

To estimate the **Potential Peak Sales** for the drug **penpulimab-kcqx** in the indication of recurrent or metastatic non-keratinizing nasopharyngeal carcinoma (NPC) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach based on epidemiology, market size, treatment rates, pricing, and market share assumptions. Since specific data for penpulimab-kcqx or NPC may not be fully available in the public domain, I will make reasonable assumptions based on general oncology market trends, NPC prevalence, and immunotherapy pricing.

Step 1: Key Assumptions

1. **Indication and Patient Population:** Penpulimab-kcqx is approved for:

- First-line treatment of recurrent or metastatic non-keratinizing NPC in combination with cisplatin/carboplatin and gemcitabine.
- Second-line or later treatment as a single agent for metastatic non-keratinizing NPC after progression on platinum-based chemotherapy and at least one other prior therapy.

2. **Market Share:** As per the query, we assume a 20% to 30% share of treated patients for penpulimab-kcqx in this indication.

3. **Pricing:** Immunotherapy drugs (e.g., PD-1 inhibitors like pembrolizumab or nivolumab) typically have annual treatment costs in the range of \$100,000–\$150,000 per patient in the US. Pricing in EU5 and Japan may be 70–80% of US prices due to healthcare system negotiations, while pricing in China may be significantly lower (30–50% of US prices) due to market access policies and local competition.

4. **Treatment Duration:** Assume an average treatment duration of 6–12 months per patient for NPC, depending on line of therapy and response.

5. **Epidemiology:** NPC incidence varies significantly by geography, with higher prevalence in China and Southeast Asia compared to the US and Europe. Non-keratinizing NPC accounts for a majority of cases in endemic areas.

Step 2: Estimate Treated Patient Population for NPC

NPC incidence and prevalence data are used to estimate the eligible patient population for treatment. Below are approximate figures for recurrent or metastatic NPC based on available epidemiology data (e.g., WHO, GLOBOCAN, and published studies):

- **US:** ~1,000–1,500 new NPC cases annually; ~30–40% are recurrent/metastatic, with ~70% non-keratinizing. Eligible patients: ~300–500.
- **EU5:** ~2,000–2,500 new NPC cases annually; ~30–40% recurrent/metastatic, ~70% non-keratinizing. Eligible patients: ~600–1,000.
- **China:** ~60,000–70,000 new NPC cases annually (highly endemic); ~30–40% recurrent/metastatic, ~90% non-keratinizing. Eligible patients: ~20,000–25,000.
- **Japan:** ~2,000–2,500 new NPC cases annually; ~30–40% recurrent/metastatic, ~70% non-keratinizing. Eligible patients: ~600–1,000.

Total Eligible Patients (Recurrent/Metastatic Non-Keratinizing NPC):

- US: ~400 (midpoint)

- EU5: ~800 (midpoint)
- China: ~22,500 (midpoint)
- Japan: ~800 (midpoint)
- **Total across geographies:** ~24,500 patients

Treated Patients: Not all eligible patients receive treatment due to access, cost, or clinical factors. Assume ~80% of eligible patients are treated:

- US: ~320
- EU5: ~640
- China: ~18,000
- Japan: ~640
- **Total treated patients:** ~19,600

Step 3: Estimate Market Share for Penpulimab-kcqx

Assuming a 20% to 30% market share of treated patients:

- **20% share:**
 - US: 64 patients
 - EU5: 128 patients
 - China: 3,600 patients
 - Japan: 128 patients
 - Total: ~3,920 patients
- **30% share:**
 - US: 96 patients
 - EU5: 192 patients
 - China: 5,400 patients
 - Japan: 192 patients
 - Total: ~5,880 patients

Step 4: Estimate Annual Treatment Cost per Patient

- **US:** \$120,000 per patient (midpoint of \$100K–\$150K range for immunotherapy).
- **EU5:** \$90,000 per patient (75% of US price due to discounts/negotiations).
- **Japan:** \$90,000 per patient (similar to EU5).
- **China:** \$40,000 per patient (lower pricing due to market dynamics and local competition).

Step 5: Calculate Potential Peak Sales

Peak sales are calculated as (number of treated patients with penpulimab-kcqx) × (annual treatment cost per patient).

At 20% Market Share:

- **US:** 64 patients × \$120,000 = \$7.7 million
- **EU5:** 128 patients × \$90,000 = \$11.5 million
- **China:** 3,600 patients × \$40,000 = \$144.0 million
- **Japan:** 128 patients × \$90,000 = \$11.5 million
- **Total Peak Sales (20% share):** \$7.7M + \$11.5M + \$144.0M + \$11.5M = **\$174.7 million**

At 30% Market Share:

- **US:** 96 patients × \$120,000 = \$11.5 million
- **EU5:** 192 patients × \$90,000 = \$17.3 million
- **China:** 5,400 patients × \$40,000 = \$216.0 million
- **Japan:** 192 patients × \$90,000 = \$17.3 million
- **Total Peak Sales (30% share):** \$11.5M + \$17.3M + \$216.0M + \$17.3M = **\$262.1 million**

Potential Peak Sales Range: \$174.7 million to \$262.1 million annually across the US, EU5, China, and Japan.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total treated patient population (~19,600 patients) = ~196 patients.

- **US:** 1% of 320 = 3.2 patients × \$120,000 = \$0.38 million
- **EU5:** 1% of 640 = 6.4 patients × \$90,000 = \$0.58 million
- **China:** 1% of 18,000 = 180 patients × \$40,000 = \$7.20 million
- **Japan:** 1% of 640 = 6.4 patients × \$90,000 = \$0.58 million
- **Total \$ Value of 1% Share:** \$0.38M + \$0.58M + \$7.20M + \$0.58M = **\$8.74 million**

Final Answer:

1. **Potential Peak Sales for penpulimab-kcqx** in the indication of recurrent or metastatic non-keratinizing NPC (assuming 20% to 30% market share):

- **Range: \$174.7 million to \$262.1 million annually** across the US, EU5, China, and Japan.

2. **\$ Value of 1% Share of Treated Patients:**

- **Total: \$8.74 million annually** across the US, EU5, China, and Japan.

Notes:

- These estimates are based on assumptions and may vary depending on actual pricing, market penetration, competition (e.g., other PD-1 inhibitors like pembrolizumab), and real-world treatment rates.
- China's market dominates due to the high incidence of NPC, even at a lower price point.
- Adjustments can be made if more specific data on patient numbers, pricing, or treatment duration for penpulimab-kcqx becomes available.