

To estimate the **Potential Peak Sales** for brentuximab vedotin (Adcetris) in the indication of previously untreated high-risk classical Hodgkin lymphoma (cHL) in pediatric patients (aged 2 years and older) 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. Since specific data on patient populations, pricing, and market penetration may not be fully available, I will make reasonable assumptions based on available epidemiology data, pricing trends, and market dynamics for rare diseases and oncology drugs. Let's break this down step by step.

Step 1: Define the Target Population

Classical Hodgkin lymphoma (cHL) is a rare cancer, and pediatric cases (ages 2-18) represent a small subset of the overall incidence. High-risk cHL in previously untreated patients further narrows the population. We will estimate the annual incidence of pediatric high-risk cHL in each geography.

- **US:** Incidence of cHL in children and adolescents (0-19 years) is approximately 1,200 cases per year (based on SEER data). Assuming 50% are high-risk and previously untreated, this results in ~600 eligible patients annually. Adjusting for ages 2-18, we estimate ~550 patients.
- **EU5:** Incidence rates are similar to the US. With a combined population of ~330 million (vs. 330 million in the US), we estimate ~550 cases annually, adjusted for high-risk and untreated status.
- **Japan:** With a population of ~125 million, and lower incidence rates of cHL compared to Western countries (about 0.5 per 100,000), we estimate ~50-60 cases annually, adjusted to ~30 high-risk untreated patients.
- **China:** With a population of ~1.4 billion but lower incidence rates of cHL (0.3-0.5 per 100,000) and limited pediatric data, we estimate ~400-500 cases annually, adjusted to ~200 high-risk untreated patients.

Total Annual Eligible Patients (approximate):

- US: 550
- EU5: 550
- Japan: 30
- China: 200
- **Total:** 1,330 patients per year

Step 2: Market Penetration (20%-30% Share of Treated Patients)

As per the query, we assume brentuximab vedotin captures 20%-30% of the treated patient population in this indication. This accounts for competition from other therapies (e.g., standard chemotherapy regimens like ABVD or escalated BEACOPP), physician adoption, and reimbursement dynamics.

- **Low-end (20% penetration):** $1,330 \times 0.2 = 266$ treated patients annually
- **High-end (30% penetration):** $1,330 \times 0.3 = 399$ treated patients annually

Distribution Across Geographies (based on patient share):

- US: $550 / 1,330 \approx 41\%$ of total
- EU5: $550 / 1,330 \approx 41\%$ of total
- Japan: $30 / 1,330 \approx 2\%$ of total
- China: $200 / 1,330 \approx 15\%$ of total

Thus:

- **US treated patients:** $266-399 \times 41\% = 109-164$ patients
- **EU5 treated patients:** $266-399 \times 41\% = 109-164$ patients
- **Japan treated patients:** $266-399 \times 2\% = 5-8$ patients
- **China treated patients:** $266-399 \times 15\% = 40-60$ patients

Step 3: Pricing per Patient

Brentuximab vedotin is a high-cost biologic drug used in oncology. Pricing varies by region due to differences in healthcare systems, reimbursement, and purchasing power. The drug is typically administered in multiple cycles (e.g., 6 cycles for cHL, with dosing based on body weight). Based on available data for adult indications and adjusting for pediatric dosing (lower body weight), we estimate the annual cost per patient as follows:

- **US:** ~\$150,000 per patient per treatment course (based on historical pricing for Adcetris, ~\$15,000-\$20,000 per cycle for adults, adjusted for pediatric weight-based dosing and 6-8 cycles).
- **EU5:** ~\$100,000 per patient (lower due to negotiated pricing and discounts in European markets).
- **Japan:** ~\$120,000 per patient (similar to US but slightly discounted due to government pricing controls).
- **China:** ~\$50,000 per patient (significantly lower due to pricing pressures, tiered pricing, and potential local manufacturing or biosimilars in the future).

Step 4: Potential Peak Sales Calculation

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

Low-End (20% Penetration)

- **US:** $109 \text{ patients} \times \$150,000 = \$16.35 \text{ million}$
- **EU5:** $109 \text{ patients} \times \$100,000 = \$10.9 \text{ million}$
- **Japan:** $5 \text{ patients} \times \$120,000 = \$0.6 \text{ million}$

- **China:** 40 patients × \$50,000 = \$2.0 million
- **Total Peak Sales (20%):** \$16.35M + \$10.9M + \$0.6M + \$2.0M = **\$29.85 million**

High-End (30% Penetration)

- **US:** 164 patients × \$150,000 = \$24.6 million
- **EU5:** 164 patients × \$100,000 = \$16.4 million
- **Japan:** 8 patients × \$120,000 = \$0.96 million
- **China:** 60 patients × \$50,000 = \$3.0 million
- **Total Peak Sales (30%):** \$24.6M + \$16.4M + \$0.96M + \$3.0M = **\$44.96 million**

Potential Peak Sales Range: \$29.85 million to \$44.96 million annually across the US, EU5, Japan, and China for this pediatric indication.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient pool (1,330 patients) = 13.3 patients annually.

Using the same pricing per patient as above, the value of treating these 13.3 patients is calculated based on their distribution across geographies (using the same proportions as above):

- **US:** 13.3 × 41% = 5.45 patients × \$150,000 = \$0.818 million
- **EU5:** 13.3 × 41% = 5.45 patients × \$100,000 = \$0.545 million
- **Japan:** 13.3 × 2% = 0.27 patients × \$120,000 = \$0.032 million
- **China:** 13.3 × 15% = 2.0 patients × \$50,000 = \$0.1 million
- **Total Value of 1% Share:** \$0.818M + \$0.545M + \$0.032M + \$0.1M = **\$1.495 million**

\$ Value of 1% Share of Treated Patients: \$1.5 million (approximately) annually.

Final Answer

1. **Potential Peak Sales for Brentuximab Vedotin** in the indication of previously untreated high-risk classical Hodgkin lymphoma in pediatric patients (2 years and older) at 20%-30% market penetration:

- **Range: \$29.85 million to \$44.96 million annually** across the US, EU5, Japan, and China.
- Breakdown:
 - US: \$16.35M - \$24.6M
 - EU5: \$10.9M - \$16.4M

- Japan: \$0.6M - \$0.96M
- China: \$2.0M - \$3.0M

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

- **Approximately \$1.5 million annually** across the specified geographies.

Notes and Caveats

- These estimates are based on assumptions about patient numbers, pricing, and market penetration. Actual figures may vary due to real-world data on incidence, adoption rates, competition, and pricing negotiations.
- Peak sales may take several years to achieve due to gradual market uptake, especially in a rare disease setting.
- Pricing in China is highly speculative due to evolving reimbursement policies and potential local competition.
- The indication is niche (pediatric high-risk cHL), so sales in this segment are relatively small compared to adult indications for brentuximab vedotin.