

To estimate the **Potential Peak Sales** for isatuximab-irfc (Sarclisa) in the indication of relapsed or refractory multiple myeloma (RRMM) 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 exact data on patient populations, pricing, and market dynamics may not be publicly available, I will provide a framework and reasonable assumptions based on typical market research methodologies for oncology drugs. The final numbers are illustrative and should be validated with real-world data.

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

Isatuximab-irfc is approved for adult patients with relapsed or refractory multiple myeloma (RRMM) who have received 1-3 prior lines of therapy. We need to estimate the number of eligible patients in each geography.

- **US:** Approximately 34,000 new cases of multiple myeloma are diagnosed annually (American Cancer Society). About 50-60% of patients relapse or become refractory after first-line therapy, and a subset of these will fall into the 1-3 prior lines category. Let's estimate ~15,000-20,000 eligible patients annually.

- **EU5:** The incidence of multiple myeloma in Europe is ~4.5-6 per 100,000 people. With a population of ~330 million in EU5, this translates to ~15,000-20,000 new cases annually. Assuming a similar relapse rate, ~7,000-10,000 patients may be eligible.

- **China:** Incidence is lower, at ~1-2 per 100,000, but with a population of 1.4 billion, this translates to ~14,000-28,000 new cases annually. Assuming underdiagnosis and limited access to advanced therapies, eligible patients might be ~5,000-10,000.

- **Japan:** Incidence is ~2-3 per 100,000, with a population of 125 million, leading to ~2,500-3,750 new cases annually. Eligible patients might be ~1,000-1,500.

Summarizing **eligible patients annually** (mid-range estimates):

- US: 17,500
- EU5: 8,500
- China: 7,500
- Japan: 1,250
- **Total:** 34,750 patients

## **Step 2: Estimate Market Penetration (20%-30% Share of Treated Patients)**

The problem assumes a 20%-30% share of treated patients. This accounts for competition from other drugs (e.g., daratumumab, pomalidomide, carfilzomib) and access barriers. Using the mid-point of 25% for peak penetration:

- **Treated patients at peak share (25%):**

- US:  $17,500 \times 0.25 = 4,375$
- EU5:  $8,500 \times 0.25 = 2,125$
- China:  $7,500 \times 0.25 = 1,875$

- Japan:  $1,250 \times 0.25 = 313$
- **Total:** 8,688 patients

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

Isatuximab-irfc is a monoclonal antibody administered in combination with carfilzomib and dexamethasone. Pricing varies by region due to healthcare systems and negotiations. Based on similar drugs (e.g., daratumumab), annual costs can be estimated as follows (hypothetical figures, adjusted for purchasing power and market access):

- US: \$150,000 per patient per year
- EU5: \$100,000 per patient per year (lower due to price negotiations)
- China: \$50,000 per patient per year (reflecting lower pricing and access issues)
- Japan: \$120,000 per patient per year (similar to US but slightly lower)

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

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

- **US:**  $4,375 \text{ patients} \times \$150,000 = \$656.25 \text{ million}$
- **EU5:**  $2,125 \text{ patients} \times \$100,000 = \$212.5 \text{ million}$
- **China:**  $1,875 \text{ patients} \times \$50,000 = \$93.75 \text{ million}$
- **Japan:**  $313 \text{ patients} \times \$120,000 = \$37.56 \text{ million}$
- **Total Peak Sales:**  $\$656.25\text{M} + \$212.5\text{M} + \$93.75\text{M} + \$37.56\text{M} = \$1,000.06 \text{ million (or ~\$1 billion)}$

Using the range of 20%-30% market share:

- At 20%: Total treated patients = 6,950 → Peak Sales ~ **\$800 million**
- At 30%: Total treated patients = 10,425 → Peak Sales ~ **\$1.2 billion**

Thus, **Potential Peak Sales** for isatuximab-irfc in this indication across the specified geographies are estimated to be **\$800 million to \$1.2 billion**, with a midpoint of ~\$1 billion.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population (since share is defined as a percentage of treated patients, and we assume all eligible patients are potentially treatable for this calculation).

- **Total eligible patients:** 34,750
- **1% of eligible patients:** 347.5 patients

Using the same per-patient cost as above:

- **US:**  $(17,500 \times 0.01) \times \$150,000 = 175 \text{ patients} \times \$150,000 = \text{\$26.25 million}$
- **EU5:**  $(8,500 \times 0.01) \times \$100,000 = 85 \text{ patients} \times \$100,000 = \text{\$8.5 million}$
- **China:**  $(7,500 \times 0.01) \times \$50,000 = 75 \text{ patients} \times \$50,000 = \text{\$3.75 million}$
- **Japan:**  $(1,250 \times 0.01) \times \$120,000 = 12.5 \text{ patients} \times \$120,000 = \text{\$1.5 million}$
- **Total \$ Value of 1% Share:**  $\$26.25\text{M} + \$8.5\text{M} + \$3.75\text{M} + \$1.5\text{M} = \text{\$40 million}$

### **Final Answer:**

1. **Potential Peak Sales for isatuximab-irfc** in the indication of relapsed or refractory multiple myeloma (RRMM) across the US, EU5, China, and Japan, assuming a 20%-30% share of treated patients:

- Range: **\\$800 million to \\$1.2 billion**
- Midpoint: **~\\$1 billion**

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

- **\\$40 million**

### **Caveats and Assumptions:**

- Patient population estimates are based on general incidence and relapse rates for multiple myeloma and may vary based on real-world data.
- Pricing assumptions are illustrative and based on typical costs for monoclonal antibodies in oncology; actual pricing may differ due to negotiations, rebates, and access programs.
- Market penetration (20%-30%) assumes competition and access barriers; the actual share could be influenced by clinical differentiation, payer policies, and marketing efforts.
- These figures represent peak sales, which may take several years to achieve post-launch and depend on patent life and generic/biosimilar entry.

For precise figures, primary market research, epidemiology data, and pricing information specific to isatuximab-irfc would be required.