

To estimate the **Potential Peak Sales** for **amivantamab-vmjw (Rybrevant)** in the specified indication (locally advanced or metastatic non-small cell lung cancer [NSCLC] with EGFR exon 20 insertion mutations, post-platinum-based chemotherapy) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, and to calculate the **\$ value of a 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 might not be fully available, I will outline the methodology and provide reasonable assumptions based on publicly available data and industry standards. The final numbers are illustrative and should be validated with more precise data if available.

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

- **Indication:** Locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations, progressed on or after platinum-based chemotherapy.

- **Epidemiology:**

- NSCLC accounts for ~85% of all lung cancer cases.
- EGFR mutations are present in ~15-20% of NSCLC cases in Western populations (US, EU5) and ~30-40% in Asian populations (China, Japan).
- EGFR exon 20 insertion mutations specifically account for ~4-10% of all EGFR-mutated NSCLC cases (i.e., ~0.6-2% of total NSCLC cases).
- Of these, we focus on patients with advanced/metastatic disease who have progressed on platinum-based chemotherapy (second-line or later).

#### Estimated NSCLC Incidence (2023, approximate numbers):

- **US:** ~200,000 new lung cancer cases; ~170,000 NSCLC; ~1,000-3,400 EGFR exon 20 insertion cases.
- **EU5:** ~300,000 new lung cancer cases; ~255,000 NSCLC; ~1,500-5,100 EGFR exon 20 insertion cases.
- **China:** ~800,000 new lung cancer cases; ~680,000 NSCLC; ~8,000-27,000 EGFR exon 20 insertion cases (higher EGFR mutation prevalence).
- **Japan:** ~120,000 new lung cancer cases; ~102,000 NSCLC; ~1,200-4,000 EGFR exon 20 insertion cases.

#### Eligible Patients (Post-Platinum Chemotherapy):

Assuming ~50-60% of NSCLC patients with EGFR exon 20 insertions reach second-line treatment (advanced/metastatic and progressed on first-line therapy), the approximate eligible patient pool is:

- **US:** ~500-2,000 patients.
- **EU5:** ~750-3,000 patients.
- **China:** ~4,000-13,500 patients.
- **Japan:** ~600-2,400 patients.
- **Total:** ~5,850-20,900 patients across these geographies.

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## **Step 2: Assume Market Share of Treated Patients**

The problem states a **20-30% share of treated patients**. This likely refers to the proportion of eligible patients who will receive amivantamab-vmjw. We will use the midpoint of **25%** for calculations.

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

- **US:** 125-500 patients.
- **EU5:** 188-750 patients.
- **China:** 1,000-3,375 patients.
- **Japan:** 150-600 patients.
- **Total:** 1,463-5,225 patients.

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## **Step 3: Estimate Annual Cost of Treatment**

Amivantamab-vmjw (Rybrevant) is a novel bispecific antibody, and pricing for such targeted therapies in oncology is typically high. Based on available data:

- **US Price:** ~\$20,000-\$25,000 per month, or ~\$240,000-\$300,000 per year (assuming continuous treatment for ~12 months, though real-world duration may vary).
- **EU5 Price:** ~60-70% of US price due to pricing regulations; ~\$144,000-\$210,000 per year.
- **China Price:** ~40-50% of US price due to market access and pricing negotiations; ~\$96,000-\$150,000 per year.
- **Japan Price:** ~70-80% of US price; ~\$168,000-\$240,000 per year.

For simplicity, we use midpoint annual costs:

- **US:** \$270,000.
- **EU5:** \$177,000.
- **China:** \$123,000.
- **Japan:** \$204,000.

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## **Step 4: Calculate Potential Peak Sales (25% Market Share)**

Peak sales are calculated as: **Number of treated patients × Annual cost per patient.**

- **US:** 125-500 patients × \$270,000 = **\$33.8M - \$135M.**
- **EU5:** 188-750 patients × \$177,000 = **\$33.3M - \$132.8M.**

- **China:** 1,000-3,375 patients × \$123,000 = **\$123M - \$415.1M.**
- **Japan:** 150-600 patients × \$204,000 = **\$30.6M - \$122.4M.**
- **Total Peak Sales (Range): \$220.7M - \$805.3M.**

Using the midpoint of the patient range for a single estimate:

- **US:** 313 patients × \$270,000 = **\$84.5M.**
- **EU5:** 469 patients × \$177,000 = **\$83.0M.**
- **China:** 2,188 patients × \$123,000 = **\$269.1M.**
- **Japan:** 375 patients × \$204,000 = **\$76.5M.**
- **Total Peak Sales (Midpoint): \$513.1M.**

Thus, **Potential Peak Sales** for amivantamab-vmjw in this indication across the US, EU5, China, and Japan, assuming a 25% market share, is approximately **\$513M per year**, with a range of **\$221M - \$805M** based on low and high patient estimates.

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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 patient pool being treated with amivantamab-vmjw.

- **Eligible Patients per 1% Share:**
- **US:** 5-20 patients (1% of 500-2,000).
- **EU5:** 7.5-30 patients (1% of 750-3,000).
- **China:** 40-135 patients (1% of 4,000-13,500).
- **Japan:** 6-24 patients (1% of 600-2,400).
- **\$ Value of 1% Share** (using midpoint patient numbers and annual cost):
- **US:** 12.5 patients × \$270,000 = **\$3.4M.**
- **EU5:** 18.75 patients × \$177,000 = **\$3.3M.**
- **China:** 87.5 patients × \$123,000 = **\$10.8M.**
- **Japan:** 15 patients × \$204,000 = **\$3.1M.**
- **Total \$ Value of 1% Share: \$20.6M.**

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$20.6M per year**.

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## **Final Answer:**

1. **Potential Peak Sales** for amivantamab-vmjw in the specified indication, assuming a 20-30% market share (midpoint 25%), across the US, EU5, China, and Japan:

- **Approximately \$513M per year** (range: \$221M - \$805M).

2. **\$ Value of 1% Share of Treated Patients** across the same geographies:

- **Approximately \$20.6M per year.**

**Note:** These estimates are based on assumptions regarding patient population, market share, and pricing. Real-world factors such as competition (e.g., other EGFR-targeted therapies), reimbursement policies, treatment duration, and market access timelines could significantly impact these figures. For precise calculations, primary data on epidemiology, pricing, and market dynamics should be obtained.