

To estimate the **Potential Peak Sales** for the oral combination of decitabine and cedazuridine (INQOVI) in the indication of myelodysplastic syndromes (MDS) 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 involves estimating the total addressable patient population, the percentage of treated patients, the drug's pricing, and the market share. Since specific data (e.g., exact patient numbers, pricing, or penetration rates) may not be fully available, I will make reasonable assumptions based on publicly available information and industry standards. You can refine these numbers with more precise data if available.

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## **Step 1: Define the Indication and Patient Population**

INQOVI is approved for adult patients with myelodysplastic syndromes (MDS), a group of disorders caused by poorly formed blood cells. The drug targets a niche but significant patient population.

- **US:** Estimated incidence of MDS is ~10,000-20,000 new cases per year, with a prevalence of ~60,000-170,000 patients (depending on data sources like the American Cancer Society or SEER database). For simplicity, assume a treatable prevalent population of ~100,000.
- **EU5:** Incidence is similar to the US per capita. With a population roughly 1.5x the US (~450M vs. 330M), assume a treatable prevalent population of ~150,000.
- **China:** With a population of ~1.4B, and considering lower diagnosis rates and access to healthcare, assume a treatable prevalent population of ~200,000.
- **Japan:** With a population of ~125M and a high elderly demographic (MDS is more common in older patients), assume a treatable prevalent population of ~50,000.

**Total Treatable Population Across Geographies:** ~500,000 patients.

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## **Step 2: Estimate Treated Patients**

Not all prevalent patients receive treatment due to factors like disease severity, comorbidities, access to healthcare, and diagnosis rates. For MDS, hypomethylating agents like decitabine are typically used in intermediate- to high-risk patients, which may account for ~30-50% of the prevalent population.

- Assume **40% of prevalent patients are treated** with therapies like INQOVI.
- **Treated Population:** 40% of 500,000 = **200,000 patients**.

Given the query assumes a **20%-30% market share** of treated patients for INQOVI, the drug would target:

- **20% share:** 40,000 patients.
- **30% share:** 60,000 patients.

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### **Step 3: Estimate Annual Cost of Therapy per Patient**

INQOVI, as an oral hypomethylating agent, is a premium-priced drug. Decitabine (injectable) historically costs ~\$50,000-\$70,000 per year per patient in the US. As an oral formulation, INQOVI may have a slightly different pricing structure, potentially higher due to convenience, or lower due to competition.

- **US Pricing:** Assume ~\$60,000 per patient per year.
- **EU5 Pricing:** Typically 50-70% of US pricing due to healthcare negotiations. Assume ~\$40,000 per patient per year.
- **China Pricing:** Significantly lower due to pricing controls and generics. Assume ~\$10,000 per patient per year.
- **Japan Pricing:** Closer to EU pricing, assume ~\$40,000 per patient per year.

Now, allocate the treated population roughly proportional to the total population:

- US: ~20% of total (100,000/500,000) → 20% of 200,000 = 40,000 treated patients.
- EU5: ~30% of total (150,000/500,000) → 30% of 200,000 = 60,000 treated patients.
- China: ~40% of total (200,000/500,000) → 40% of 200,000 = 80,000 treated patients.
- Japan: ~10% of total (50,000/500,000) → 10% of 200,000 = 20,000 treated patients.

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### **Step 4: Calculate Potential Peak Sales for 20%-30% Market Share**

Peak sales are calculated as: (Number of treated patients with the drug) x (Annual cost per patient).

#### **#### 20% Market Share (40,000 patients treated with INQOVI)**

- **US:** 20% of 40,000 treated patients = 8,000 patients x \$60,000 = **\$480M**.
- **EU5:** 20% of 60,000 treated patients = 12,000 patients x \$40,000 = **\$480M**.
- **China:** 20% of 80,000 treated patients = 16,000 patients x \$10,000 = **\$160M**.
- **Japan:** 20% of 20,000 treated patients = 4,000 patients x \$40,000 = **\$160M**.
- **Total Peak Sales (20% share):** \$480M + \$480M + \$160M + \$160M = **\$1,280M (\$1.28B)**.

#### **#### 30% Market Share (60,000 patients treated with INQOVI)**

- **US:** 30% of 40,000 treated patients = 12,000 patients x \$60,000 = **\$720M**.
- **EU5:** 30% of 60,000 treated patients = 18,000 patients x \$40,000 = **\$720M**.
- **China:** 30% of 80,000 treated patients = 24,000 patients x \$10,000 = **\$240M**.
- **Japan:** 30% of 20,000 treated patients = 6,000 patients x \$40,000 = **\$240M**.
- **Total Peak Sales (30% share):** \$720M + \$720M + \$240M + \$240M = **\$1,920M (\$1.92B)**.

**Potential Peak Sales Range: \$1.28B to \$1.92B** annually, depending on whether INQOVI captures 20% or 30% market share.

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

A 1% share of treated patients corresponds to 1% of the total treated population (200,000 patients) = **2,000 patients**.

- **US:** 1% of 40,000 treated patients = 400 patients x \$60,000 = **\$24M**.
- **EU5:** 1% of 60,000 treated patients = 600 patients x \$40,000 = **\$24M**.
- **China:** 1% of 80,000 treated patients = 800 patients x \$10,000 = **\$8M**.
- **Japan:** 1% of 20,000 treated patients = 200 patients x \$40,000 = **\$8M**.
- **Total \$ Value of 1% Share:** \$24M + \$24M + \$8M + \$8M = **\$64M**.

**\$ Value of 1% Share of Treated Patients: \$64M annually.**

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## **Final Answer**

- **Potential Peak Sales** for INQOVI in MDS across the US, EU5, China, and Japan (assuming 20%-30% market share): **\$1.28B to \$1.92B annually**.
- **\$ Value of 1% Share of Treated Patients** across these geographies: **\$64M annually**.

## **Notes and Assumptions**

1. Patient population numbers are rough estimates based on prevalence data for MDS and may vary by source.
2. Treatment rates (40%) and market share (20%-30%) are assumptions based on typical penetration for specialty drugs in rare diseases.
3. Pricing is estimated based on historical data for hypomethylating agents and may differ based on payer negotiations, generics, or biosimilars.
4. Peak sales assume stable pricing and no significant competition or patent expiry during the peak period.
5. If more specific data (e.g., exact patient numbers, real-world pricing, or uptake rates) is available, these estimates can be refined.

Let me know if you'd like to adjust any assumptions or dive deeper into a specific region or factor!