

To estimate the **Potential Peak Sales** for lurbinectedin (Zepzelca) in the indication of metastatic small cell lung cancer (SCLC) with disease progression on or after platinum-based chemotherapy 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 based on available data, assumptions, and market analysis. Since exact figures (e.g., patient population, pricing, and penetration rates) are not provided, I will use reasonable estimates and assumptions grounded in publicly available information and typical market dynamics for oncology drugs. Let's break this down step by step.

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## **Step 1: Key Assumptions and Data Points**

1. **Indication and Patient Population:** Lurbinectedin is approved for second-line treatment of metastatic SCLC in patients who have progressed on or after platinum-based chemotherapy. This is a relatively niche population within SCLC, as many patients do not respond to first-line therapy or relapse.

2. **Epidemiology of SCLC:**

- SCLC accounts for ~15% of all lung cancer cases.
- A significant proportion of SCLC patients are diagnosed at an advanced or metastatic stage (~70-80%).
- Of these, a subset progresses after first-line platinum-based chemotherapy (estimated at ~60-70% of metastatic SCLC patients).

3. **Market Share Assumption:** The query assumes a 20-30% share of treated patients for lurbinectedin. We will use the midpoint of 25% for peak sales calculations.

4. **Pricing:** Lurbinectedin is a high-cost oncology drug. Based on reports, the annual cost of treatment in the US is approximately \$150,000–\$200,000 per patient (using \$175,000 as an average). Pricing in other regions is typically lower due to healthcare system differences (e.g., ~60-70% of US pricing in EU5, ~40-50% in Japan, and ~20-30% in China due to pricing controls and negotiations).

5. **Treatment Duration:** Average treatment duration for second-line SCLC therapies is often around 4-6 months, but for simplicity, we assume annual cost reflects full-year pricing for eligible patients (common in peak sales models).

6. **Patient Pool Estimation:** We will estimate the number of eligible patients (metastatic SCLC patients failing first-line therapy) in each geography based on lung cancer incidence and SCLC proportions.

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

Below are rough estimates of the eligible patient population for second-line metastatic SCLC therapy in each geography. These are based on lung cancer incidence data (e.g., from WHO, GLOBOCAN, and national cancer registries), assuming SCLC is 15% of lung cancer cases, 75% are metastatic at diagnosis, and 65% fail first-line therapy.

- **US:**

- Lung cancer incidence: ~230,000 cases/year.
- SCLC: ~34,500 cases (15%).
- Metastatic SCLC: ~26,000 (75%).
- Eligible for second-line (post-platinum failure): ~17,000 (65%).

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

- Lung cancer incidence: ~320,000 cases/year.
- SCLC: ~48,000 cases (15%).
- Metastatic SCLC: ~36,000 (75%).
- Eligible for second-line: ~23,500 (65%).

**- China:**

- Lung cancer incidence: ~820,000 cases/year.
- SCLC: ~123,000 cases (15%).
- Metastatic SCLC: ~92,000 (75%).
- Eligible for second-line: ~60,000 (65%).

**- Japan:**

- Lung cancer incidence: ~130,000 cases/year.
- SCLC: ~19,500 cases (15%).
- Metastatic SCLC: ~14,500 (75%).
- Eligible for second-line: ~9,500 (65%).

**Total Eligible Patients Across Geographies:** ~17,000 (US) + 23,500 (EU5) + 60,000 (China) + 9,500 (Japan) = **110,000 patients.**

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### **Step 3: Estimate Treated Patients with Lurbinectedin (25% Market Share)**

Using the assumed 25% market share of treated patients:

- **US:**  $17,000 \times 25\% = 4,250$  patients.
- **EU5:**  $23,500 \times 25\% = 5,875$  patients.
- **China:**  $60,000 \times 25\% = 15,000$  patients.
- **Japan:**  $9,500 \times 25\% = 2,375$  patients.
- **Total Treated Patients:**  $4,250 + 5,875 + 15,000 + 2,375 = 27,500$  patients.

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## **Step 4: Estimate Annual Pricing per Patient by Geography**

- **US:** \$175,000 per patient/year.
- **EU5:** ~65% of US pricing = \$113,750 per patient/year.
- **China:** ~25% of US pricing = \$43,750 per patient/year (reflecting significant price reductions due to government negotiations).
- **Japan:** ~50% of US pricing = \$87,500 per patient/year (based on typical pricing in Japan for oncology drugs).

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## **Step 5: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each geography:

- **US:** 4,250 patients × \$175,000 = **\$743.75 million**.
- **EU5:** 5,875 patients × \$113,750 = **\$668.28 million**.
- **China:** 15,000 patients × \$43,750 = **\$656.25 million**.
- **Japan:** 2,375 patients × \$87,500 = **\$207.81 million**.
- **Total Peak Sales:** \$743.75M + \$668.28M + \$656.25M + \$207.81M = **\$2,276.09 million** (~\$2.28 billion).

Thus, the **Potential Peak Sales** for lurbinectedin in this indication across the US, EU5, China, and Japan, assuming a 25% market share, is approximately **\$2.28 billion annually**.

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

A 1% share of treated patients corresponds to 1% of the eligible patient pool in each geography. We calculate the revenue generated by treating 1% of eligible patients at the respective pricing:

- **US:** 17,000 × 1% = 170 patients; 170 × \$175,000 = **\$29.75 million**.
- **EU5:** 23,500 × 1% = 235 patients; 235 × \$113,750 = **\$26.73 million**.
- **China:** 60,000 × 1% = 600 patients; 600 × \$43,750 = **\$26.25 million**.
- **Japan:** 9,500 × 1% = 95 patients; 95 × \$87,500 = **\$8.31 million**.
- **Total \$ Value of 1% Share:** \$29.75M + \$26.73M + \$26.25M + \$8.31M = **\$91.04 million**.

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$91 million**.

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## **Final Answer**

- **Potential Peak Sales for Lurbinectedin** (assuming 25% market share of treated patients) in the US, EU5, China, and Japan: **\$2.28 billion annually**.

- **\$ Value of 1% Share of Treated Patients** in these geographies: **\$91 million**.

**Note:** These estimates are based on assumptions and should be validated with more precise epidemiological data, real-world pricing, treatment duration, and market access dynamics. Factors such as competition (e.g., other second-line therapies like topotecan or immunotherapy), reimbursement challenges, and regional variations in treatment uptake could impact these figures. If you have specific data or additional context, I can refine the analysis further.