To calculate the **Potential Peak Sales** for isatuximab-irfc (Sarclisa) in the indication of multiple myeloma (MM) for adult patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor, 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 exact data on patient populations, pricing, and market dynamics are not provided, I will outline the methodology and use reasonable assumptions based on publicly available information and market trends for multiple myeloma drugs. If you have specific data (e.g., patient numbers, pricing), I can refine the calculations accordingly.

Step 1: Key Assumptions and Methodology

1. **Indication and Target Population**: Isatuximab-irfc is approved for relapsed/refractory multiple myeloma (RRMM) patients who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor. This is typically a third-line (3L) or later treatment setting.

2. **Market Share**: The problem assumes a 20% to 30% share of treated patients for isatuximab-irfc in this indication.

3. **Geographies**: US, EU5 (combined), China, and Japan.

4. **Peak Sales**: Peak sales are estimated based on the total addressable patient population, market share, annual treatment cost, and treatment duration.

5. **$ Value of 1% Share**: This is calculated as the total market value for the treated population divided by 100.

Data Assumptions

Since exact data is unavailable, I will use the following approximations based on industry reports and literature for RRMM:

- **Patient Population (3L+ RRMM)**:

- US: ~10,000–12,000 eligible patients annually (based on MM incidence and progression to 3L+).

- EU5: ~15,000–18,000 eligible patients annually (larger population but similar MM incidence rates).

- China: ~10,000–15,000 eligible patients annually (large population but lower diagnosis and treatment rates).

- Japan: ~3,000–5,000 eligible patients annually (smaller population with high treatment access).

- **Annual Cost of Therapy**: Isatuximab-irfc's list price in the US is approximately $650 per 100 mg vial, with a typical regimen costing ~$150,000–$200,000 per patient per year (based on dosing and combination with pomalidomide/dexamethasone). Costs in other regions are typically lower due to pricing differences:

- US: ~$180,000 per patient/year.

- EU5: ~$120,000 per patient/year (lower due to negotiated pricing).

- China: ~$60,000 per patient/year (significant discounts and lower access).

- Japan: ~$140,000 per patient/year (similar to EU5 but with high access).

- **Treatment Duration**: Assumed as 1 year for simplicity (actual duration may vary based on progression-free survival).

- **Total Market Value**: Calculated as (Eligible Patients) × (Annual Cost per Patient).

- **Peak Sales for Isatuximab-irfc**: Calculated as (Total Market Value) × (Market Share of 20% to 30%).

- **$ Value of 1% Share**: (Total Market Value) / 100.

Step 2: Estimate Eligible Patients and Total Market Value

| Geography | Eligible Patients (3L+ RRMM) | Annual Cost per Patient ($) | Total Market Value ($ Million) |

|---|---|---|---|

| US | 11,000 | 180,000 | 1,980 |

| EU5 | 16,500 | 120,000 | 1,980 |

| China | 12,500 | 60,000 | 750 |

| Japan | 4,000 | 140,000 | 560 |

| **Total** | **44,000** | - | **5,268** |

Step 3: Calculate Potential Peak Sales for Isatuximab-irfc (20% to 30% Market Share)

- **20% Market Share**:

- Total Peak Sales = 5,268 × 0.20 = **$1,053.6 Million**

- **30% Market Share**:

- Total Peak Sales = 5,268 × 0.30 = **$1,580.4 Million**

Breakdown by Geography (20% Market Share):

| Geography | Peak Sales at 20% Share ($ Million) |

|---|---|

| US | 1,980 × 0.20 = 396 |

| EU5 | 1,980 × 0.20 = 396 |

| China | 750 × 0.20 = 150 |

| Japan | 560 × 0.20 = 112 |

| **Total** | **1,054** |

Breakdown by Geography (30% Market Share):

| Geography | Peak Sales at 30% Share ($ Million) |

|---|---|

| US | 1,980 × 0.30 = 594 |

| EU5 | 1,980 × 0.30 = 594 |

| China | 750 × 0.30 = 225 |

| Japan | 560 × 0.30 = 168 |

| **Total** | **1,581** |

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

- **Total Market Value** = $5,268 Million

- **1% Share** = 5,268 / 100 = **$52.68 Million**

Breakdown by Geography for 1% Share:

| Geography | 1% Share Value ($ Million) |

|-----------|----------------------------|

| US | 1,980 / 100 = 19.80 |

| EU5 | 1,980 / 100 = 19.80 |

| China | 750 / 100 = 7.50 |

| Japan | 560 / 100 = 5.60 |

| **Total** | **52.68** |

Final Answer

1. **Potential Peak Sales for Isatuximab-irfc** (20% to 30% market share) in the US, EU5, China, and Japan for the specified indication:

- At 20% share: **$1,054 Million**

- At 30% share: **$1,581 Million**

Breakdown by Geography:

- US: $396M (20%) to $594M (30%)

- EU5: $396M (20%) to $594M (30%)

- China: $150M (20%) to $225M (30%)

- Japan: $112M (20%) to $168M (30%)

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

- Total across all geographies: **$52.68 Million**

- US: $19.80M

- EU5: $19.80M

- China: $7.50M

- Japan: $5.60M

Notes

- These estimates are based on assumptions for patient population and pricing. Actual numbers may vary due to differences in market access, reimbursement, competition (e.g., daratumumab, other anti-CD38 therapies), and real-world treatment patterns.

- If you have specific data on patient numbers, pricing, or market dynamics, I can adjust the calculations for greater accuracy.

- Peak sales typically occur several years after launch as market penetration increases, and these figures assume full market access and no major disruptions (e.g., biosimilars or new competitors).