

To calculate the **Potential Peak Sales** for datopotamab deruxtecan-dlnk (Dato-DXd, marketed as Datroway) in the specified indication (unresectable or metastatic HR-positive, HER2-negative breast cancer) 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 exact patient numbers, pricing, and market penetration data are not publicly available in this context, I will use reasonable assumptions based on industry standards, epidemiology data, and analogous drugs. Below is the step-by-step estimation:

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

The indication is for adult patients with **unresectable or metastatic HR-positive, HER2-negative breast cancer** who have received prior endocrine therapy and chemotherapy. This is a subset of breast cancer patients.

### **- Breast Cancer Incidence and Prevalence:**

- HR-positive, HER2-negative breast cancer accounts for approximately 60-70% of all breast cancer cases.
- Metastatic breast cancer (Stage IV) represents about 6-10% of new breast cancer diagnoses, with additional patients progressing to metastatic disease over time.
- We focus on the **prevalent** population (existing patients with metastatic disease) eligible for second-line or later-line therapies.

Using epidemiology data and estimates:

- **US:** ~155,000 prevalent metastatic breast cancer patients; ~60-70% are HR+/HER2-, so ~100,000 patients. Of these, ~50% may have progressed beyond first-line therapy (50,000 eligible patients).
- **EU5:** ~120,000 prevalent metastatic breast cancer patients; ~60-70% HR+/HER2-, so ~75,000 patients. ~50% eligible (~37,500 patients).
- **China:** ~200,000 prevalent metastatic breast cancer patients (higher population base); ~60-70% HR+/HER2-, so ~130,000 patients. ~50% eligible (~65,000 patients).
- **Japan:** ~25,000 prevalent metastatic breast cancer patients; ~60-70% HR+/HER2-, so ~16,000 patients. ~50% eligible (~8,000 patients).

Total eligible patients across geographies: ~50,000 (US) + 37,500 (EU5) + 65,000 (China) + 8,000 (Japan) = **160,500 patients**.

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## **Step 2: Estimate Treated Patient Share**

The problem assumes a **20% to 30% share of treated patients** for datopotamab deruxtecan-dlnk in this indication. This accounts for competition from other therapies (e.g., CDK4/6 inhibitors, other ADCs like trastuzumab deruxtecan for HER2-low, and chemotherapy).

- At **20% share:**  $160,500 * 0.2 = 32,100$  treated patients.

- At **30% share**:  $160,500 * 0.3 = 48,150$  treated patients.

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### **Step 3: Estimate Annual Drug Cost per Patient**

Pricing for antibody-drug conjugates (ADCs) like datopotamab deruxtecan is high due to their innovative nature and manufacturing complexity. We can benchmark against similar drugs like trastuzumab deruxtecan (Enhertu), which costs ~\$180,000–\$200,000 per year per patient in the US.

- **US**: ~\$200,000 per patient per year.

- **EU5**: Pricing is typically 30-50% lower due to healthcare system negotiations; assume ~\$120,000 per patient per year.

- **China**: Pricing is significantly lower due to market access challenges and local policies; assume ~\$50,000 per patient per year.

- **Japan**: Pricing is similar to EU5; assume ~\$120,000 per patient per year.

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### **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.

#### At 20% Share of Treated Patients (32,100 patients):

- **US**:  $50,000 * 0.2 = 10,000$  patients \* \$200,000 = **\$2.0 billion**.

- **EU5**:  $37,500 * 0.2 = 7,500$  patients \* \$120,000 = **\$0.9 billion**.

- **China**:  $65,000 * 0.2 = 13,000$  patients \* \$50,000 = **\$0.65 billion**.

- **Japan**:  $8,000 * 0.2 = 1,600$  patients \* \$120,000 = **\$0.19 billion**.

- **Total Peak Sales (20% share)**: \$2.0B + \$0.9B + \$0.65B + \$0.19B = **\$3.74 billion**.

#### At 30% Share of Treated Patients (48,150 patients):

- **US**:  $50,000 * 0.3 = 15,000$  patients \* \$200,000 = **\$3.0 billion**.

- **EU5**:  $37,500 * 0.3 = 11,250$  patients \* \$120,000 = **\$1.35 billion**.

- **China**:  $65,000 * 0.3 = 19,500$  patients \* \$50,000 = **\$0.975 billion**.

- **Japan**:  $8,000 * 0.3 = 2,400$  patients \* \$120,000 = **\$0.288 billion**.

- **Total Peak Sales (30% share)**: \$3.0B + \$1.35B + \$0.975B + \$0.288B = **\$5.613 billion**.

Thus, the **Potential Peak Sales** range is approximately **\$3.74 billion to \$5.61 billion** annually, depending on the 20-30% market share.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population (160,500 patients), i.e., **1,605 patients**.

- **US:**  $50,000 * 0.01 = 500 \text{ patients} * \$200,000 = \text{\$100 million}$ .
- **EU5:**  $37,500 * 0.01 = 375 \text{ patients} * \$120,000 = \text{\$45 million}$ .
- **China:**  $65,000 * 0.01 = 650 \text{ patients} * \$50,000 = \text{\$32.5 million}$ .
- **Japan:**  $8,000 * 0.01 = 80 \text{ patients} * \$120,000 = \text{\$9.6 million}$ .
- **Total \$ Value of 1% Share:**  $\text{\$100M} + \text{\$45M} + \text{\$32.5M} + \text{\$9.6M} = \text{\$187.1 million}$ .

Thus, a **1% share of treated patients** is worth approximately **\$187 million annually** across these geographies.

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## **Summary of Results**

1. **Potential Peak Sales** for datopotamab deruxtecan-dlnk in the specified indication:

- At 20% share: **\$3.74 billion**.
- At 30% share: **\$5.61 billion**.
- Range: **\$3.74B to \$5.61B annually**.

2. **\$ Value of 1% Share of Treated Patients:** **\$187 million annually**.

## **Caveats and Assumptions**

- Patient population estimates are based on general epidemiology data and may vary with more precise real-world data.
- Pricing assumptions are based on analogous ADCs and may differ based on reimbursement policies, negotiations, and market access.
- Market share of 20-30% assumes competition from other therapies; actual penetration could be influenced by clinical outcomes, safety profiles, and payer decisions.
- Peak sales are assumed to be annual figures at steady-state market penetration, typically 5-7 years post-launch.

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