

To estimate the **Potential Peak Sales** for ivosidenib (Tibsovo) in the indication of relapsed or refractory myelodysplastic syndromes (MDS) with IDH1 mutation 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 data, assumptions, and market analysis. Since exact figures for patient populations, pricing, and market penetration may not be publicly available, I will outline a methodology using reasonable estimates and assumptions. Note that these calculations are illustrative and should be validated with real-world data or proprietary market research.

Step 1: Key Assumptions and Inputs

1. **Indication and Target Population:** Ivosidenib is approved for relapsed or refractory MDS with IDH1 mutation. IDH1 mutations occur in approximately 3-5% of MDS patients.

2. **Patient Population:**

- MDS incidence and prevalence vary by region. We will estimate the number of relapsed/refractory MDS patients and apply the IDH1 mutation rate.

- Relapsed/refractory MDS patients are typically a subset of the total MDS population (assumed ~30-40% of diagnosed patients).

3. **Market Share:** Given the query, we assume ivosidenib captures **20-30% of treated patients** in this indication.

4. **Pricing:** Ivosidenib's price in the US is approximately \$30,000 per month (based on publicly available data for other indications like AML). Pricing in other regions is typically lower due to healthcare system differences (e.g., 50-70% of US price in EU5/Japan, and 30-50% in China).

5. **Treatment Duration:** Assume an average treatment duration of **6-12 months** for relapsed/refractory patients.

6. **Geographies:** US, EU5, China, Japan.

Step 2: Estimate Target Patient Population

We will estimate the number of relapsed/refractory MDS patients with IDH1 mutation in each region.

- **US:**

- MDS incidence: ~10,000-15,000 new cases/year.

- Prevalence of diagnosed MDS: ~60,000-70,000 patients.

- Relapsed/Refractory MDS: ~30-40% of diagnosed patients → ~20,000-25,000 patients.

- IDH1 mutation (3-5%): ~600-1,250 patients.

- **Target Population:** ~900 patients (midpoint).

- **EU5:**

- MDS incidence: ~15,000-20,000 new cases/year (based on population size relative to US).

- Prevalence: ~80,000-100,000 patients.
- Relapsed/Refractory MDS: ~25,000-35,000 patients.
- IDH1 mutation (3-5%): ~750-1,750 patients.
- **Target Population:** ~1,250 patients (midpoint).
- **China:**
 - MDS incidence: ~20,000-30,000 new cases/year (larger population, lower diagnosis rates).
 - Prevalence: ~100,000-150,000 patients.
 - Relapsed/Refractory MDS: ~30,000-50,000 patients.
 - IDH1 mutation (3-5%): ~900-2,500 patients.
 - **Target Population:** ~1,700 patients (midpoint).
- **Japan:**
 - MDS incidence: ~5,000-7,000 new cases/year (aging population, high diagnosis rates).
 - Prevalence: ~30,000-40,000 patients.
 - Relapsed/Refractory MDS: ~10,000-15,000 patients.
 - IDH1 mutation (3-5%): ~300-750 patients.
 - **Target Population:** ~525 patients (midpoint).
- **Total Target Population (IDH1 mutation, relapsed/refractory MDS):**
 - US: 900
 - EU5: 1,250
 - China: 1,700
 - Japan: 525
 - **Total:** ~4,375 patients.

Step 3: Estimate Treated Patients and Market Share

- Assume that **70-80% of eligible patients** receive treatment (accounting for access, affordability, and clinical decisions).
- Treated Patients:
 - US: $900 \times 75\% = \sim 675$
 - EU5: $1,250 \times 75\% = \sim 940$
 - China: $1,700 \times 70\% = \sim 1,190$
 - Japan: $525 \times 80\% = \sim 420$

- **Total Treated Patients:** ~3,225
- Market Share for Ivosidenib: **20-30% of treated patients.**
- At 20%: ~645 patients treated with ivosidenib.
- At 30%: ~970 patients treated with ivosidenib.

Step 4: Estimate Annual Cost per Patient

- **US Pricing:** \$30,000/month × 9 months (average treatment duration) = **\$270,000/year.**
- **EU5 Pricing:** ~60% of US price = \$18,000/month × 9 months = **\$162,000/year.**
- **China Pricing:** ~40% of US price = \$12,000/month × 9 months = **\$108,000/year.**
- **Japan Pricing:** ~70% of US price = \$21,000/month × 9 months = **\$189,000/year.**

Step 5: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of patients treated with ivosidenib by the annual cost per patient in each region.

At 20% Market Share:

- US: 675 patients × 20% = 135 patients × \$270,000 = **\$36.5 million**
- EU5: 940 patients × 20% = 188 patients × \$162,000 = **\$30.5 million**
- China: 1,190 patients × 20% = 238 patients × \$108,000 = **\$25.7 million**
- Japan: 420 patients × 20% = 84 patients × \$189,000 = **\$15.9 million**
- **Total Peak Sales at 20% Share: \$108.6 million**

At 30% Market Share:

- US: 675 patients × 30% = 203 patients × \$270,000 = **\$54.8 million**
- EU5: 940 patients × 30% = 282 patients × \$162,000 = **\$45.7 million**
- China: 1,190 patients × 30% = 357 patients × \$108,000 = **\$38.6 million**
- Japan: 420 patients × 30% = 126 patients × \$189,000 = **\$23.8 million**
- **Total Peak Sales at 30% Share: \$162.9 million**

Potential Peak Sales Range: \$108.6 million to \$162.9 million annually across US, EU5, China, and Japan for this indication.

Step 6: Calculate \$ Value of 1% Share of Treated Patients

1% of treated patients corresponds to 1% of the total treated population (~3,225 patients) = **32.25 patients**.

- US: $675 \times 1\% = 6.75$ patients \times \$270,000 = **\$1.82 million**

- EU5: $940 \times 1\% = 9.4$ patients \times \$162,000 = **\$1.52 million**

- China: $1,190 \times 1\% = 11.9$ patients \times \$108,000 = **\$1.29 million**

- Japan: $420 \times 1\% = 4.2$ patients \times \$189,000 = **\$0.79 million**

- **Total \$ Value of 1% Share: \$5.42 million**

Final Answer:

1. **Potential Peak Sales for Ivosidenib** in relapsed/refractory MDS with IDH1 mutation (assuming 20-30% market share):

- **\$108.6 million to \$162.9 million annually** across the US, EU5, China, and Japan.

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

- **\$5.42 million annually** across the US, EU5, China, and Japan.

Note: These figures are based on assumptions and should be refined with actual epidemiology data, pricing agreements, market access conditions, and competitive landscape analysis. Factors such as reimbursement, generic competition, and alternative therapies could impact these estimates.