

FDA approves Roche's Alecensa for resectable *ALK*-positive NSCLC

Market Event Summary

Alecensa offers a new biomarker-driven adjuvant therapy for early-stage NSCLC

Background

- **Resection** with curative intent is the standard of care for early-stage NSCLC cases eligible for surgery.
- **Adjuvant** drug therapy improves the outcome of surgery.
- **Previously**, available nonchemotherapy adjuvant options were indicated only for 1) patients without actionable driver mutations, or 2) patients with *EGFR* mutations.
- **An unmet need** existed for the small but underserved population of patients with *ALK*-mutations, whose only adjuvant option was chemotherapy.

Event

- **The Phase 3 ALINA trial** assessed adjuvant Alecensa versus adjuvant chemotherapy in patients with completely resected stage IB (≥ 4 cm) to IIIA *ALK*-positive NSCLC.
- **Adjuvant Alecensa showed a 76% lower risk of disease recurrence or death.** Median DFS was not reached vs. 41.4 months. The 36-month DFS rate was 88.7% vs. 54.0%.
- **The FDA approval** of adjuvant Alecensa in April 2024, based on ALINA, makes Alecensa the first and only therapy approved specifically for this patient population.
- **Regulatory filings in Europe and Japan** are also under review, with a recommendation for approval in Europe issued by the CHMP in April 2024.

Clarivate's takeaways



Significant sales in the adjuvant setting

We forecast that adjuvant use of Alecensa will account for 26% of its total NSCLC sales in 2032 across the major markets.



Alecensa will hold a market monopoly

We expect Alecensa to maintain a monopoly in the *ALK*-positive adjuvant setting, with no competing agents forecast to enter during the forecast period.



Success hinges on biomarker testing

The commercial success of Alecensa in this setting will depend on wider and routine adoption of *ALK* testing in early-stage NSCLC.

About the author



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Charlotte Jago, Ph.D. is a pharmaceutical industry analyst with more than 19 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.

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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 (due to publish May 2024).
- Non-small-cell lung cancer *Unmet Need - Detailed, Expanded Analysis* on metastatic squamous non-small-cell lung cancer (US/EU) (due to publish May 2024).



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