

To estimate the **Potential Peak Sales** for pafolacianine (Cytalux) in the indication of ovarian cancer 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 specific data on pricing, patient population, and market penetration may not be fully available, I will outline the methodology and make reasonable assumptions based on publicly available data and typical market dynamics for oncology drugs. Let's break this down step by step.

Step 1: Key Assumptions

1. **Indication:** Pafolacianine is approved for intraoperative identification of malignant lesions in ovarian cancer patients. It is not a therapeutic drug but an imaging agent used during surgery.
2. **Market Share:** The problem assumes a 20% to 30% share of treated patients. We will calculate potential peak sales using this range.
3. **Patient Population:** We will estimate the number of ovarian cancer patients undergoing surgery in each geography.
4. **Pricing:** As an imaging agent, pafolacianine is likely priced lower than therapeutic drugs but higher than standard imaging agents due to its targeted nature. A reasonable price per dose could range from \$2,000 to \$5,000 per procedure (based on pricing of similar intraoperative imaging agents like indocyanine green or other fluorescent dyes).
5. **Frequency of Use:** Assume one dose per surgical procedure (most patients will likely receive it once per surgery).

Step 2: Estimate Ovarian Cancer Surgical Cases (Treated Population)

Ovarian cancer incidence and the proportion of patients undergoing surgery vary by region. Below are approximate annual incidence numbers and surgical rates:

- US:

- Annual incidence: ~22,000 cases (American Cancer Society, 2023 estimate).
- ~60-70% undergo surgery (debulking or staging surgery): ~13,000 to 15,000 surgeries.

- EU5 (France, Germany, Italy, Spain, UK):

- Annual incidence: ~45,000 cases (combined estimate from European Cancer Information System).
- ~60-70% undergo surgery: ~27,000 to 31,500 surgeries.

- China:

- Annual incidence: ~55,000 cases (GLOBOCAN 2020 estimate).
- ~50-60% undergo surgery (lower access to advanced care in some regions): ~27,500 to 33,000 surgeries.

- Japan:

- Annual incidence: ~13,000 cases (GLOBOCAN 2020 estimate).
- ~60-70% undergo surgery: ~7,800 to 9,100 surgeries.

Total Treated Population (Surgical Cases):

- US: ~14,000 (midpoint)
- EU5: ~29,250 (midpoint)
- China: ~30,250 (midpoint)
- Japan: ~8,450 (midpoint)
- **Total across geographies:** ~82,000 surgeries annually.

Step 3: Estimate Market Share (20%-30% of Treated Patients)

Using the assumed market share of 20% to 30%:

- 20% share:

- US: 2,800 patients
- EU5: 5,850 patients
- China: 6,050 patients
- Japan: 1,690 patients
- Total: 16,390 patients

- 30% share:

- US: 4,200 patients
- EU5: 8,775 patients
- China: 9,075 patients
- Japan: 2,535 patients
- Total: 24,585 patients

Step 4: Estimate Pricing per Dose

Pricing for pafolacianine is not publicly disclosed, but based on similar intraoperative imaging agents (e.g., indocyanine green or other fluorescence-guided surgery tools), we can estimate:

- **US:** \$3,500 per dose (higher due to healthcare costs).
- **EU5:** \$3,000 per dose (slightly lower due to pricing controls).
- **China:** \$1,500 per dose (lower due to cost sensitivity and pricing regulations).

- **Japan:** \$2,500 per dose (moderate pricing due to advanced healthcare system but cost controls).

Step 5: Calculate Potential Peak Sales

Peak sales are calculated as: (Number of treated patients at given market share) × (Price per dose).

At 20% Market Share:

- **US:** 2,800 patients × \$3,500 = **\$9.8 million**
- **EU5:** 5,850 patients × \$3,000 = **\$17.55 million**
- **China:** 6,050 patients × \$1,500 = **\$9.075 million**
- **Japan:** 1,690 patients × \$2,500 = **\$4.225 million**
- **Total Peak Sales (20%): \$40.65 million**

At 30% Market Share:

- **US:** 4,200 patients × \$3,500 = **\$14.7 million**
- **EU5:** 8,775 patients × \$3,000 = **\$26.325 million**
- **China:** 9,075 patients × \$1,500 = **\$13.6125 million**
- **Japan:** 2,535 patients × \$2,500 = **\$6.3375 million**
- **Total Peak Sales (30%): \$60.975 million**

Range of Potential Peak Sales: \$40.65 million to \$60.975 million annually across the specified geographies.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

A 1% share of treated patients is calculated as 1% of the total surgical cases in each geography multiplied by the price per dose.

- **US:** 1% of 14,000 = 140 patients × \$3,500 = **\$0.49 million (\$490,000)**
- **EU5:** 1% of 29,250 = 292.5 patients × \$3,000 = **\$0.8775 million (\$877,500)**
- **China:** 1% of 30,250 = 302.5 patients × \$1,500 = **\$0.45375 million (\$453,750)**
- **Japan:** 1% of 8,450 = 84.5 patients × \$2,500 = **\$0.21125 million (\$211,250)**
- **Total Value of 1% Share: \$2.0325 million (\$2,032,500)**

Final Answer

1. Potential Peak Sales for Pafolacianine (20%-30% market share):

- **US:** \$9.8M - \$14.7M
- **EU5:** \$17.55M - \$26.325M
- **China:** \$9.075M - \$13.6125M
- **Japan:** \$4.225M - \$6.3375M
- **Total: \$40.65M - \$60.975M annually**

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

- **US:** \$490,000
- **EU5:** \$877,500
- **China:** \$453,750
- **Japan:** \$211,250
- **Total: \$2,032,500**

Notes and Caveats

- These estimates are based on assumptions for pricing and surgical rates. Actual pricing for pafolacianine may differ based on negotiations, reimbursement policies, and market access.
- Market penetration (20%-30%) assumes competition from other imaging agents or techniques and adoption rates by surgeons.
- The patient population may vary based on updated epidemiology data or differences in surgical practices across regions.
- Additional costs (e.g., imaging system requirements) or bundled pricing could impact the final revenue.
- If you have access to specific pricing or market data for pafolacianine, these figures can be refined accordingly.