

To estimate the **Potential Peak Sales** for belumosudil (Rezurock) in the indication of chronic graft-versus-host disease (cGVHD) 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. Since specific data on patient populations, pricing, and market penetration may not be fully available, I will outline the methodology and provide reasonable assumptions based on publicly available information and typical market dynamics for rare disease drugs. Please note that these are illustrative calculations, and real-world figures may vary based on proprietary data, pricing negotiations, and market access.

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

Chronic GVHD is a complication following allogeneic hematopoietic stem cell transplantation (HSCT). Belumosudil is approved for patients who have failed at least two prior lines of systemic therapy, which represents a third-line or later treatment setting.

- **US:** Approximately 14,000-20,000 HSCTs are performed annually, with 30-50% developing cGVHD. Of these, ~30-40% may fail two prior therapies, leading to an estimated **2,000-3,000 eligible patients** annually.
- **EU5:** HSCT numbers are similar to the US on a per capita basis, with a slightly larger population (~450 million vs. 330 million in the US). Estimated eligible patients: **3,000-4,500**.
- **Japan:** HSCT volume is lower, with ~5,000-6,000 procedures annually. Eligible patients: **500-800**.
- **China:** HSCT is growing rapidly, with ~10,000-15,000 procedures annually, though access to advanced therapies like belumosudil may be limited. Eligible patients: **1,500-2,500**.

Total eligible patients across these geographies: **7,000-10,800**.

## **Step 2: Estimate Treated Patients (Market Penetration)**

The query assumes a **20-30% share of treated patients** among the eligible population. This accounts for competition (e.g., ruxolitinib, ibrutinib), access barriers, and physician/payer adoption.

- **US:** 20-30% of 2,000-3,000 = **400-900 treated patients**.
- **EU5:** 20-30% of 3,000-4,500 = **600-1,350 treated patients**.
- **Japan:** 20-30% of 500-800 = **100-240 treated patients**.
- **China:** 20-30% of 1,500-2,500 = **300-750 treated patients**.

Total treated patients at peak: **1,400-3,240**.

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

Belumosudil's pricing in the US is approximately **\$150,000-\$200,000 per patient per year** (based on typical pricing for rare disease drugs and kinase inhibitors like ruxolitinib). Pricing in other regions is often lower due to healthcare system negotiations:

- **US:** \$175,000/year (midpoint).
- **EU5:** ~60-70% of US price = \$105,000-\$122,500/year (assume \$115,000).

- **Japan:** ~70-80% of US price = \$122,500-\$140,000/year (assume \$130,000).
- **China:** ~30-50% of US price due to market access and affordability = \$52,500-\$87,500/year (assume \$70,000).

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

Peak sales are calculated as (number of treated patients) × (annual cost per patient) at the assumed 20-30% market share.

### **- US:**

- Low end (20% share, 400 patients):  $400 \times \$175,000 = \text{\$70 million}$ .
- High end (30% share, 900 patients):  $900 \times \$175,000 = \text{\$157.5 million}$ .

### **- EU5:**

- Low end (600 patients):  $600 \times \$115,000 = \text{\$69 million}$ .
- High end (1,350 patients):  $1,350 \times \$115,000 = \text{\$155.25 million}$ .

### **- Japan:**

- Low end (100 patients):  $100 \times \$130,000 = \text{\$13 million}$ .
- High end (240 patients):  $240 \times \$130,000 = \text{\$31.2 million}$ .

### **- China:**

- Low end (300 patients):  $300 \times \$70,000 = \text{\$21 million}$ .
- High end (750 patients):  $750 \times \$70,000 = \text{\$52.5 million}$ .

### **Total Potential Peak Sales Across Geographies:**

- Low end (20% share): \$70M (US) + \$69M (EU5) + \$13M (Japan) + \$21M (China) = **\$173 million**.
- High end (30% share): \$157.5M (US) + \$155.25M (EU5) + \$31.2M (Japan) + \$52.5M (China) = **\$396.45 million**.

**Range for Potential Peak Sales: \$173 million to \$396 million annually.**

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

A 1% share of treated patients corresponds to 1% of the eligible patient population being treated with belumosudil. Using the midpoint of eligible patients for simplicity:

- **US:** 1% of 2,500 = 25 patients × \$175,000 = **\$4.375 million**.
- **EU5:** 1% of 3,750 = 37.5 patients × \$115,000 = **\$4.3125 million**.
- **Japan:** 1% of 650 = 6.5 patients × \$130,000 = **\$0.845 million**.
- **China:** 1% of 2,000 = 20 patients × \$70,000 = **\$1.4 million**.

**Total \$ Value of 1% Share Across Geographies:** \$4.375M (US) + \$4.3125M (EU5) + \$0.845M (Japan) + \$1.4M (China) = **\$10.9325 million.**

## **Final Answer**

**- Potential Peak Sales for Belumosudil in cGVHD (20-30% share of treated patients):**

- US: \$70M - \$157.5M

- EU5: \$69M - \$155.25M

- Japan: \$13M - \$31.2M

- China: \$21M - \$52.5M

**- Total: \$173M - \$396M annually.**

**- \$ Value of 1% Share of Treated Patients:**

- US: \$4.375M

- EU5: \$4.3125M

- Japan: \$0.845M

- China: \$1.4M

**- Total: \$10.93M annually.**

## **Caveats**

- These estimates are based on assumptions for patient numbers, pricing, and market penetration. Actual sales could vary due to competition, reimbursement, regulatory approvals (e.g., belumosudil may not yet be approved in all regions like China), and patient access.

- Peak sales may take several years to achieve post-launch as adoption grows.

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