

To estimate the **Potential Peak Sales** for atezolizumab (Tecentriq) in the indication of BRAF V600 mutation-positive unresectable or metastatic melanoma in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data (e.g., exact patient numbers, pricing, or market penetration) is not provided, I will outline the methodology and use reasonable assumptions based on publicly available data and typical market dynamics for oncology drugs. Please note that these are illustrative calculations and actual figures may vary based on real-world data.

Step 1: Define the Target Population

Atezolizumab is approved for BRAF V600 mutation-positive unresectable or metastatic melanoma in combination with cobimetinib and vemurafenib. We need to estimate the number of eligible patients in each geography.

- **Prevalence of Melanoma:** According to various cancer statistics, melanoma incidence varies by region, with higher rates in Western countries (US, EU5) compared to Asia (China, Japan).
- **BRAF V600 Mutation:** Approximately 40-50% of melanoma patients have the BRAF V600 mutation.
- **Unresectable or Metastatic Melanoma:** Around 20-30% of melanoma cases are diagnosed at an advanced stage (Stage III unresectable or Stage IV).
- **Incident Cases:** We will focus on incident (newly diagnosed) cases per year, as peak sales are often driven by annual treatment cohorts.

Estimated Incident Cases (per year) for Advanced Melanoma with BRAF V600 Mutation:

- **US:** ~100,000 new melanoma cases/year; ~25% advanced stage = 25,000; ~45% BRAF V600 = ~11,250 patients.
- **EU5:** ~80,000 new cases/year; ~25% advanced = 20,000; ~45% BRAF V600 = ~9,000 patients.
- **China:** ~20,000 new cases/year (lower incidence); ~25% advanced = 5,000; ~45% BRAF V600 = ~2,250 patients.
- **Japan:** ~5,000 new cases/year; ~25% advanced = 1,250; ~45% BRAF V600 = ~560 patients.
- **Total Eligible Patients:** ~11,250 (US) + 9,000 (EU5) + 2,250 (China) + 560 (Japan) = ~23,060 patients/year.

Step 2: Estimate Treated Patients (Market Penetration)

The problem assumes a **20-30% share of treated patients** for atezolizumab in this indication. This accounts for competition from other therapies (e.g., other immune checkpoint inhibitors like pembrolizumab, nivolumab, or targeted therapies for BRAF V600 melanoma).

- **Low End (20%):** $23,060 * 0.2 = \sim 4,612$ treated patients/year.
- **High End (30%):** $23,060 * 0.3 = \sim 6,918$ treated patients/year.

Breakdown by Geography (20-30% share):

- **US:** $11,250 * 0.2-0.3 = 2,250-3,375$ patients.
- **EU5:** $9,000 * 0.2-0.3 = 1,800-2,700$ patients.
- **China:** $2,250 * 0.2-0.3 = 450-675$ patients.
- **Japan:** $560 * 0.2-0.3 = 112-168$ patients.

Step 3: Estimate Annual Treatment Cost per Patient

Atezolizumab is an immune checkpoint inhibitor, and its cost varies by region due to pricing differences, healthcare systems, and reimbursement policies. Additionally, it is used in combination with cobimetinib and vemurafenib, which are expensive targeted therapies. For simplicity, we will estimate the total cost of the combination regimen per patient per year.

- **US:** Annual cost of atezolizumab alone is ~\$150,000-\$180,000. With cobimetinib (~\$100,000/year) and vemurafenib (~\$100,000/year), total cost ~\$350,000-\$400,000/year.
- **EU5:** Pricing is typically 30-50% lower than the US due to negotiations and health technology assessments. Estimated total cost ~\$200,000-\$250,000/year.
- **China:** Pricing is significantly lower due to market access challenges and local pricing policies. Estimated total cost ~\$100,000-\$150,000/year.
- **Japan:** Pricing is somewhat comparable to the EU5, with total cost ~\$200,000-\$250,000/year.

