

To calculate the **Potential Peak Sales** for irinotecan liposome (Onivyde) in the indication of first-line treatment of metastatic pancreatic adenocarcinoma in the US, EU5 (France, Germany, 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 on patient numbers, pricing, and market penetration may not be publicly available or provided in the query, I will outline the methodology and make reasonable assumptions based on general market data and trends in oncology. You can adjust these assumptions with more precise data if available.

## **Step 1: Key Assumptions and Methodology**

1. **Indication:** Metastatic pancreatic adenocarcinoma (first-line treatment).
2. **Market Share:** Assuming 20% to 30% share of treated patients as given in the query.
3. **Geographies:** US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan.
4. **Patient Population:** Estimate the number of eligible patients for first-line treatment of metastatic pancreatic cancer in each geography.
5. **Pricing:** Estimate the annual cost of treatment per patient for irinotecan liposome (Onivyde) based on typical oncology drug pricing in each region.
6. **Peak Sales:** Calculate based on the number of treated patients, market share, and pricing at peak adoption (typically 5-7 years post-launch).
7. **1% Share Value:** Calculate the revenue associated with 1% of treated patients in each geography.

## **Step 2: Estimate Patient Population**

Metastatic pancreatic cancer has a relatively low incidence but high mortality, with a significant proportion of patients diagnosed at an advanced stage. Below are rough estimates of first-line metastatic pancreatic cancer patients based on incidence data and the proportion of metastatic cases (approximately 50-60% of pancreatic cancer cases are metastatic at diagnosis):

- **US:** ~60,000 new pancreatic cancer cases/year; ~30,000 metastatic; ~25,000 eligible for first-line treatment.
- **EU5:** ~80,000 new cases/year; ~40,000 metastatic; ~35,000 eligible for first-line treatment.
- **China:** ~120,000 new cases/year; ~60,000 metastatic; ~50,000 eligible for first-line treatment.
- **Japan:** ~40,000 new cases/year; ~20,000 metastatic; ~18,000 eligible for first-line treatment.

These numbers are approximate and based on cancer epidemiology data from sources like GLOBOCAN and local health statistics. Adjust these based on more precise data if available.

## **Step 3: Estimate Pricing**

Onivyde is a specialty oncology drug, often priced high due to its targeted nature and liposomal formulation. Pricing varies significantly by region due to healthcare systems and reimbursement policies:

- **US:** ~\$100,000–\$120,000 per patient per year (based on typical costs for oncology drugs like liposomal formulations).

- **EU5:** ~\$60,000–\$80,000 per patient per year (lower due to price negotiations and universal healthcare).
- **China:** ~\$30,000–\$50,000 per patient per year (lower due to pricing controls and generics competition).
- **Japan:** ~\$70,000–\$90,000 per patient per year (similar to EU5 but with specific pricing mechanisms).

These are rough estimates and can vary based on treatment duration, combination therapy costs, and local pricing agreements.

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

Peak sales are calculated as:

**Peak Sales = Number of Eligible Patients × Market Share × Annual Cost per Patient**

Using the mid-point of the 20%-30% market share range (25%) for simplicity:

### **#### US**

- Eligible Patients: 25,000
- Market Share: 25% → 6,250 treated patients
- Annual Cost: \$110,000
- Peak Sales:  $6,250 \times \$110,000 = \text{\$687.5 million}$

### **#### EU5**

- Eligible Patients: 35,000
- Market Share: 25% → 8,750 treated patients
- Annual Cost: \$70,000
- Peak Sales:  $8,750 \times \$70,000 = \text{\$612.5 million}$

### **#### China**

- Eligible Patients: 50,000
- Market Share: 25% → 12,500 treated patients
- Annual Cost: \$40,000
- Peak Sales:  $12,500 \times \$40,000 = \text{\$500 million}$

### **#### Japan**

- Eligible Patients: 18,000
- Market Share: 25% → 4,500 treated patients
- Annual Cost: \$80,000
- Peak Sales:  $4,500 \times \$80,000 = \text{\$360 million}$

#### #### Total Peak Sales Across Geographies

- Total = \$687.5M (US) + \$612.5M (EU5) + \$500M (China) + \$360M (Japan) = **\$2,160 million** or **~\$2.16 billion**

#### #### Range of Peak Sales (20%-30% Market Share)

- At 20% share: ~\$1.73 billion
- At 30% share: ~\$2.59 billion

Thus, the Potential Peak Sales for irinotecan liposome in this indication across the specified geographies is approximately **\$1.7–\$2.6 billion**, with a midpoint of **\$2.16 billion**.

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

The value of 1% share of treated patients is calculated as:

**1% Share Value = Number of Eligible Patients × 1% × Annual Cost per Patient**

#### #### US

- Eligible Patients: 25,000
- 1% of Patients: 250
- Annual Cost: \$110,000
- 1% Share Value:  $250 \times \$110,000 = \textbf{\$27.5 million}$

#### #### EU5

- Eligible Patients: 35,000
- 1% of Patients: 350
- Annual Cost: \$70,000
- 1% Share Value:  $350 \times \$70,000 = \textbf{\$24.5 million}$

#### #### China

- Eligible Patients: 50,000
- 1% of Patients: 500
- Annual Cost: \$40,000
- 1% Share Value:  $500 \times \$40,000 = \textbf{\$20 million}$

#### #### Japan

- Eligible Patients: 18,000
- 1% of Patients: 180
- Annual Cost: \$80,000

- 1% Share Value:  $180 \times \$80,000 = \$14.4 \text{ million}$

## **Step 6: Summary of Results**

### **#### Potential Peak Sales (20%-30% Market Share)**

- **US:** \$550M–\$825M (midpoint \$687.5M)
- **EU5:** \$490M–\$735M (midpoint \$612.5M)
- **China:** \$400M–\$600M (midpoint \$500M)
- **Japan:** \$288M–\$432M (midpoint \$360M)
- **Total:** **\$1.73B–\$2.59B** (midpoint **\$2.16B**)

### **#### \$ Value of 1% Share of Treated Patients**

- **US:** \$27.5 million
- **EU5:** \$24.5 million
- **China:** \$20.0 million
- **Japan:** \$14.4 million

## **Caveats and Notes**

- **Patient Population:** The estimates for eligible patients are rough and based on general epidemiology data. Real numbers may differ based on local diagnosis rates, treatment access, and guidelines.
- **Pricing:** Drug pricing can vary widely due to negotiations, reimbursement policies, and competition (e.g., generics or biosimilars). The assumed costs are indicative.
- **Market Share:** The 20%-30% range assumes successful adoption, but actual uptake depends on clinical efficacy, safety profile, competition (e.g., FOLFIRINOX, gemcitabine-based regimens), and payer willingness.
- **Combination Therapy:** Onivyde is approved in combination with oxaliplatin, fluorouracil, and leucovorin, which may impact overall treatment costs and market share calculations.

If you have access to more specific data on patient numbers, pricing, or market dynamics, these calculations can be refined further. Let me know if you'd like to adjust any assumptions or dive deeper into a specific geography or aspect!