Clarivate™

FDA approves Keytruda for perioperative use in PD-L1+ locally advanced SCCHN

Market Event Summary

Esther Coronado | June 2025

Keytruda FDA approval marks the entry of PD-1 inhibitors in locally advanced SCCHN

Background

- **Locally advanced SCCHN** is primarily treated with surgery followed by adjuvant concurrent CRT (in ~40–50% of patients) or with definitive CRT, both associated with **poor survival** and **high toxicity**.
- **Previous trials combining immunotherapy with CRT** in this setting have **failed** to improve outcomes.
- About 40-45% of patients experience recurrence despite treatment, highlighting a substantial **unmet clinical need**.

Event

- On June 12, 2025, the **FDA approved Keytruda for perioperative use** in resectable, locally advanced SCCHN with PD-L1 CPS ≥1.
- Approval was based on the **Phase 3 KEYNOTE-689 trial**, which showed a reduction of 30% in risk of recurrence, progression, or death compared with the SOC of adjuvant CRT or RT alone.
- An **improvement of 30.1 months was observed in median EFS**, 59.7 in the Keytruda arm versus 29.6 in the SOC arm. No new safety signals were observed in Keytruda arm.

Clarivate's takeaways

Commercial opportunity

The treatment paradigm for locally advanced SCCHN has been static for more than two decades. This approval represents a significant treatment advance for select patients; hence, it can position Keytruda in an otherwise largely untapped market.

Lack of clear benefit

The FDA has previously questioned perioperative trial designs and expressed concerns about potential overtreatment. **KEYNOTE-689's** multiphase design raises questions about the **relative benefit** of treatment arms. OS data are still awaited, which would strengthen Keytruda's position if they turn out to be significantly positive.

Close competition

The Phase 3 **NIVOPSTOP** trial has demonstrated a positive **DFS benefit** with adjuvant Opdivo in high-risk locally advanced SCCHN, **regardless of PD-L1 status.** If approved, Opdivo could secure a broader label without PD-L1 expression restriction, which could challenge Keytruda's first-mover advantage.

About the author

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Esther is a market research analyst with 6+ years of oncology research experience in academia and a Ph.D. in Biotechnology from the Health Research Institute Hospital La Fe (Spain). She trained in immunotherapy at the Children's Hospital of Philadelphia and brings scientific expertise to support strategic decision-making in healthcare and life sciences.

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Clarivate coverage of SCCHN

- SCCHN | Disease Landscape & Forecast (G7) Comprehensive market intelligence and actionable insights help you optimize your long-term disease strategy.
- SCCHN | Unmet Need (US/EU) Offers insight into key treatment drivers and goals, the performance of current therapies, and the remaining commercial opportunities.
- SCCHN | Current Treatment: Physician Insights Provides physician insights on treatment dynamics, prescribing behavior, and drivers of brand use.

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