

# ODAC votes that perioperative NSCLC trials must ascertain each treatment phase's effect

Market Trend Summary

# ODAC vote adds clarity, but potential complexity, to resectable NSCLC trial design

- **Resection with curative intent** is the standard of care for early-stage NSCLC. (Neo)adjuvant drug therapy improves the outcome of surgery. Marketed (neo)adjuvant drugs include neoadjuvant Opdivo, adjuvant Tecentriq, adjuvant Keytruda, and perioperative (neoadjuvant plus adjuvant) Keytruda.
- **U.S. regulatory filings are under review** for perioperative Imfinzi and Opdivo. Perioperative Tecentriq is in Phase 3 development. The FDA has also received applications for trials of other perioperative regimens.
- **Concerned with potential overtreatment risk with perioperative regimens**, the FDA convened the ODAC in July 2024 to discuss two points: 1) the design of future perioperative trials; and 2) whether the Phase 3 AEGEAN trial of perioperative Imfinzi was sufficient to support approval given the inability of the trial's design to determine the relative contributions of the neoadjuvant and adjuvant treatment phases.
- **The ODAC voted unanimously (11 to 0)** that the FDA should require future perioperative trials to assess the individual contribution of each treatment phase (which may necessitate more treatment arms and/or patients). No vote was held on AEGEAN.
- **Like Imfinzi, the trials of perioperative Keytruda, Opdivo and Tecentriq** were not designed to assess the effect of each treatment phase. Although perioperative Keytruda was approved in the United States in October 2023 without a determination of the effect of each phase, treatment paradigms in this fast-evolving setting are as yet unsettled. It is unclear whether the FDA will follow the ODAC advice and how this could impact (if at all) ongoing trials and regulatory reviews.
- **An FDA decision regarding the AEGEAN filing is awaited.**

## Clarivate's takeaways



### Vote adds clarity to trial design needs

The ODAC vote has to an extent added clarity to the design requirements for future perioperative trials in the resectable NSCLC space. How the FDA will act on the ODAC's advice is yet to be determined.



### Trials may be more complex

To measure the individual impact of neoadjuvant and adjuvant phases, perioperative trials may require more arms, and/or more patients.



### Impact on current trials is unclear

The impact of the ODAC vote upon trials already filed for approval or ongoing in this setting remains unclear. The FDA's decision on the Imfinzi filing based on the AEGEAN trial is awaited.



### Significant sales in the resectable setting

We forecast major-market sales in resectable NSCLC to exceed \$6 billion within 5 years.

# 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 – Detailed, Expanded Analysis on metastatic squamous non-small-cell lung cancer (US/EU)*.



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