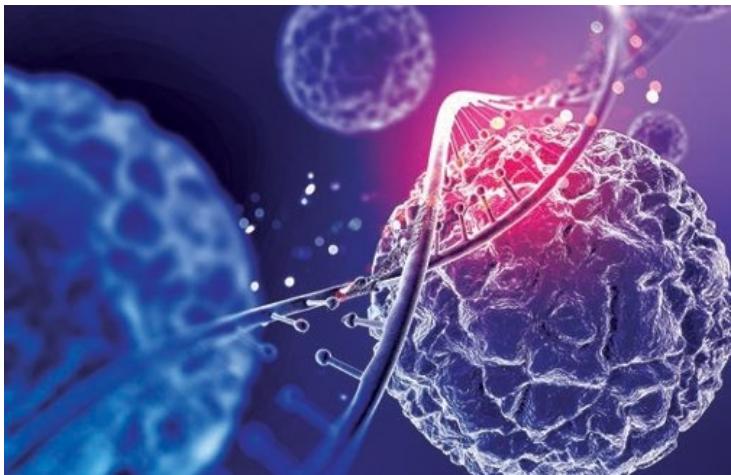


mRNA's Cancer Breakthrough

October 1, 2026 | Analysis | By Ayesha Siddiqui

mRNA vaccines came into the spotlight during COVID-19. Now, the technology is making headlines again in cancer treatment. For the first time, a personalised mRNA cancer vaccine has shown positive Phase 3 results in melanoma, reducing the risk of recurrence when used with Keytruda. The result marks an important milestone for mRNA-based cancer therapy and personalised medicine. Could mRNA become the next major platform in cancer treatment, and what could this mean for the future of personalised cancer care? Let's explore.



The success of mRNA vaccines during the COVID-19 pandemic transformed the technology from a promising scientific approach into a proven therapeutic platform. That experience has now accelerated interest in using mRNA beyond infectious diseases, with cancer emerging as one of its most closely watched applications.

A 2026 analysis published in *Human Vaccines & Immunotherapeutics* identified a total of 244 vaccine and therapeutic candidates: 123 targeting 23 communicable diseases and 121 targeting 69 non-communicable diseases, including 102 cancer-focused candidates. Of these, 227 candidates (93 per cent) were in early clinical development, while 12 were in late-stage development. A total of 85 developers, comprising 50 companies and 35 institutes and hospitals, are engaged in this space.

One landmark development in this field came when Merck and Moderna announced positive Phase 3 results from the INTerpath-001 trial of intismeran autogene (V940/mRNA-4157) in combination with Keytruda in patients with completely resected stage IIB-IV melanoma. The trial met its primary endpoint of recurrence-free survival and its key secondary endpoint of distant metastasis-free survival. It was the first positive Phase 3 readout for an individualised neoantigen therapy and an mRNA-based cancer therapy.

The result is important for the field, as several personalised cancer vaccine programmes have faced setbacks in clinical trials. Just a few days later, BioNTech and Genentech ended a Phase 2 trial of their personalised mRNA vaccine, autogene cevumeran (BNT122), in colorectal cancer.

"I think the Merck/Moderna results are highly significant as they are the first successful Phase 3 readouts for a combination therapy involving an individualised cancer vaccine. Excitingly, this opens the door for a similar combination to be administered

in other solid cancer types. I also hope that with the ease and speed of manufacturing mRNA, this approach may be more broadly applicable than other cancer vaccine modalities, such as peptides or cell therapy. Although even with this, the likely cost for individual patients or governments to pay for these treatments will be high. I'm still curious to see the data from these Phase 3 readouts once they are released, to see the numbers and determine just how much of an improvement the vaccine adds compared with immunotherapy alone. I am also curious to see how long regulatory agencies such as the FDA will take to allow Moderna to bring this to market, and what it will cost patients," said **Professor Archa Fox, The University of Western Australia's School of Human Sciences, Director of the Australian Centre for RNA Therapeutics in Cancer and Director of the RNA Innovation Foundry.**

She added, "Another interesting aspect of this trial and approach is that the vaccine is administered intramuscularly, just like a typical vaccine. This route of administration is much more patient-friendly than the hours-long intravenous infusion required for chemotherapy. However, in this case, intravenous administration was still needed for the immunotherapy. Will we ever see a monotherapy mRNA cancer vaccine? That would be a big win for patients and the field."

