

To calculate 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 19 deletions or exon 21 L858R mutations, post-EGFR TKI progression) in the US, EU5 (Germany, France, 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. This involves estimating the target patient population, treatment rates, pricing, and market share assumptions. Since exact data may not be publicly available, I will use reasonable assumptions based on industry standards, epidemiology, and market research insights. All figures are approximate and should be validated with primary data if available.

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## **Step 1: Define the Indication and Target Population**

- **Indication:** Amivantamab-vmjw is approved for adult patients with locally advanced or metastatic NSCLC with EGFR exon 19 deletions or exon 21 L858R mutations, whose disease has progressed after treatment with an EGFR tyrosine kinase inhibitor (TKI).

- **Epidemiology:**

- EGFR mutations occur in ~15-20% of NSCLC patients in Western populations (US, EU5) and ~30-40% in Asian populations (China, Japan).
- Of these, exon 19 deletions and exon 21 L858R mutations account for ~85-90% of EGFR mutations.
- A subset of these patients will progress after first-line EGFR TKI therapy (e.g., osimertinib, gefitinib, erlotinib), making them eligible for amivantamab-vmjw.
- NSCLC incidence (new cases per year) and prevalence (total patients living with the disease) vary by region. We will focus on prevalence for peak sales estimation, as it reflects the total addressable market at a given time.

### #### Estimated Prevalence of NSCLC and Target Population

Using approximate NSCLC prevalence and mutation rates:

- **US:** ~225,000 new NSCLC cases/year; prevalence ~600,000 patients. EGFR mutations: ~18% (108,000 patients). Exon 19/21: ~90% (97,200). Post-TKI progression: ~50-60% (assume 50%, so ~48,600 patients).
- **EU5:** ~300,000 new NSCLC cases/year; prevalence ~800,000 patients. EGFR mutations: ~15% (120,000). Exon 19/21: ~90% (108,000). Post-TKI progression: ~50% (54,000 patients).
- **China:** ~800,000 new NSCLC cases/year; prevalence ~2,000,000 patients. EGFR mutations: ~35% (700,000). Exon 19/21: ~90% (630,000). Post-TKI progression: ~50% (315,000 patients).
- **Japan:** ~125,000 new NSCLC cases/year; prevalence ~300,000 patients. EGFR mutations: ~35% (105,000). Exon 19/21: ~90% (94,500). Post-TKI progression: ~50% (47,250 patients).

Total target population (eligible for amivantamab-vmjw):

- US: ~48,600 patients
- EU5: ~54,000 patients
- China: ~315,000 patients

- Japan: ~47,250 patients
- **Total across geographies:** ~464,850 patients

#### #### Treatment Rate

Not all eligible patients receive treatment due to access issues, comorbidities, or patient/physician choice. Assume:

- US/EU5/Japan: ~70% of eligible patients treated.
- China: ~50% of eligible patients treated (due to access and cost barriers).

Treated population:

- US:  $48,600 \times 70\% = \sim 34,000$  patients
- EU5:  $54,000 \times 70\% = \sim 37,800$  patients
- China:  $315,000 \times 50\% = \sim 157,500$  patients
- Japan:  $47,250 \times 70\% = \sim 33,075$  patients
- **Total treated patients:** ~262,375 patients

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## **Step 2: Market Share Assumption**

The query assumes a **20-30% share of treated patients** for amivantamab-vmjw. We will calculate peak sales for this range and use the midpoint (25%) for a baseline estimate.

