

To estimate the **Potential Peak Sales** for telisotuzumab vedotin-tlrv (Emrelis) in the specified indication (locally advanced or metastatic, non-squamous non-small cell lung cancer (NSCLC) with high c-Met protein overexpression in adults who have received prior systemic therapy) 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 will involve several assumptions and estimates due to the lack of specific, publicly available data on pricing, exact patient populations, and market penetration. Below is the methodology and calculation:

Step 1: Define the Target Patient Population

The indication is for **locally advanced or metastatic non-squamous NSCLC with high c-Met overexpression ($\geq 50\%$ of tumor cells with 3+ staining)** in patients who have received prior systemic therapy. Let's estimate the eligible patient population.

1.1. NSCLC Incidence and Non-Squamous Subtype

- **NSCLC** accounts for ~85% of all lung cancer cases.
- Non-squamous NSCLC represents ~70% of NSCLC cases.
- Annual incidence of lung cancer (2023 estimates based on public data):
- **US**: ~238,000 new cases (American Cancer Society).
- **EU5**: ~315,000 new cases (combined estimate based on GLOBOCAN 2020).
- **China**: ~815,000 new cases (GLOBOCAN 2020).
- **Japan**: ~125,000 new cases (GLOBOCAN 2020).
- Non-squamous NSCLC incidence (70% of NSCLC):
- US: $238,000 * 0.85 * 0.7 = \sim 141,600$ cases/year.
- EU5: $315,000 * 0.85 * 0.7 = \sim 187,400$ cases/year.
- China: $815,000 * 0.85 * 0.7 = \sim 485,200$ cases/year.
- Japan: $125,000 * 0.85 * 0.7 = \sim 74,400$ cases/year.

1.2. Advanced/Metastatic Stage

- Approximately 60% of NSCLC cases are diagnosed at an advanced or metastatic stage (Stage IIIB/IV).
- US: $141,600 * 0.6 = \sim 85,000$ patients/year.
- EU5: $187,400 * 0.6 = \sim 112,400$ patients/year.
- China: $485,200 * 0.6 = \sim 291,100$ patients/year.
- Japan: $74,400 * 0.6 = \sim 44,600$ patients/year.

1.3. High c-Met Overexpression ($\geq 50\%$ of tumor cells with 3+ staining)

- Studies suggest that c-Met overexpression occurs in ~25-50% of NSCLC patients, with high overexpression (3+ staining in $\geq 50\%$ of cells) in ~10-20% of cases. We'll assume **15%** for this calculation.

- US: $85,000 * 0.15 = \sim 12,750$ patients/year.

- EU5: $112,400 * 0.15 = \sim 16,860$ patients/year.

- China: $291,100 * 0.15 = \sim 43,665$ patients/year.

- Japan: $44,600 * 0.15 = \sim 6,690$ patients/year.

1.4. Second-Line or Later (Prior Systemic Therapy)

- The indication specifies patients who have received prior systemic therapy (second-line or later). Approximately 50-60% of advanced NSCLC patients progress to second-line therapy. We'll assume **55%**.

- US: $12,750 * 0.55 = \sim 7,013$ patients/year.

- EU5: $16,860 * 0.55 = \sim 9,273$ patients/year.

- China: $43,665 * 0.55 = \sim 24,016$ patients/year.

- Japan: $6,690 * 0.55 = \sim 3,680$ patients/year.

Total Eligible Patient Population (Annual Incident Cases):

- US: $\sim 7,013$ patients.

- EU5: $\sim 9,273$ patients.

- China: $\sim 24,016$ patients.

- Japan: $\sim 3,680$ patients.

- **Global (US+EU5+China+Japan):** $\sim 43,982$ patients/year.

Step 2: Market Share Assumption

The problem assumes a **20% to 30% share of treated patients**. This reflects the drug's market penetration among eligible patients, considering competition (e.g., other targeted therapies, immunotherapies like PD-1/PD-L1 inhibitors), physician adoption, and payer coverage. We'll calculate peak sales using both ends of the range and provide a midpoint estimate (25%).

Treated Patients at Peak Sales (25% Midpoint):

- US: $7,013 * 0.25 = \sim 1,753$ patients.

- EU5: $9,273 * 0.25 = \sim 2,318$ patients.

- China: $24,016 * 0.25 = \sim 6,004$ patients.

- Japan: $3,680 * 0.25 = \sim 920$ patients.