Average Annual Cost per Patient (Combination Therapy):

- US: \$375,000
- EU5: \$225,000
- China: \$125,000
- Japan: \$225,000

Step 4: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each geography.

Low End (20% Share):

- **US:** $2,250 \text{ patients} * \$375,000 = \$843.75 \text{ million}$
- **EU5:** $1,800 \text{ patients} * \$225,000 = \$405 \text{ million}$
- **China:** $450 \text{ patients} * \$125,000 = \56.25 million
- **Japan:** $112 \text{ patients} * \$225,000 = \25.2 million

- **Total Peak Sales (20%):** $\$843.75\text{M} + \$405\text{M} + \$56.25\text{M} + \$25.2\text{M} = \sim\$1,330.2 \text{ million } (\sim\$1.33 \text{ billion})$

High End (30% Share):

- **US:** $3,375 \text{ patients} * \$375,000 = \$1,265.63 \text{ million}$

- **EU5:** $2,700 \text{ patients} * \$225,000 = \$607.5 \text{ million}$

- **China:** $675 \text{ patients} * \$125,000 = \84.38 million

- **Japan:** $168 \text{ patients} * \$225,000 = \37.8 million

- **Total Peak Sales (30%):** $\$1,265.63\text{M} + \$607.5\text{M} + \$84.38\text{M} + \$37.8\text{M} = \sim\$1,995.31 \text{ million } (\sim\$1.995 \text{ billion})$

Summary of Potential Peak Sales:

- **Range:** **\$1.33 billion to \$1.995 billion** annually across US, EU5, China, and Japan for a 20-30% market share.

Step 5: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients corresponds to 1% of the total eligible patients (23,060) = 230.6 patients/year.

Breakdown by Geography (1% Share):

- **US:** $11,250 * 0.01 = 112.5 \text{ patients}$

- **EU5:** $9,000 * 0.01 = 90 \text{ patients}$

- **China:** $2,250 * 0.01 = 22.5 \text{ patients}$

- **Japan:** $560 * 0.01 = 5.6 \text{ patients}$

Revenue from 1% Share:

- **US:** $112.5 \text{ patients} * \$375,000 = \$42.19 \text{ million}$

- **EU5:** $90 \text{ patients} * \$225,000 = \20.25 million

- **China:** $22.5 \text{ patients} * \$125,000 = \$2.81 \text{ million}$

- **Japan:** $5.6 \text{ patients} * \$225,000 = \1.26 million

- **Total Value of 1% Share:** $\$42.19\text{M} + \$20.25\text{M} + \$2.81\text{M} + \$1.26\text{M} = \sim\$66.51 \text{ million}$

Summary of \$ Value of 1% Share:

- **Total:** **\$66.51 million** annually across US, EU5, China, and Japan.

Final Answer

1. Potential Peak Sales for Atezolizumab (in combination therapy) in BRAF V600 mutation-positive unresectable or metastatic melanoma:

- **Range: \$1.33 billion to \$1.995 billion** annually (assuming 20-30% market share) across US, EU5, China, and Japan.

- Breakdown:

- US: \$843.75M - \$1,265.63M

- EU5: \$405M - \$607.5M

- China: \$56.25M - \$84.38M

- Japan: \$25.2M - \$37.8M

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

- **Total: \$66.51 million** annually across US, EU5, China, and Japan.

- Breakdown:

- US: \$42.19M

- EU5: \$20.25M

- China: \$2.81M

- Japan: \$1.26M

Notes and Assumptions

- These estimates are based on approximate patient numbers, mutation prevalence, and pricing data. Real-world figures may differ due to variations in diagnosis rates, access to therapy, reimbursement, and competition.

- The cost of combination therapy (atezolizumab + cobimetinib + vemurafenib) is assumed to be additive, though discounts or bundled pricing may apply in some markets.

- Peak sales assume steady-state market penetration and do not account for patent expiry or biosimilar competition.

- If you have access to specific epidemiology or pricing data, these calculations can be refined further.