Treated patients receiving amivantamab-vmjw (at 25% share):

- US:  $34,000 \times 25\% = 8,500$  patients
- EU5:  $37,800 \times 25\% = 9,450$  patients
- China:  $157,500 \times 25\% = 39,375$  patients
- Japan:  $33,075 \times 25\% = 8,269$  patients
- **Total:** ~65,594 patients

For 20% share: ~52,475 patients

For 30% share: ~78,713 patients

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## **Step 3: Pricing Assumption**

Amivantamab-vmjw is a targeted biologic therapy, and pricing for such drugs in oncology is high, especially in the US. Based on publicly available data and analogs (e.g., other NSCLC therapies like osimertinib):

- **US:** ~\$20,000/month per patient; annual cost ~\$240,000 (assuming 12 months of treatment).
- **EU5:** ~\$12,000/month; annual cost ~\$144,000 (lower due to pricing negotiations).
- **Japan:** ~\$15,000/month; annual cost ~\$180,000.
- **China:** ~\$5,000/month; annual cost ~\$60,000 (reflecting lower pricing due to market dynamics and reimbursement challenges).

Note: Duration of treatment may vary (e.g., 6-12 months or until progression), but for simplicity, we assume a full year for peak sales estimation.

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

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

#### At 25% Market Share

- **US:** 8,500 patients × \$240,000 = **\$2.04 billion**
- **EU5:** 9,450 patients × \$144,000 = **\$1.36 billion**
- **China:** 39,375 patients × \$60,000 = **\$2.36 billion**
- **Japan:** 8,269 patients × \$180,000 = **\$1.49 billion**
- **Total Peak Sales (25% share): \$7.25 billion**

#### At 20% Market Share

- **US:** 6,800 patients × \$240,000 = **\$1.63 billion**
- **EU5:** 7,560 patients × \$144,000 = **\$1.09 billion**
- **China:** 31,500 patients × \$60,000 = **\$1.89 billion**
- **Japan:** 6,615 patients × \$180,000 = **\$1.19 billion**
- **Total Peak Sales (20% share): \$5.80 billion**

#### At 30% Market Share

- **US:** 10,200 patients × \$240,000 = **\$2.45 billion**
- **EU5:** 11,340 patients × \$144,000 = **\$1.63 billion**
- **China:** 47,250 patients × \$60,000 = **\$2.84 billion**
- **Japan:** 9,923 patients × \$180,000 = **\$1.79 billion**
- **Total Peak Sales (30% share): \$8.71 billion**

**Potential Peak Sales Range (20-30% share): \$5.8 billion to \$8.71 billion annually**, with a midpoint of ~\$7.25 billion at 25% share.

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

A 1% share of treated patients corresponds to 1% of the total treated population (~262,375 patients), which is ~2,624 patients.

Calculate revenue for 1% share:

- **US:**  $(34,000 \times 1\%) \times \$240,000 = 340 \text{ patients} \times \$240,000 = \text{\$81.6 million}$
- **EU5:**  $(37,800 \times 1\%) \times \$144,000 = 378 \text{ patients} \times \$144,000 = \text{\$54.4 million}$
- **China:**  $(157,500 \times 1\%) \times \$60,000 = 1,575 \text{ patients} \times \$60,000 = \text{\$94.5 million}$
- **Japan:**  $(33,075 \times 1\%) \times \$180,000 = 331 \text{ patients} \times \$180,000 = \text{\$59.6 million}$
- **Total \$ Value of 1% Share: \$290.1 million**

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## **Final Answer**

- **Potential Peak Sales for Amivantamab-vmjw (20-30% share of treated patients):**

- Range: **\$5.8 billion to \$8.71 billion annually**

- Midpoint (25% share): **\$7.25 billion annually**

- Breakdown by region (at 25% share):

- US: \$2.04 billion

- EU5: \$1.36 billion

- China: \$2.36 billion

- Japan: \$1.49 billion

- **\$ Value of 1% Share of Treated Patients: \$290.1 million annually**

- Breakdown by region:

- US: \$81.6 million

- EU5: \$54.4 million

- China: \$94.5 million

- Japan: \$59.6 million

**Caveats:** These estimates are based on assumptions for epidemiology, treatment rates, pricing, and market share. Real-world factors such as competition (e.g., other therapies for EGFR-mutant NSCLC), reimbursement, and patient adherence may impact these figures. For precise calculations, primary market research and real-world data are recommended.