

To estimate the **Potential Peak Sales** for tebentafusp-tebn (Kimmtrak) in the indication of unresectable or metastatic uveal melanoma in the US, EU5 (France, Germany, 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. Since specific data such as exact patient numbers, pricing, and penetration rates are not provided, I will use reasonable assumptions based on publicly available information, epidemiology data, and market analysis for rare cancers like uveal melanoma. Let's break this down step by step.

****Step 1: Key Assumptions and Background****

1. **Indication:** Tebentafusp-tebn is approved for HLA-A*02:01-positive adult patients with unresectable or metastatic uveal melanoma. Approximately 50% of the population expresses the HLA-A*02:01 allele, so only half of the uveal melanoma patients are eligible for this therapy.

2. Epidemiology of Uveal Melanoma:

- Uveal melanoma is a rare cancer with an incidence of ~5-6 cases per million people annually in the US and Europe. It is less common in Asian populations (e.g., China and Japan).

- Around 50% of patients develop metastatic disease, often to the liver, at some point during their disease course.

- Using population data and incidence rates, we can estimate the total number of eligible patients.

3. **Market Share:** The query assumes a 20% to 30% share of treated patients. This reflects the drug's penetration among eligible patients.

4. **Pricing:** Tebentafusp-tebn is a novel immunotherapy, and pricing for such drugs in rare cancers is typically high. In the US, the annual cost is estimated to be around \$400,000 per patient (based on reports and comparisons with similar therapies like CAR-T or bispecific antibodies). Pricing in EU5, China, and Japan will likely be lower due to healthcare system differences (e.g., 60-80% of US price in EU5, and even lower in China and Japan).

5. **Peak Sales:** Peak sales typically occur 5-7 years after launch when market penetration stabilizes, assuming no major competitors or patent expiry.

****Step 2: Estimate Eligible Patient Population****

Using approximate population figures and incidence rates for uveal melanoma:

- **US:** Population ~330 million

- Incidence: ~5.1 per million → ~1,680 new cases per year.

- ~50% develop metastatic disease → ~840 metastatic cases.

- ~50% HLA-A*02:01-positive → ~420 eligible patients annually.

- **EU5:** Population ~320 million (combined for France, Germany, Italy, Spain, UK)

- Incidence: ~5 per million → ~1,600 new cases per year.

- ~50% metastatic → ~800 cases.
- ~50% HLA-A*02:01-positive → ~400 eligible patients annually.
- **China:** Population ~1,400 million
- Incidence: ~0.5 per million (lower in Asian populations) → ~700 new cases per year.
- ~50% metastatic → ~350 cases.
- ~50% HLA-A*02:01-positive → ~175 eligible patients annually.
- **Japan:** Population ~125 million
- Incidence: ~0.5 per million → ~63 new cases per year.
- ~50% metastatic → ~32 cases.
- ~50% HLA-A*02:01-positive → ~16 eligible patients annually.

Total Eligible Patients Annually:

- US: 420
- EU5: 400
- China: 175
- Japan: 16
- **Total: ~1,011 patients annually**

Note: These numbers represent incident cases (newly diagnosed metastatic patients). Prevalent cases (existing patients) could be higher, but for peak sales, we often focus on annual incident cases as treatment duration for metastatic uveal melanoma may be limited due to poor prognosis.

****Step 3: Estimate Treated Patients with 20%-30% Market Share****

- 20% Market Share:

- US: $420 * 0.2 = 84$ patients
- EU5: $400 * 0.2 = 80$ patients
- China: $175 * 0.2 = 35$ patients
- Japan: $16 * 0.2 = 3$ patients
- **Total: 202 patients**

- 30% Market Share:

- US: $420 * 0.3 = 126$ patients
- EU5: $400 * 0.3 = 120$ patients
- China: $175 * 0.3 = 53$ patients
- Japan: $16 * 0.3 = 5$ patients

- **Total: 304 patients**

****Step 4: Estimate Pricing per Patient****

- **US:** ~\$400,000 per patient annually (based on reported costs for Kimmtrak).
- **EU5:** ~\$300,000 per patient (75% of US price due to pricing negotiations in Europe).
- **China:** ~\$200,000 per patient (50% of US price due to lower pricing in emerging markets).
- **Japan:** ~\$300,000 per patient (similar to EU5 due to developed market status).

****Step 5: Calculate Potential Peak Sales****

Peak sales are calculated as (Number of treated patients) * (Annual cost per patient) for each region.

At 20% Market Share:

- **US:** 84 patients * \$400,000 = \$33.6 million
- **EU5:** 80 patients * \$300,000 = \$24.0 million
- **China:** 35 patients * \$200,000 = \$7.0 million
- **Japan:** 3 patients * \$300,000 = \$0.9 million
- **Total Peak Sales (20% share): \$65.5 million**

At 30% Market Share:

- **US:** 126 patients * \$400,000 = \$50.4 million
- **EU5:** 120 patients * \$300,000 = \$36.0 million
- **China:** 53 patients * \$200,000 = \$10.6 million
- **Japan:** 5 patients * \$300,000 = \$1.5 million
- **Total Peak Sales (30% share): \$98.5 million**

Potential Peak Sales Range: \$65.5 million to \$98.5 million annually across the US, EU5, China, and Japan.

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

A 1% share corresponds to 1% of the eligible patients being treated with tebentafusp-tebn.

- **US:** 420 patients * 0.01 = 4.2 patients * \$400,000 = **\$1.68 million**

- **EU5:** 400 patients * 0.01 = 4 patients * \$300,000 = **\$1.2 million**
- **China:** 175 patients * 0.01 = 1.75 patients * \$200,000 = **\$0.35 million**
- **Japan:** 16 patients * 0.01 = 0.16 patients * \$300,000 = **\$0.048 million**
- **Total \$ Value of 1% Share: \$3.278 million**

****Final Answer****

1. Potential Peak Sales for Tebentafusp-tebn (20% to 30% market share):

- **Range: \$65.5 million to \$98.5 million annually** across the US, EU5, China, and Japan.
- Breakdown:
 - US: \$33.6M (20%) to \$50.4M (30%)
 - EU5: \$24.0M (20%) to \$36.0M (30%)
 - China: \$7.0M (20%) to \$10.6M (30%)
 - Japan: \$0.9M (20%) to \$1.5M (30%)

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

- **Total: \$3.278 million**
- Breakdown:
 - US: \$1.68M
 - EU5: \$1.2M
 - China: \$0.35M
 - Japan: \$0.048M

****Caveats and Notes****

- These estimates are based on assumptions for incidence, HLA-A*02:01 prevalence, pricing, and market penetration. Actual numbers may vary depending on real-world data, competition, reimbursement policies, and treatment duration.
- Uveal melanoma is a rare disease, and peak sales in this indication are modest compared to larger oncology markets. However, tebentafusp-tebn is a first-in-class therapy, which may allow for higher market penetration if no competitors emerge.
- If additional indications are approved for tebentafusp-tebn, peak sales could increase significantly.

If you have access to more specific data (e.g., exact pricing or patient numbers), I can refine these calculations further.