- **Total Treated Patients (Midpoint):** $\sim 11,000$ patients/year.

Step 3: Pricing Assumption

Telisotuzumab vedotin-tllv is a targeted antibody-drug conjugate (ADC), similar to drugs like trastuzumab deruxtecan (Enhertu) or sacituzumab govitecan (Trodelvy). Pricing for such therapies varies by region due to healthcare system differences.

- **US:** Annual cost for ADCs is typically \$150,000–\$200,000 per patient. Assume **\$180,000/year**.
- **EU5:** Pricing is lower due to negotiated discounts; assume ~60% of US price, or **\$108,000/year**.
- **Japan:** Pricing is similar to EU5, assume **\$108,000/year**.
- **China:** Pricing is significantly lower due to market access programs and local competition; assume ~30% of US price, or **\$54,000/year**.

(Note: These are rough estimates as exact pricing for telisotuzumab vedotin-tllv is not publicly available.)

Step 4: Potential Peak Sales Calculation

Peak sales are calculated as: **Number of Treated Patients * Annual Cost per Patient.**

At 25% Market Share (Midpoint):

- **US:** 1,753 patients * \$180,000 = **\$315.5 million**.
- **EU5:** 2,318 patients * \$108,000 = **\$250.3 million**.
- **China:** 6,004 patients * \$54,000 = **\$324.2 million**.
- **Japan:** 920 patients * \$108,000 = **\$99.4 million**.
- **Total Peak Sales (25% share): \$989.4 million/year.**

Range (20% to 30% Market Share):

- **At 20% Share:**

- US: 7,013 * 0.2 * \$180,000 = \$252.5 million.
- EU5: 9,273 * 0.2 * \$108,000 = \$200.3 million.
- China: 24,016 * 0.2 * \$54,000 = \$259.4 million.
- Japan: 3,680 * 0.2 * \$108,000 = \$79.5 million.
- **Total Peak Sales (20% share): \$791.7 million/year.**

- **At 30% Share:**

- US: 7,013 * 0.3 * \$180,000 = \$378.7 million.

- EU5: $9,273 * 0.3 * \$108,000 = \300.4 million.
- China: $24,016 * 0.3 * \$54,000 = \389.1 million.
- Japan: $3,680 * 0.3 * \$108,000 = \119.2 million.
- **Total Peak Sales (30% share): \$1,187.4 million/year.**

Potential Peak Sales Range: \$791.7 million to \$1,187.4 million per year, with a midpoint of **~\$990 million/year**.

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

A 1% share of treated patients corresponds to 1% of the eligible patient population being treated with telisotuzumab vedotin-tllv.

Eligible Patients per 1% Share:

- US: $7,013 * 0.01 = 70$ patients.
- EU5: $9,273 * 0.01 = 93$ patients.
- China: $24,016 * 0.01 = 240$ patients.
- Japan: $3,680 * 0.01 = 37$ patients.

Revenue from 1% Share (using regional pricing):

- US: $70 * \$180,000 = \12.6 million.
- EU5: $93 * \$108,000 = \10.0 million.
- China: $240 * \$54,000 = \13.0 million.
- Japan: $37 * \$108,000 = \4.0 million.
- **Total \$ Value of 1% Share: \$39.6 million/year.**

Final Answer

1. Potential Peak Sales for Telisotuzumab Vedotin-tllv (20% to 30% market share):

- **Range:** \$791.7 million to \$1,187.4 million per year.
- **Midpoint (25% share):** ~\$990 million per year.
- Breakdown by region (at 25% share):
- US: \$315.5 million.
- EU5: \$250.3 million.
- China: \$324.2 million.

- Japan: \$99.4 million.

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

- Total: \$39.6 million per year.

- Breakdown by region:

- US: \$12.6 million.

- EU5: \$10.0 million.

- China: \$13.0 million.

- Japan: \$4.0 million.

Caveats and Assumptions

- Patient population estimates are based on publicly available epidemiology data and assumptions about c-Met overexpression rates and second-line eligibility.

- Pricing is assumed based on comparable ADCs and regional pricing trends; actual pricing may differ.

- Market share assumptions (20-30%) are as provided, but real-world penetration depends on competition, clinical outcomes, and reimbursement.

- Peak sales assume steady-state adoption and do not account for launch ramp-up or patent expiry.

If more specific data (e.g., trial results, pricing, or updated epidemiology) becomes available, these estimates can be refined.