To estimate the **Potential Peak Sales** for ivosidenib (Tibsovo) in the indication of newly diagnosed acute myeloid leukemia (AML) with a susceptible IDH1 mutation in the specified geographies (US, EU5, China, and Japan), as well as the **$ value of a 1% share of treated patients**, we need to follow a structured approach. Since specific data on patient populations, pricing, and penetration rates are not provided, I will make reasonable assumptions based on available information and industry standards. Let's break this down step by step.

Key Assumptions and Methodology

1. **Indication and Target Population**:

- Ivosidenib is approved for newly diagnosed AML with IDH1 mutation in patients ≥75 years or those with comorbidities precluding intensive chemotherapy.

- IDH1 mutations occur in approximately 6-10% of AML cases (source: general literature on AML genetics).

- AML incidence varies by region, and the target population is a subset of newly diagnosed patients (elderly or with comorbidities).

2. **Treated Patient Share**:

- The problem states a 20% to 30% share of treated patients. This likely refers to the market penetration of ivosidenib among eligible patients.

- We will calculate peak sales using this range.

3. **Geographies**:

- US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan.

- Incidence rates, healthcare access, and pricing differ across these regions.

4. **Pricing**:

- Ivosidenib pricing in the US is approximately $25,000–$30,000 per month (based on reported costs for AML therapies and Tibsovo’s pricing in other indications like cholangiocarcinoma).

- Pricing in EU5 and Japan is typically 60-80% of US pricing due to healthcare system negotiations.

- Pricing in China is assumed to be lower (30-50% of US pricing) due to market access and affordability constraints.

- Treatment duration is assumed to be 6-12 months on average for AML patients.

5. **Peak Sales**:

- Peak sales are calculated as:

Peak Sales = Eligible Patients × Market Share × Annual Cost per Patient

- We will estimate eligible patients based on AML incidence, IDH1 mutation prevalence, and the proportion of elderly/comorbid patients.

6. **1% Share of Treated Patients**:

- This is calculated as the $ value of treating 1% of the eligible patient population in each geography.

Step 1: Estimate AML Incidence and Eligible Patients

- **US**:

- AML incidence: ~20,000 new cases/year (American Cancer Society).

- IDH1 mutation: ~8% → ~1,600 patients.

- Elderly (≥75) or comorbid: ~50% of AML patients → ~800 eligible patients.

- **EU5**:

- AML incidence: ~18,000 new cases/year (combined, based on population and incidence rates similar to US).

- IDH1 mutation: ~8% → ~1,440 patients.

- Elderly/comorbid: ~50% → ~720 eligible patients.

- **China**:

- AML incidence: ~40,000 new cases/year (higher population, estimated based on global incidence rates).

- IDH1 mutation: ~8% → ~3,200 patients.

- Elderly/comorbid: ~50% → ~1,600 eligible patients.

- **Japan**:

- AML incidence: ~5,000 new cases/year (based on population and incidence rates).

- IDH1 mutation: ~8% → ~400 patients.

- Elderly/comorbid: ~50% → ~200 eligible patients.

Total Eligible Patients Across Geographies: ~3,320 patients (800 US + 720 EU5 + 1,600 China + 200 Japan).

Step 2: Estimate Annual Cost per Patient

- **US**: $30,000/month × 9 months (average treatment duration) = **$270,000/year**.

- **EU5**: $20,000/month × 9 months = **$180,000/year** (lower pricing due to negotiations).

- **China**: $10,000/month × 9 months = **$90,000/year** (significantly lower pricing).

- **Japan**: $22,000/month × 9 months = **$198,000/year** (similar to EU5 but slightly higher).

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

Peak Sales = Eligible Patients × Market Share × Annual Cost per Patient

US:

- 20% share: 800 × 0.2 × $270,000 = **$43.2 million**

- 30% share: 800 × 0.3 × $270,000 = **$64.8 million**

EU5:

- 20% share: 720 × 0.2 × $180,000 = **$25.9 million**

- 30% share: 720 × 0.3 × $180,000 = **$38.9 million**

China:

- 20% share: 1,600 × 0.2 × $90,000 = **$28.8 million**

- 30% share: 1,600 × 0.3 × $90,000 = **$43.2 million**

Japan:

- 20% share: 200 × 0.2 × $198,000 = **$7.9 million**

- 30% share: 200 × 0.3 × $198,000 = **$11.9 million**

Total Peak Sales Across Geographies:

- 20% share: $43.2M (US) + $25.9M (EU5) + $28.8M (China) + $7.9M (Japan) = **$105.8 million**

- 30% share: $64.8M (US) + $38.9M (EU5) + $43.2M (China) + $11.9M (Japan) = **$158.8 million**

Potential Peak Sales Range: **$105.8 million to $158.8 million annually**.

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

1% Share Value = Eligible Patients × 0.01 × Annual Cost per Patient

US:

- 800 × 0.01 × $270,000 = **$2.16 million**

EU5:

- 720 × 0.01 × $180,000 = **$1.30 million**

China:

- 1,600 × 0.01 × $90,000 = **$1.44 million**

Japan:

- 200 × 0.01 × $198,000 = **$0.40 million**

Total Value of 1% Share Across Geographies:

- $2.16M (US) + $1.30M (EU5) + $1.44M (China) + $0.40M (Japan) = **$5.30 million**

Final Answer

1. **Potential Peak Sales for Ivosidenib** in the US, EU5, China, and Japan for newly diagnosed AML with IDH1 mutation (20%-30% market share):

$105.8 million to $158.8 million annually.

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

- US: **$2.16 million**

- EU5: **$1.30 million**

- China: **$1.44 million**

- Japan: **$0.40 million**

- Total: **$5.30 million**

Caveats and Notes

- These estimates are based on assumptions for patient numbers, pricing, and treatment duration. Actual figures may vary depending on real-world data, market access, competition (e.g., other IDH1 inhibitors like enasidenib), and reimbursement policies.

- The elderly/comorbid proportion (50%) is an approximation; the actual percentage may differ based on demographic and clinical data.

- Peak sales could be influenced by off-label use, combination therapy adoption, or changes in treatment guidelines.

- If more specific data (e.g., exact patient numbers or pricing) is available, these calculations can be refined further.