

Field	Data
Drug Name	KEYTRUDA QLEX (pembrolizumab and berahyaluronidase alfa-pmph)
Chemical Formula	Pembrolizumab: Not applicable (monoclonal antibody); Berahyaluronidase alfa-pmph: Not applicable (recombinant enzyme)
Molecular Weight	Pembrolizumab: 146 kDa; Berahyaluronidase alfa-pmph: ~61 kDa (approximate for variant of hyaluronidase PH20)
Therapeutic Class	PD-1 Inhibitor / Immune Checkpoint Inhibitor (with hyaluronidase adjuvant for subcutaneous delivery)

Mechanism of Action

KEYTRUDA QLEX is a fixed-dose combination of pembrolizumab, a humanized IgG4-kappa monoclonal antibody that binds to the PD-1 receptor on T-cells, blocking its interaction with PD-L1 and PD-L2 ligands. This enhances the anti-tumor immune response. Berahyaluronidase alfa-pmph temporarily degrades hyaluronan in the subcutaneous extracellular matrix, increasing the dispersion and absorption of co-administered pembrolizumab to achieve pharmacokinetic comparability with intravenous administration.

Indications

Adult and pediatric patients (≥12 years) with solid tumors including:

- Metastatic NSCLC (PD-L1 TPS ≥1%, post-platinum or first-line)
- Resectable locally advanced HNSCC (PD-L1 CPS ≥1, neoadjuvant/adjuvant)
- Unresectable/recurrent metastatic HNSCC (PD-L1 CPS ≥1, first-line)
- MSI-H/dMMR solid tumors (post-treatment)
- TMB-H solid tumors
- Melanoma (advanced/unresectable or adjuvant)
- Classical Hodgkin lymphoma
- Urothelial carcinoma
- Gastric/GEJ adenocarcinoma
- Esophageal carcinoma
- Cervical cancer
- Hepatocellular carcinoma
- Biliary tract cancer
- Merkel cell carcinoma
- Renal cell carcinoma
- Endometrial carcinoma

- Cutaneous squamous cell carcinoma
- Triple-negative breast cancer
- And others (38 total indications mirroring IV pembrolizumab).

-----2. Regulatory Information

Field	Data
FDA Approval Status	Approved
EMA Approval Status	Under Review (CHMP positive opinion September 2025; final decision expected Q4 2025)
Approval Date	September 19, 2025
Patent Expiry	2036

-----3. Commercial & Clinical Data

Field	Data
CAS Number	Pembrolizumab: 1374853-91-4; Berahyaluronidase alfa-pmph: Not assigned
Brand Names	KEYTRUDA QLEX (related: KEYTRUDA for IV formulation)
Market Size	\$29.5 Billion (2024 global sales for KEYTRUDA franchise; peak forecast \$32.7 Billion in 2026)
Competitors	Opdivo (nivolumab), Tecentriq (atezolizumab), Imfinzi (durvalumab), Libtayo (cemiplimab), Bavencio (avelumab)

Key Clinical Trial Data

- **MK-3475A-D77 (Phase 3):** Comparable PK exposure and ORR (45% SC vs. 42% IV) in first-line metastatic NSCLC with platinum chemotherapy, meeting non-inferiority criteria.
- **KEYNOTE-905/EV-303 (Phase 3):** 60% reduction in EFS risk (HR=0.40) and 50% reduction in death risk vs. surgery alone in perioperative MIBC (cisplatin-ineligible).
- **KEYNOTE-689 (Phase 3):** 27% reduction in EFS risk vs. SOC in resectable LA-HNSCC.