

# FDA approves Merck & Co.'s Keytruda Qlex for subcutaneous administration across 38 indications

Market Event Summary

# FDA approves Keytruda Qlex (subcutaneous pembrolizumab)

## Event

- On September 19, 2025, the **FDA approved Keytruda Qlex** for **most solid tumor indications** for which the Keytruda IV formulation is approved for adult and pediatric patients aged 12 or older. It is the **first and only** SC formulation of an immune checkpoint inhibitor that can be administered in **one minute** (when given every 3 weeks).
- This approval was based on data from the Phase 3 **MK-3475A-D77** study, in which Keytruda Qlex demonstrated **comparable pharmacokinetic exposure** to Keytruda, in addition to a **similar ORR** (45 vs. 42%), PFS, and OS, in combination with chemotherapy in certain treatment-naïve patients with **metastatic NSCLC**.

## Background

- PD-(L)1 immune checkpoint inhibitors**, including Keytruda, Opdivo, and Tecentriq, have revolutionized cancer treatment in the last decade; in many oncology indications these drugs have **improved patient outcomes**, either as monotherapy or in combination with other standard treatments (e.g., targeted therapies / chemotherapy).
- Keytruda**, Merck & Co.'s **IV-administered PD-1 inhibitor**, is the top-selling drug globally; it garnered U.S. sales of **\$17.9 billion** in 2024.
- Merck & Co.'s **Keytruda Qlex** is a fixed-dose coformulation of pembrolizumab and berahyaluronidase alfa-pmph. Other SC formulations of competitor PD-(L)1 inhibitors, **Tecentriq Hybreza** and **Opdivo Qvantig**, launched in 2023 and 2024, respectively.

## Clarivate's takeaways



### U.S. launch of Keytruda Qlex and EC approval are imminent

Merck & Co. expects to have Keytruda Qlex available in the United States by **late September**. On September 19, 2025, the **EMA's CHMP** also granted **positive opinions** for SC pembrolizumab for all adult indications approved in the EU for Keytruda. Clarivate forecasts **EC approval** under the brand name Keytruda SC before the **end of 2025**.



### Time savings will drive uptake in certain settings

Keytruda Qlex is injected SC in **1-2 minutes**, compared with 30 minutes for Keytruda. SC administration enables treatment in **outpatient settings** and reduces demand for **chair time** (a pressing concern for cost-constrained markets), which will **drive uptake**, particularly when given as a **monotherapy** or in combination with **oral therapies**.



### Keytruda Qlex is key to Merck's Keytruda lifecycle strategy

Key **patents** protecting Keytruda are expected to expire starting in 2028, and **pembrolizumab IV biosimilars** are in development. We believe that Keytruda Qlex's differentiated **convenience of administration** and thus patient / hospital preference **will slow the forecast decline in branded sales**; however, competitively priced IV biosimilars could **impact future SC prescribing** and **market shares**.

# About the author



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Dr. Willoughby is a pharmaceutical industry analyst with more than 10 years of experience in oncology research and drug discovery. She has been the principal author of several market forecasting and competitive intelligence projects for a range of hematological malignancy and solid tumor indications. Prior to joining Clarivate, she was a Sara Borrell Postdoctoral Fellow at IDIBAPS-Hospital Clinic in Barcelona, and a postdoctoral fellow at IRB Barcelona. She obtained her Ph.D. at Newcastle University in the United Kingdom. Dr. Willoughby also holds a B.Sc. (Honors) in medical biochemistry with industrial experience from the University of Manchester and an M.Res. in cancer research from Newcastle University.

### Clarivate coverage of Keytruda and Keytruda Qlex

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