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Analysis of today
Assessment of tomorrow

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Biotechnology at a turning point: a drug that changes the course of carcinoma

Biotechnology, the branch of science that uses living organisms and biological processes to develop new products and technologies, is making rapid progress and revolutionising healthcare.

In oncology in particular, immunotherapy and genetic approaches are becoming key in the fight against cancer, including locally advanced head and neck squamous cell carcinoma (HNSCC), which has a high recurrence and mortality rate.

Recent developments, in particular the results of Merck's KEYNOTE-689 clinical trial published on 2 March 2025, indicate significant progress.

When the first cross-sectional data from the KEYNOTE-689 trial was presented at the 2025 American Association for Cancer Research (AACR) annual meeting in Chicago, the results marked a significant moment for modern oncology.

The study indicated that the administration of pembrolizumab—a drug that "awakens" the immune system to attack tumour cells—in the period immediately before and after surgery can significantly extend the time during which patients do not experience a recurrence of the disease or death.

An encouraging study

The study included 714 patients with operable stage III or IVA cancers. Half received pembrolizumab before surgery and up to 15 cycles after surgery in combination with radiotherapy (with or without chemotherapy), while the other half continued with the current standard therapy (radiotherapy ± chemotherapy) only.

The patients receiving pembrolizumab had a 27% lower risk of disease recurrence or death compared to the control group (i.e., 27% more likely to remain "event-free"—time without disease worsening refers to the period from the start of treatment to the time of cancer recurrence or patient death).

In practice, this means that patients with locally advanced head and neck carcinoma – cancers that can be surgically removed but often recur quickly anyway – can expect better results than ever before in the coming years.

> The current gold standard of treatment no longer statistically guarantees a peaceful period of event-free survival

The current gold standard of treatment, which includes surgery, radiotherapy, and chemotherapy, no longer statistically guarantees a peaceful period of event-free survival (EFS)—a period without worsening of the disease.

In the group that received pembrolizumab, the risk of recurrence or death was 27% lower than in the group that only received conventional therapy.

A similarly important data set comes from the analysis of the major pathological response (mPR, the percentage of tumour shrinkage in the tissue sample after surgery). Patients whose cancer had a high level of PD-L1 protein—as many as 13.7%—had a residual tumour of less than 10% in the sample, while no such reduction occurred in the control group.

This means that more tumour cells are destroyed immediately after removal, which promises fewer complications and better speech and swallowing function during convalescence.

The final data on overall survival (OS), the length of time from the start of treatment to death, have not yet reached statistical significance, but the trend is clear: patients receiving pembrolizumab live longer, particularly those with CPS ≥ 10.

Changing the economic calculation

Apart from the obvious clinical benefits, this difference also changes the economic calculation: investing in a more expensive drug today will lead to savings later through lower costs for repeated hospitalisations and therapies.

The regulatory machinery is already in motion. Merck has submitted an application for priority review to the US Food and Drug Administration (FDA), which is expected to be decided on 23 June 2025.

If the FDA gives the green light, pembrolizumab, which is administered before and after surgery, will become the new standard of care in this patient group for the first time in more than 20 years without any new discoveries.

However, this success comes at a price. Annual treatment with pembrolizumab often costs more than USD 100,000 per patient in developed countries.

> The "pay-by-results" model can mitigate risk for both the healthcare system and patients

Such figures can lead to major inequalities in access—while patients in countries with developed insurance systems can easily obtain the drug, those in developing countries have to wait.

The solution is self-imposed: the accelerated release of "biosimilars" (drugs that are similar to the original after patents expire) between 2028 and 2030 could reduce the price by 30-50%.

But even that will not be enough. The "pay-by-results" model (where the state only pays part of the cost of the drug if the patient actually stays longer without the disease recurrence) can mitigate risk for both the healthcare system and patients but requires advanced regulatory mechanisms and transparent data.

Motivation to invest in new technologies

While politicians and pharmacists are dealing with pricing ultimatums, clinics and patients are facing practical questions: how to ensure that all patients are tested for PD-L1 before surgery (a basic requirement for selecting those who will benefit most from immunotherapy), how to monitor long-term side effects and how to adapt protocols to different healthcare settings?

Looking ahead, the same strategy is already being tested in lung and oesophageal cancer. If the results also indicate that immunotherapy applied before and after surgery shortens the time to recurrence and reduces tumour mass, pembrolizumab could become a universal pillar of oncological treatment for locally advanced tumours.

The blockbuster status of pembrolizumab, which generated over $20 billion in sales for Merck last year, is motivating them to invest in new technologies

This potential expansion emphasises the need and obligation for societies to build a network of financial and technical support over time.

In the meantime, pharmaceutical companies are looking at the bigger picture: the blockbuster status of pembrolizumab, which generated over $20 billion in sales for Merck last year, is motivating them to invest in new technologies — from artificial intelligence in genome analysis to the mass production of monoclonal antibodies.

The capital that flows into infrastructure and

data creates new challenges: How to balance profit with the public good?

The image of tomorrow's biotechnology will depend on three factors. Firstly, on the speed with which biosimilars will reduce costs. Secondly, on the willingness of regulators to introduce result-based payment models. And thirdly, on global co-operation to ensure that medicine does not remain a privilege of wealthy markets.

Otherwise, there is a risk that the revolution in the treatment of head and neck carcinoma will become a lesson in healthcare inequality.

KEYNOTE-689 has shown that a better disease-free period and a longer life are achievable. Now society must ensure that everyone who needs this medicine actually gets it.