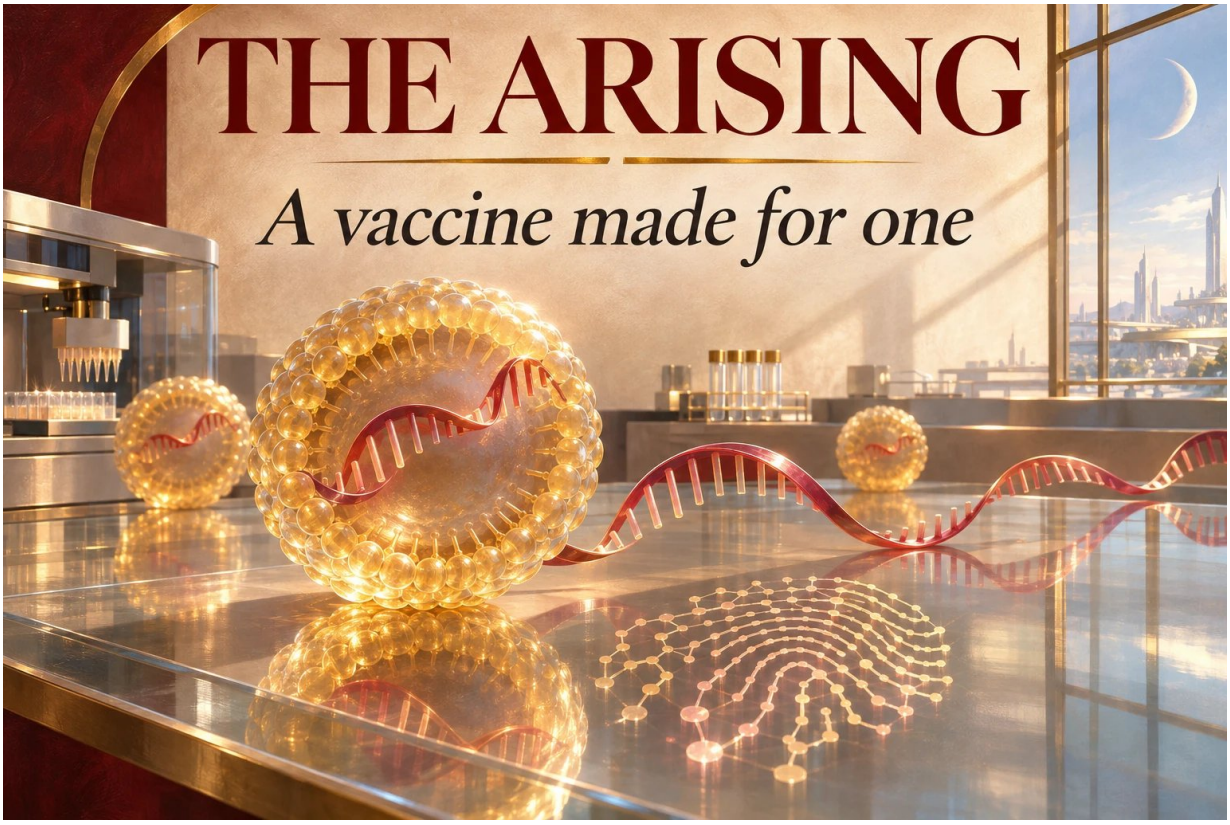
THE ARISING

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A vaccine made for one



A vaccine designed from one person’s tumor has helped more patients with high-risk melanoma remain alive without their cancer returning. It is a striking step toward a different kind of medicine: use the cancer’s own identifying features to teach the immune system what to find.

The moment after successful cancer surgery contains two truths. The visible tumor is gone. The future is still uncertain. Treatment given afterward aims to deal with cells that may remain, before they grow into another tumor. That interval is where Moderna and Merck are putting personalized mRNA medicine to work.

And it is where the human stakes become clear. A recurrence-free year can hold work, travel, a child’s graduation, an ordinary dinner that does not revolve around the next treatment. The laboratory’s achievement matters because of the life it might leave room for.

A vaccine made for one

Moderna's treatment is called intismeran autogene, previously known as V940 or mRNA-4157. Its starting material is information: the genetic differences between a patient's tumor and healthy tissue.

Some tumor mutations produce distinctive protein fragments called neoantigens. Researchers compare tumor and normal samples, then use computational methods to select up to 34 targets that the immune system may recognize. The resulting mRNA carries instructions for making those targets. Tiny fatty particles deliver the message; the goal is to build a population of T cells that recognizes the cancer.

Pembrolizumab, also called Keytruda, supplies the other half of the strategy. It blocks an inhibitory signal that can restrain T cells. One treatment teaches recognition; the other helps release an immune brake. Moderna describes the process in its account of how the individualized therapy works.

This is vaccination used as cancer treatment after diagnosis. Its targets come from the tumor the person has already developed.

The result that moves the field forward

In INTerpath-001, a randomized, blinded phase 3 trial sponsored by Merck and Moderna, 1,137 people with completely removed stage IIB–IV melanoma received pembrolizumab plus either the personalized vaccine or placebo. At two years, an estimated **82.2% were alive without recurrence in the vaccine group, compared with 70.0% in the comparison group**.

That is an absolute difference of about 12 percentage points. Across follow-up, the hazard of recurrence or death was 42% lower with the combination. The results reported for the October ESMO meeting also favored the combination for distant spread or death. Longer follow-up is tracking overall survival, and the vaccine remains investigational.

Treatment has a cost in symptoms and time. Fever, injection-site pain and fatigue were common; the investigators' research summary reports treatment discontinuation because of adverse events in 17% with the combination and 9% with the comparison treatment. Those burdens belong alongside the gain in recurrence-free time.

The central advance is substantial: a medicine whose sequence changes from patient to patient has produced a favorable result in a large randomized cancer trial. That makes personalization a practical therapeutic approach to develop, with a measurable clinical outcome to build on.

What Moderna is testing now

The next question is how far that approach can travel. Moderna and Merck are testing it in several settings, each with its own biology and clinical aim:

- **Lung cancer:** phase 3 studies cover treatment after surgery, after preoperative treatment leaves residual cancer, and high-risk stage I disease. A separate phase 2 study in metastatic squamous lung cancer combines the vaccine with pembrolizumab and chemotherapy.
- **Kidney and bladder cancer:** trials are evaluating treatment after surgery for renal cell carcinoma and muscle-invasive bladder cancer. Another phase 2 trial combines it with BCG in non-muscle-invasive bladder cancer.
- **Melanoma that has spread:** a phase 2 trial asks whether the vaccine can add to pembrolizumab in metastatic disease.

These trials are testing whether the melanoma result can be extended to other situations. They are not additional successful results already in hand.

Moderna is also exploring a different mRNA cancer strategy. In the phase 1/2 Mobilize trial, mRNA-4359 is being studied alone and with pembrolizumab in selected advanced solid tumors. It aims to direct immunity against targets on cancer cells and certain immune cells, rather than making a unique vaccine from each patient's tumor.

That is the state of the science in useful terms: personalized mRNA has a positive phase 3 melanoma result; several cancer applications are in active testing; other mRNA designs are pursuing different ways to enlist the immune system. A single platform is opening several distinct clinical questions.

The life in the days

A recurrence-free year can make room for work, family, travel and the freedom to make plans. The purpose of better cancer treatment is more life outside treatment.

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