While the result is an important win, it does not by itself usher in an era of personalised cancer treatment. Scaling personalised vaccines will require manufacturing to keep pace. Provenge, an autologous cellular immunotherapy for prostate cancer, offers a cautionary example. Approved by the FDA in 2010, its complex manufacturing process and high costs contributed to commercial struggles. Dendreon could not overcome the high manufacturing costs, which some reports initially estimated at close to 77 per cent of Provenge's selling price. The treatment launched at \$93,000, and Dendreon filed for bankruptcy in 2014.

"Personalised cancer vaccines demand a very different manufacturing model from conventional medicines. Rather than making one large batch for many patients, manufacturers need to produce individual treatments at scale, each with the same standards for quality and reliability. So, simply adding more capacity to our existing systems is not enough. We need processes designed for patient-specific production, with speed and cost considered from the outset so they don't become barriers to access," said **Christine Wolosin, Chief Commercial Officer, 4basebio**, which is enabling next-generation cell and gene therapies and vaccines through its technologies and solutions.

"For me, the long-term significance of these results is the prospect of personalised cancer vaccines becoming a more established part of care. Getting there will take continued clinical progress and investment in manufacturing that makes these treatments practical to produce and deliver, because a treatment can only change cancer care when the patients who need it can receive it," said Christine.

Which other drugs are in the pipeline?

Several other candidates are also in development. BioNTech's BNT113 is in Phase 2 for HPV16-positive head and neck cancer, while BNT116 is in Phase 1 for non-small cell lung cancer. Moderna and Merck's mRNA-5671/V941 is in Phase 1 development for KRAS-mutated non-small cell lung, colorectal and pancreatic cancers.

In APAC, China is rapidly building a home-grown mRNA cancer vaccine pipeline, with several companies, including Jiangsu Hengrui Pharmaceuticals, Everest Medicines, Akeso, Abogen, CSPC and Neocura, advancing candidates into clinical development. However, most remain at an early stage of development.

Everest Medicines' EVM16 is a personalised neoantigen mRNA vaccine delivered in a lipid nanoparticle and is being evaluated in an investigator-initiated Phase 1 study with tislelizumab. Everest is now moving EVM16 into a Phase 1b study. Its other candidate, EVM14, an off-the-shelf tumour-associated antigen mRNA vaccine, has also entered a global Phase 1/2a trial in combination with pembrolizumab following IND clearances in the US and China.

Abogen's ABO2102 is another off-the-shelf approach, encoding five common KRAS mutations in a single LNP-mRNA construct. The candidate received FDA IND clearance in 2025 and entered a Phase 1 study in China.

Ruihongdi Pharmaceutical, a subsidiary of or partner of Hengrui Pharma, is developing RGL-270, a personalised neoantigen mRNA vaccine, and RGL-232, an off-the-shelf vaccine targeting four KRAS mutations. Both are in Phase 1 development.

The pipeline also includes CSPC Pharmaceutical Group's SYS6026, an off-the-shelf LNP-mRNA vaccine targeting HPV16/18 E6/E7, which has entered Phase 2 development for high-grade cervical lesions.

Akeso's AK154 entered Phase 1 development in resected pancreatic cancer in 2025. Together, these programmes show that China's mRNA oncology efforts span personalised neoantigen vaccines, off-the-shelf tumour-antigen vaccines and mutation-specific approaches, although most remain in early clinical development.

With these developments, mRNA is emerging as an important platform for cancer vaccines. The growing pipeline, advances in personalised approaches and encouraging clinical results are pushing the technology beyond COVID-19 and towards a new chapter in cancer treatment.

Ayesha Siddiqui