To estimate the **Potential Peak Sales** for tepotinib (Tepmetko) in the indication of metastatic non-small cell lung cancer (NSCLC) with MET exon 14 skipping alterations in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **$ value of 1% share of treated patients** in these geographies, we need to follow a structured approach. Since specific data such as exact patient numbers, pricing, and market penetration may not be publicly available, I will outline the methodology and use reasonable assumptions based on available information and industry standards.

Please note that this is a high-level estimation, and actual figures may vary based on real-world data, pricing negotiations, reimbursement policies, and market dynamics. For precise numbers, consulting proprietary market research reports (e.g., from GlobalData, EvaluatePharma, or IQVIA) or company disclosures would be necessary.

Step 1: Define the Target Patient Population

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

Incidence of NSCLC and MET Exon 14 Skipping:

- **NSCLC Incidence**: NSCLC accounts for ~85% of all lung cancer cases. Using approximate annual incidence rates for lung cancer in each geography (data sourced from GLOBOCAN 2020 and other public health statistics):

- **US**: ~230,000 new lung cancer cases; ~195,500 NSCLC cases.

- **EU5**: ~320,000 new lung cancer cases; ~272,000 NSCLC cases.

- **China**: ~820,000 new lung cancer cases; ~697,000 NSCLC cases.

- **Japan**: ~130,000 new lung cancer cases; ~110,500 NSCLC cases.

- **MET Exon 14 Skipping**: ~3.5% of NSCLC cases.

- **US**: ~6,800 patients.

- **EU5**: ~9,500 patients.

- **China**: ~24,400 patients.

- **Japan**: ~3,900 patients.

- **Metastatic NSCLC**: Approximately 50-60% of NSCLC patients are diagnosed at a metastatic stage (Stage IV). Assuming 55%:

- **US**: ~3,750 patients.

- **EU5**: ~5,200 patients.

- **China**: ~13,400 patients.

- **Japan**: ~2,100 patients.

These are rough estimates of the annual eligible patient population for tepotinib.

Treated Patient Share:

- Assuming 20-30% of eligible patients are treated with tepotinib (due to factors like diagnosis rates, access to testing for MET alterations, physician adoption, and competition from other therapies like capmatinib):

- **US**: 750-1,125 patients.

- **EU5**: 1,040-1,560 patients.

- **China**: 2,680-4,020 patients.

- **Japan**: 420-630 patients.

Step 2: Estimate Drug Pricing

Pricing for targeted oncology drugs like tepotinib varies by region due to differences in healthcare systems, reimbursement policies, and purchasing power. Tepotinib's pricing can be approximated based on similar drugs (e.g., capmatinib) and publicly available data:

- **US**: ~$20,000 per month or ~$240,000 per year (typical for targeted NSCLC therapies).

- **EU5**: ~$10,000-$15,000 per month or ~$120,000-$180,000 per year (lower due to price negotiations and public health systems).

- **Japan**: ~$15,000 per month or ~$180,000 per year (similar to EU but with specific pricing rules).

- **China**: ~$5,000-$8,000 per month or ~$60,000-$96,000 per year (lower due to market access programs and generics competition post-patent expiry, though tepotinib is still under patent).

For simplicity, let's assume a conservative annual cost per patient (net price after discounts):

- **US**: $200,000.

- **EU5**: $150,000.

- **Japan**: $160,000.

- **China**: $70,000.

Duration of Treatment:

- Median progression-free survival (PFS) for tepotinib in MET exon 14 skipping NSCLC is ~11 months (based on clinical trial data from the VISION study). Assuming patients are treated for ~1 year on average.

Step 3: Calculate Potential Peak Sales (20-30% Treated Share)

Peak sales are calculated as:

Peak Sales = Number of Treated Patients x Annual Cost per Patient

At 20% Treated Share:

- **US**: 750 patients x $200,000 = **$150 million**.

- **EU5**: 1,040 patients x $150,000 = **$156 million**.

- **China**: 2,680 patients x $70,000 = **$188 million**.

- **Japan**: 420 patients x $160,000 = **$67 million**.

- **Total Peak Sales (20% share)**: $150M + $156M + $188M + $67M = **$561 million**.

At 30% Treated Share:

- **US**: 1,125 patients x $200,000 = **$225 million**.

- **EU5**: 1,560 patients x $150,000 = **$234 million**.

- **China**: 4,020 patients x $70,000 = **$281 million**.

- **Japan**: 630 patients x $160,000 = **$101 million**.

- **Total Peak Sales (30% share)**: $225M + $234M + $281M + $101M = **$841 million**.

Thus, **Potential Peak Sales** for tepotinib in this indication across the specified geographies range from **$561 million to $841 million annually**, assuming 20-30% market share of treated patients.

Step 4: Calculate $ Value of 1% Share of Treated Patients

To calculate the value of 1% share, we divide the number of eligible patients by 100 and multiply by the annual cost per patient.

Eligible Patients (from Step 1):

- **US**: 3,750 patients $\rightarrow$ 1% = 37.5 patients.

- **EU5**: 5,200 patients $\rightarrow$ 1% = 52 patients.

- **China**: 13,400 patients $\rightarrow$ 1% = 134 patients.

- **Japan**: 2,100 patients $\rightarrow$ 1% = 21 patients.

$ Value of 1% Share:

- **US**: 37.5 patients x $200,000 = **$7.5 million**.

- **EU5**: 52 patients x $150,000 = **$7.8 million**.

- **China**: 134 patients x $70,000 = **$9.4 million**.

- **Japan**: 21 patients x $160,000 = **$3.4 million**.

- **Total $ Value of 1% Share**: $7.5M + $7.8M + $9.4M + $3.4M = **$28.1 million**.

Thus, the **$ value of 1% share of treated patients** across these geographies is approximately **$28.1 million annually**.

Final Answer:

1. **Potential Peak Sales for tepotinib** in metastatic NSCLC with MET exon 14 skipping alterations (20-30% treated share):

- **US**: $150M - $225M.

- **EU5**: $156M - $234M.

- **China**: $188M - $281M.

- **Japan**: $67M - $101M.

- **Total**: **$561M - $841M annually**.

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

- **US**: $7.5M.

- **EU5**: $7.8M.

- **China**: $9.4M.

- **Japan**: $3.4M.

- **Total**: **$28.1M annually**.

Caveats:

- These estimates are based on assumptions for pricing, patient population, and treatment duration. Real-world data may differ.

- Competition from capmatinib (Tabrecta) and other emerging therapies could impact market share.

- Access to genetic testing for MET exon 14 skipping alterations may limit the treated population in some regions, especially China.

- Pricing in China may be further reduced due to inclusion in the National Reimbursement Drug List (NRDL) or volume-based procurement policies.

For more accurate forecasts, consult market research reports or financial disclosures from EMD Serono/Merck KGaA.