

To estimate the **Potential Peak Sales** for polatuzumab vedotin-piiq (Polivy) in the indication of previously untreated diffuse large B-cell lymphoma (DLBCL) and high-grade B-cell lymphoma (HGBL) with an IPI score of 2 or greater 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 exact data on patient populations, pricing, and market dynamics may not be fully available, I will outline the methodology and use reasonable assumptions based on publicly available information and industry standards. You can refine these numbers with more specific data if available.

## **Step 1: Define the Target Patient Population**

DLBCL is the most common type of non-Hodgkin lymphoma (NHL), accounting for about 25-30% of NHL cases. We are focusing on previously untreated (first-line) DLBCL and HGBL patients with an IPI score of  $\geq 2$ , which indicates intermediate to high-risk patients. Approximately 60-70% of DLBCL patients fall into this category (IPI  $\geq 2$ ).

#### Incidence of DLBCL (Annual New Cases):

- **US:** ~25,000 new DLBCL cases per year (based on NHL incidence of ~80,000 and DLBCL being ~30%).
- **EU5:** ~30,000 new DLBCL cases per year (combined population ~330 million, similar incidence rates to the US).
- **China:** ~30,000 new DLBCL cases per year (higher population but lower diagnosis rates; NHL incidence is rising).
- **Japan:** ~10,000 new DLBCL cases per year (population ~125 million, high diagnosis rate).

#### First-Line Patients with IPI  $\geq 2$ :

Assuming 65% of DLBCL patients have an IPI score  $\geq 2$ :

- **US:**  $25,000 * 0.65 = \sim 16,250$  patients.
- **EU5:**  $30,000 * 0.65 = \sim 19,500$  patients.
- **China:**  $30,000 * 0.65 = \sim 19,500$  patients.
- **Japan:**  $10,000 * 0.65 = \sim 6,500$  patients.

**Total Target Population:** 16,250 (US) + 19,500 (EU5) + 19,500 (China) + 6,500 (Japan) = **61,750 patients annually.**

## **Step 2: Estimate Market Share of Treated Patients**

The problem states a 20-30% share of treated patients. This assumes Polivy captures 20-30% of the first eligible first-line DLBCL/HGBL patients with IPI  $\geq 2$ . Let's calculate for both ends of the range:

- At 20% share:  $61,750 * 0.20 = \mathbf{12,350}$  patients treated.
- At 30% share:  $61,750 * 0.30 = \mathbf{18,525}$  patients treated.

## **Step 3: Estimate Treatment Cost per Patient**

Polivy is typically administered in combination with R-CHP for 6 cycles (as per clinical trial data from the POLARIX study). The cost of Polivy varies by region due to pricing differences, reimbursement policies, and healthcare systems. Approximate annual cost per patient (for 6 cycles) based on available data and assumptions:

- **US:** ~\$150,000 per patient (based on list prices and reported costs for antibody-drug conjugates in oncology).
- **EU5:** ~\$100,000 per patient (lower due to negotiated pricing and public healthcare systems).
- **China:** ~\$50,000 per patient (lower pricing due to market access challenges and generics competition).
- **Japan:** ~\$120,000 per patient (similar to US but slightly lower due to pricing controls).

### **Step 4: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients by the cost per patient in each geography. We will calculate for both 20% and 30% market share scenarios.

#### At 20% Market Share (12,350 patients):

- **US:**  $16,250 * 0.20 = 3,250$  patients \* \$150,000 = **\$487.5 million**.
- **EU5:**  $19,500 * 0.20 = 3,900$  patients \* \$100,000 = **\$390 million**.
- **China:**  $19,500 * 0.20 = 3,900$  patients \* \$50,000 = **\$195 million**.
- **Japan:**  $6,500 * 0.20 = 1,300$  patients \* \$120,000 = **\$156 million**.
- **Total Peak Sales at 20%:** \$487.5M + \$390M + \$195M + \$156M = **\$1,228.5 million** (~\$1.23 billion).

#### At 30% Market Share (18,525 patients):

- **US:**  $16,250 * 0.30 = 4,875$  patients \* \$150,000 = **\$731.25 million**.
- **EU5:**  $19,500 * 0.30 = 5,850$  patients \* \$100,000 = **\$585 million**.
- **China:**  $19,500 * 0.30 = 5,850$  patients \* \$50,000 = **\$292.5 million**.
- **Japan:**  $6,500 * 0.30 = 1,950$  patients \* \$120,000 = **\$234 million**.
- **Total Peak Sales at 30%:** \$731.25M + \$585M + \$292.5M + \$234M = **\$1,842.75 million** (~\$1.84 billion).

**Potential Peak Sales Range: \$1.23 billion to \$1.84 billion annually.**

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

A 1% share of the total target population (61,750 patients) is 617.5 patients. Using the same cost per patient as above:

- **US:**  $16,250 * 0.01 = 162.5$  patients \* \$150,000 = **\$24.38 million**.
- **EU5:**  $19,500 * 0.01 = 195$  patients \* \$100,000 = **\$19.5 million**.
- **China:**  $19,500 * 0.01 = 195$  patients \* \$50,000 = **\$9.75 million**.

- **Japan:**  $6,500 * 0.01 = 65 \text{ patients} * \$120,000 = \text{\$7.8 million}$ .
- **Total \$ Value of 1% Share:**  $\$24.38\text{M} + \$19.5\text{M} + \$9.75\text{M} + \$7.8\text{M} = \text{\$61.43 million}$ .

### **Final Answer:**

- **Potential Peak Sales for Polivy** in the specified indication across the US, EU5, China, and Japan, assuming a 20-30% share of treated patients, is approximately **\$1.23 billion to \$1.84 billion annually**.
- **\$ Value of 1% Share of Treated Patients** in these geographies is approximately **\$61.43 million**.

### **Notes:**

- These estimates are based on assumptions for incidence rates, market share, and pricing. Real-world data may differ due to competition (e.g., other therapies like CAR-T, bispecific antibodies), reimbursement hurdles, and regional access.
- Peak sales typically occur 5-10 years post-launch after market penetration stabilizes, assuming no major disruptions (e.g., patent expiry or new competitors).
- Costs per patient are rough estimates and may vary based on discounts, rebates, and local pricing negotiations.
- HGBL patients are included in DLBCL estimates as they are often grouped together, though HGBL is a smaller subset.

If you have more precise data (e.g., exact pricing, updated incidence, or market share forecasts), I can refine these calculations further.