

To estimate the **Potential Peak Sales** for capmatinib (Tabrecta) in the indication of metastatic non-small cell lung cancer (NSCLC) with MET exon 14 skipping mutation 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. Since specific data on patient numbers, pricing, and market share may not be fully available, I will make reasonable assumptions based on publicly available data, epidemiology, and market trends for NSCLC and targeted therapies. I will outline the methodology and provide approximate figures.

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

Capmatinib is approved for metastatic NSCLC patients with MET exon 14 skipping mutation. This is a niche indication, as MET exon 14 skipping mutations occur in approximately **3-4% of NSCLC patients**.

Epidemiology of NSCLC and MET Exon 14 Skipping Mutation

- NSCLC Incidence (Annual New Cases):

- US: ~225,000 new cases/year (American Cancer Society)
- EU5: ~320,000 new cases/year (combined estimate based on GLOBOCAN data)
- China: ~780,000 new cases/year (high incidence due to smoking and pollution)
- Japan: ~125,000 new cases/year (GLOBOCAN data)
- **Metastatic NSCLC:** Approximately 50-60% of NSCLC cases are diagnosed at a metastatic stage (Stage IV).
- **MET Exon 14 Skipping Mutation:** ~3-4% of NSCLC patients have this mutation.

Estimated Eligible Patient Population (Metastatic NSCLC with MET Exon 14 Skipping)

Using the midpoint of 3.5% prevalence for MET exon 14 skipping and assuming 55% of NSCLC cases are metastatic:

- US: $225,000 * 0.55 * 0.035 = \sim 4,330$ patients/year
- EU5: $320,000 * 0.55 * 0.035 = \sim 6,160$ patients/year
- China: $780,000 * 0.55 * 0.035 = \sim 15,015$ patients/year
- Japan: $125,000 * 0.55 * 0.035 = \sim 2,406$ patients/year
- **Total Eligible Patients Across Geographies:** ~27,911 patients/year

****Step 2: Estimate Treated Patients (Market Penetration)****

Not all eligible patients will receive treatment due to factors like lack of diagnosis, access to testing, healthcare system barriers, or patient ineligibility for therapy. Assuming a **20-30% share of treated patients** among eligible patients (as per the question), we calculate the number of treated patients.

- 20% Share of Treated Patients:

- US: $4,330 * 0.20 = 866$ patients
- EU5: $6,160 * 0.20 = 1,232$ patients
- China: $15,015 * 0.20 = 3,003$ patients
- Japan: $2,406 * 0.20 = 481$ patients
- Total: ~5,582 treated patients

- 30% Share of Treated Patients:

- US: $4,330 * 0.30 = 1,299$ patients
- EU5: $6,160 * 0.30 = 1,848$ patients
- China: $15,015 * 0.30 = 4,505$ patients
- Japan: $2,406 * 0.30 = 722$ patients
- Total: ~8,374 treated patients

****Step 3: Estimate Annual Treatment Cost per Patient****

Capmatinib's pricing varies by geography due to differences in healthcare systems, pricing negotiations, and purchasing power. Based on available data for targeted therapies in NSCLC (e.g., osimertinib, crizotinib), I assume the following annual costs per patient (approximate figures for 2023):

- US: ~\$200,000/year (high pricing due to private insurance and lack of universal healthcare)
- EU5: ~\$120,000/year (lower due to government negotiations and price controls)
- China: ~\$50,000/year (significant price reductions due to national drug price negotiations and generics competition)
- Japan: ~\$150,000/year (high pricing but slightly below US levels due to national health insurance)

These are rough estimates and may vary based on actual pricing data, discounts, and patient assistance programs.

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

Peak sales are calculated by multiplying the number of treated patients by the annual treatment cost per patient for each geography.

Peak Sales at 20% Share of Treated Patients

- US: $866 \text{ patients} * \$200,000 = \text{\$173.2 million}$
- EU5: $1,232 \text{ patients} * \$120,000 = \text{\$147.8 million}$
- China: $3,003 \text{ patients} * \$50,000 = \text{\$150.2 million}$

- Japan: 481 patients * \$150,000 = **\$72.2 million**
- **Total Peak Sales (20% Share): \$543.4 million**

Peak Sales at 30% Share of Treated Patients

- US: 1,299 patients * \$200,000 = **\$259.8 million**
- EU5: 1,848 patients * \$120,000 = **\$221.8 million**
- China: 4,505 patients * \$50,000 = **\$225.3 million**
- Japan: 722 patients * \$150,000 = **\$108.3 million**
- **Total Peak Sales (30% Share): \$815.2 million**

Thus, the **Potential Peak Sales** for capmatinib in this indication across the US, EU5, China, and Japan range from **\$543 million to \$815 million**, depending on the market share (20-30%).

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

A 1% share of treated patients corresponds to 1% of the eligible patient population being treated with capmatinib. Using the total eligible patient numbers calculated earlier:

- US: 4,330 * 0.01 = 43.3 patients
- EU5: 6,160 * 0.01 = 61.6 patients
- China: 15,015 * 0.01 = 150.2 patients
- Japan: 2,406 * 0.01 = 24.1 patients

Now, multiply by the annual treatment cost per patient:

- US: 43.3 * \$200,000 = **\$8.66 million**
- EU5: 61.6 * \$120,000 = **\$7.39 million**
- China: 150.2 * \$50,000 = **\$7.51 million**
- Japan: 24.1 * \$150,000 = **\$3.62 million**
- **Total \$ Value of 1% Share Across Geographies: \$27.18 million**

****Final Answer****

1. Potential Peak Sales for Capmatinib (20-30% Share of Treated Patients):

- US: \$173.2M - \$259.8M
- EU5: \$147.8M - \$221.8M
- China: \$150.2M - \$225.3M

- Japan: \$72.2M - \$108.3M

- **Total: \$543.4M - \$815.2M**

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

- US: \$8.66M

- EU5: \$7.39M

- China: \$7.51M

- Japan: \$3.62M

- **Total: \$27.18M**

****Notes and Caveats****

- These estimates are based on assumptions about epidemiology, market penetration, and pricing. Actual figures may differ due to real-world factors like competition (e.g., other MET inhibitors such as tepotinib), diagnostic testing rates, reimbursement policies, and patient access.

- Peak sales typically occur several years after launch as market penetration increases, and sales may decline later due to generics or new therapies.

- The pricing assumptions are rough and may need adjustment based on country-specific data or Novartis' pricing strategy for capmatinib.