

To estimate the **Potential Peak Sales** for **amivantamab-vmjw (Rybrevant)** in the first-line treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) with EGFR exon 20 insertion mutations in 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 based on available epidemiology data, pricing assumptions, and market penetration rates. Since exact figures for treated patient populations, pricing, and penetration may not be publicly available for this specific indication and drug, I will outline a methodology and provide approximate values based on reasonable assumptions and publicly available data as of my last update (October 2023).

Step 1: Define the Target Patient Population

- **Indication:** First-line treatment for locally advanced or metastatic NSCLC with EGFR exon 20 insertion mutations.
- **Epidemiology:**
 - NSCLC accounts for ~85% of all lung cancer cases.
 - EGFR mutations are present in ~10-15% 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., ~0.4-1.5% of all NSCLC cases in Western populations and ~1.2-4% in Asian populations).
 - Incidence of lung cancer (2020 data from sources like GLOBOCAN):
 - **US:** ~228,000 new lung cancer cases/year → NSCLC (~194,000) → EGFR exon 20 insertions (~1,940-2,910 patients/year assuming 1-1.5% of NSCLC).
 - **EU5:** ~320,000 new lung cancer cases/year → NSCLC (~272,000) → EGFR exon 20 insertions (~2,720-4,080 patients/year).
 - **China:** ~820,000 new lung cancer cases/year → NSCLC (~697,000) → EGFR exon 20 insertions (~8,364-27,880 patients/year, assuming 1.2-4% of NSCLC).
 - **Japan:** ~138,000 new lung cancer cases/year → NSCLC (~117,000) → EGFR exon 20 insertions (~1,404-4,680 patients/year).
 - Total incident cases (newly diagnosed eligible for first-line treatment) across these geographies: ~14,428-39,448 patients/year.
 - Assuming only a fraction of these are diagnosed and treated (due to access, late-stage diagnosis, etc.), let's estimate **treated patients** as ~60-70% of incident cases: ~8,657-27,614 treated patients/year.

Step 2: Market Penetration (20-30% Share of Treated Patients)

- Given the assumption of a 20-30% share of treated patients, the number of patients treated with amivantamab-vmjw annually would be:
 - **Low end (20%):** $8,657 \times 0.2 = \sim 1,731$ patients/year.
 - **High end (30%):** $27,614 \times 0.3 = \sim 8,284$ patients/year.
- Distribute these across geographies based on incidence proportions (approximate):
 - **US:** ~20% of total treated → 346-1,657 patients/year.

- **EU5:** ~25% of total treated → 433-2,071 patients/year.
- **China:** ~40% of total treated → 692-3,314 patients/year.
- **Japan:** ~15% of total treated → 260-1,242 patients/year.

Step 3: Pricing and Treatment Cost

- **Annual Cost per Patient:** Amivantamab-vmjw (Rybrevant) is a targeted therapy administered intravenously. Based on pricing in the US for similar biologics and targeted therapies for NSCLC (e.g., osimertinib costs ~\$15,000-\$18,000/month), and initial reports of Rybrevant's cost, we can estimate:

- **US:** ~\$180,000-\$200,000/year per patient.
- **EU5:** ~\$100,000-\$120,000/year (lower due to price negotiations and healthcare systems).
- **China:** ~\$50,000-\$70,000/year (significant discounts due to market access programs and local pricing).
- **Japan:** ~\$120,000-\$140,000/year (similar to EU5 but with some variation).
- For simplicity, use midpoint estimates:
- US: \$190,000/year.
- EU5: \$110,000/year.
- China: \$60,000/year.
- Japan: \$130,000/year.

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as the number of treated patients × annual cost per patient in each geography, summed across all regions.

- **Low End (20% penetration, lower patient numbers):**

- US: 346 patients × \$190,000 = \$65.7M.
- EU5: 433 patients × \$110,000 = \$47.6M.
- China: 692 patients × \$60,000 = \$41.5M.
- Japan: 260 patients × \$130,000 = \$33.8M.
- **Total Peak Sales:** ~\$188.6M/year.

- **High End (30% penetration, higher patient numbers):**

- US: 1,657 patients × \$190,000 = \$314.8M.
- EU5: 2,071 patients × \$110,000 = \$227.8M.
- China: 3,314 patients × \$60,000 = \$198.8M.
- Japan: 1,242 patients × \$130,000 = \$161.5M.
- **Total Peak Sales:** ~\$902.9M/year.

Potential Peak Sales Range: Approximately **\$189M to \$903M per year** across the US, EU5, China, and Japan for this indication.

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

- Total treated patients across geographies: ~8,657-27,614 patients/year.
- 1% of treated patients:
- Low end: $8,657 \times 0.01 = \sim 87$ patients.
- High end: $27,614 \times 0.01 = \sim 276$ patients.
- Using the same geographic distribution and pricing as above:

- Low End (87 patients):

- US: 17 patients \times \$190,000 = \$3.2M.
- EU5: 22 patients \times \$110,000 = \$2.4M.
- China: 35 patients \times \$60,000 = \$2.1M.
- Japan: 13 patients \times \$130,000 = \$1.7M.
- **Total Value of 1% Share:** ~\$9.4M/year.

- High End (276 patients):

- US: 55 patients \times \$190,000 = \$10.5M.
- EU5: 69 patients \times \$110,000 = \$7.6M.
- China: 110 patients \times \$60,000 = \$6.6M.
- Japan: 42 patients \times \$130,000 = \$5.5M.
- **Total Value of 1% Share:** ~\$30.2M/year.

\$ Value of 1% Share of Treated Patients: Approximately **\$9.4M to \$30.2M per year** across the US, EU5, China, and Japan.

Key Assumptions and Limitations

1. **Epidemiology:** Estimates for EGFR exon 20 insertion mutations vary widely in literature, and diagnosis rates may differ by region.
2. **Pricing:** Costs are assumptions based on similar drugs; actual pricing for amivantamab-vmjw may differ, especially in China due to volume-based procurement policies.
3. **Market Penetration:** 20-30% share assumes competition from other therapies (e.g., mobocertinib, osimertinib off-label) and access barriers.
4. **Treatment Duration:** Assumes full-year treatment; real-world duration may be shorter due to progression or adverse events.

5. **Incident vs. Prevalent Cases:** Focused on incident cases (newly diagnosed first-line); prevalent cases could increase numbers if treatment extends beyond first-line in future indications.

Final Answer

- **Potential Peak Sales for amivantamab-vmjw** in the specified indication with 20-30% share of treated patients: **\$189M to \$903M per year** across the US, EU5, China, and Japan.

- **\$ Value of 1% Share of Treated Patients: \$9.4M to \$30.2M per year** across the same geographies.

These figures are rough estimates and should be refined with more precise epidemiology, pricing, and market access data specific to amivantamab-vmjw. If you have additional data or specific assumptions (e.g., exact pricing or patient numbers), I can adjust the calculations accordingly.