

# FDA approves Roche's Tecentriq Hybrea, the first subcutaneous anti-PD-(L)1 cancer therapy

Market Event Summary

# FDA approves Tecentriq Hybreza (subcutaneous atezolizumab)

## Background

- PD-(L)1 checkpoint inhibitors such as Keytruda, Opdivo, and Tecentriq have **revolutionized cancer treatment** in the last decade and are the standards of care in many settings, including in NSCLC.
- Until recently, **only intravenous forms** of these agents were available. Atezolizumab SC gained UK and European approvals in 2023 and 2024.

## Event

- In September 2024, after a year's CMC-related delay, the FDA approved atezolizumab SC **for all indications** for which the IV form is approved, including NSCLC, small cell lung cancer, hepatocellular carcinoma, and malignant melanoma. Approval was based on the Phase 1b/3 IMscin001 trial in NSCLC.
- Tecentriq Hybreza is **the first subcutaneous anti-PD-(L)1 cancer agent** to gain FDA approval.

## Expected future events

- **Subcutaneous nivolumab** was filed in May 2024 with the FDA; we expect approval by the end of 2024.
- We forecast approval of **subcutaneous pembrolizumab**, which is in clinical development for NSCLC, in 2025.

## Factors influencing the uptake of SC formulations



**Bioequivalence.** Robust demonstration of bioequivalence is essential.



**Drug price.** Price relative to the IV formulation, especially if IV biosimilars are currently or imminently available. Price is especially significant in cost-constrained markets.



**Extent of chair-time reduction.** The larger the difference in administration time between IV and SC formulations, the stronger the motivation for SC adoption in real-world practice



**Dosing.** SC use might be spurred if it employs a fixed dose in indications where the IV dose is weight-based, which takes more time and effort to prepare.



**Concomitant medications.** The convenience of SC formulations is less relevant if the treatment regimen includes other drugs that continue to be dosed IV (for example chemotherapies).



**Administration.** Home medication could be a plus in long-term treatment settings or cases where travel time to a clinic is unmanageable for patients.

# About the author



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Charlotte Jago is a pharmaceutical industry analyst with more than 20 years' experience, preceded by 5 years of laboratory research in academia (Imperial College London) and industry (Celltech, now UCB). She wrote the flagship Cortellis Drugs to Watch reports in 2013, 2014, 2015, and 2019 and led the improvement in immuno-oncology coverage on the Cortellis Competitive Intelligence platform. She holds a Ph.D. in immunology, a first-class degree in pharmacology, and a postgraduate certificate in journalism.

### Clarivate coverage of NSCLC

- Non-small-cell lung cancer *Disease Landscape & Forecast (G7)*.
- Non-small-cell lung cancer *Current Treatment: Physician Insights: US*  
- explores the current prescribing trends of medical oncologists treating non-small-cell lung cancer.
- Non-small-cell lung cancer *Current Treatment: Treatment Sequencing: US*  
- presents surveyed medical oncologists' most frequent treatment sequences for non-small-cell lung cancer.
- Non-small-cell lung cancer *Unmet Need: US/EU*  
- detailed, expanded analysis on metastatic squamous non-small-cell lung cancer.



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