

To estimate the **Potential Peak Sales** for mirvetuximab soravtansine-gynx (Elahere) in the specified indication (FR $\alpha$ -positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer) across the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **\$ value of a 1% share of treated patients**, we need to follow a structured approach. Since exact data (e.g., patient population, pricing, and market penetration) may not be fully available, I will make reasonable assumptions based on publicly available information, epidemiology data, and typical pricing for oncology drugs. I'll also outline the methodology for clarity.

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

The indication is for adult patients with **FR $\alpha$ -positive, platinum-resistant epithelial ovarian, fallopian tube, or primary peritoneal cancer** who have received 1–3 prior systemic treatments. Key points:

- **Ovarian cancer incidence:** Epithelial ovarian cancer (EOC) is the most common type of ovarian cancer, accounting for ~90% of cases. Fallopian tube and primary peritoneal cancers are often grouped with EOC due to similar treatment approaches.
- **Platinum-resistant population:** Platinum resistance is defined as disease progression within 6 months of platinum-based therapy. This subgroup represents ~20–30% of recurrent ovarian cancer patients.
- **FR $\alpha$ -positive:** Studies suggest that ~35–40% of ovarian cancer patients express high levels of folate receptor alpha (FR $\alpha$ ), making them eligible for mirvetuximab soravtansine-gynx.
- **Prior treatments:** Patients with 1–3 prior lines of therapy are typically in the recurrent setting, which narrows the population further.

### #### Estimated Incidence and Eligible Population

Using epidemiology data (e.g., GLOBOCAN, SEER, and local cancer registries), we can estimate the annual incidence of ovarian cancer and derive the eligible population for this drug.

#### 1. **US:**

- Annual incidence of ovarian cancer: ~19,000 cases (SEER data).
- Recurrent cases: ~70% of patients relapse after initial treatment (~13,300).
- Platinum-resistant: ~25% of recurrent cases (~3,325).
- FR $\alpha$ -positive: ~40% of platinum-resistant (~1,330).
- Eligible after 1–3 prior therapies: Assume ~80% (~1,064 patients).

#### 2. **EU5** (Germany, France, Italy, Spain, UK):

- Annual incidence: ~30,000 cases (combined, based on GLOBOCAN).
- Recurrent: ~70% (~21,000).
- Platinum-resistant: ~25% (~5,250).
- FR $\alpha$ -positive: ~40% (~2,100).
- Eligible: ~80% (~1,680 patients).

### 3. Japan:

- Annual incidence: ~13,000 cases.
- Recurrent: ~70% (~9,100).
- Platinum-resistant: ~25% (~2,275).
- FR $\alpha$ -positive: ~40% (~910).
- Eligible: ~80% (~728 patients).

### 4. China:

- Annual incidence: ~55,000 cases (higher due to population size, GLOBOCAN).
- Recurrent: ~70% (~38,500).
- Platinum-resistant: ~25% (~9,625).
- FR $\alpha$ -positive: ~40% (~3,850).
- Eligible: ~80% (~3,080 patients).

### Total Eligible Population Across Geographies:

- US: ~1,064
- EU5: ~1,680
- Japan: ~728
- China: ~3,080
- **Total:** ~6,552 patients annually.

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## **Step 2: Estimate Market Share (20%–30% of Treated Patients)**

The question assumes a **20%–30% share of treated patients**. Given that not all eligible patients may receive the drug due to factors like physician preference, access, or reimbursement, I'll assume the drug captures **25%** as the midpoint of the range.

### - **Treated Patients** (25% of eligible):

- US:  $1,064 \times 0.25 = \sim 266$  patients
- EU5:  $1,680 \times 0.25 = \sim 420$  patients
- Japan:  $728 \times 0.25 = \sim 182$  patients
- China:  $3,080 \times 0.25 = \sim 770$  patients
- **Total Treated:** ~1,638 patients annually.

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### **Step 3: Estimate Drug Pricing**

Mirvetuximab soravtansine-gynx is a targeted antibody-drug conjugate (ADC) for a rare oncology indication, so pricing will be high, in line with other ADCs or novel cancer therapies.

- **US Pricing:** Based on reports and pricing for similar drugs (e.g., ADCs like Enhertu or Trodelvy), the annual cost per patient is estimated at ~\$150,000–\$200,000. Assume **\$180,000/year**.

- **EU5 Pricing:** Typically 20–30% lower than the US due to healthcare system negotiations. Assume **\$135,000/year**.

- **Japan Pricing:** Similar to EU5, assume **\$135,000/year**.

- **China Pricing:** Significantly lower due to market access challenges and local pricing policies. Assume **\$50,000/year** (reflecting discounts or tiered pricing).

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

Peak sales are calculated as **number of treated patients × annual cost per patient** in each geography.

1. **US:**

- 266 patients × \$180,000 = **\$47.9 million**

2. **EU5:**

- 420 patients × \$135,000 = **\$56.7 million**

3. **Japan:**

- 182 patients × \$135,000 = **\$24.6 million**

4. **China:**

- 770 patients × \$50,000 = **\$38.5 million**

**Total Potential Peak Sales:** \$47.9M + \$56.7M + \$24.6M + \$38.5M = **\$167.7 million annually** (at 25% market share).

- **Range for 20%–30% share:**

- At 20% share: Total treated patients = 1,310 → Peak sales = **\$134.2 million**.

- At 30% share: Total treated patients = 1,966 → Peak sales = **\$201.2 million**.

Thus, **Potential Peak Sales Range: \$134 million to \$201 million annually**, with a midpoint of **~\$167 million**.

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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 eligible population being treated with the drug.

- **Eligible Population:** 6,552 patients.

- **1% of Eligible Population:**  $6,552 \times 0.01 = \sim 66$  patients.

Now calculate the revenue for these 66 patients across geographies (weighted by population distribution and pricing):

1. **US:**  $(1,064/6,552) \times 66 = \sim 11$  patients  $\times \$180,000 = \mathbf{\$1.98 \text{ million}}$

2. **EU5:**  $(1,680/6,552) \times 66 = \sim 17$  patients  $\times \$135,000 = \mathbf{\$2.30 \text{ million}}$

3. **Japan:**  $(728/6,552) \times 66 = \sim 7$  patients  $\times \$135,000 = \mathbf{\$0.95 \text{ million}}$

4. **China:**  $(3,080/6,552) \times 66 = \sim 31$  patients  $\times \$50,000 = \mathbf{\$1.55 \text{ million}}$

**Total \$ Value of 1% Share:**  $\$1.98\text{M} + \$2.30\text{M} + \$0.95\text{M} + \$1.55\text{M} = \mathbf{\$6.78 \text{ million.}}$

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## **Final Answer**

1. **Potential Peak Sales for Mirvetuximab Soravtansine-gynx** (at 20%–30% market share):

- Range: **\$134 million to \$201 million annually**

- Midpoint (25% share): **\$167 million annually**

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

- **\$6.78 million annually**

## **Caveats and Assumptions**

- Patient population estimates are based on approximate epidemiology data and may vary based on local diagnostic rates, FR $\alpha$  testing penetration, and access to prior therapies.

- Pricing assumptions are based on comparable oncology drugs and may differ based on reimbursement, discounts, or local policies (especially in China).

- Market share of 20%–30% is assumed as per the question, but actual penetration depends on competition (e.g., other ADCs or therapies in development) and clinical uptake.

- Peak sales assume steady-state adoption and do not account for patent cliffs or generics/biosimilars.

If more specific data (e.g., exact pricing or updated epidemiology) is available, these estimates can be refined further.