

To estimate the **Potential Peak Sales** for abatacept (Orencia) in the prophylaxis of acute graft versus host disease (aGVHD) 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 numbers, pricing, and market penetration may not be fully available, I will outline the methodology and make reasonable assumptions based on available information and industry standards. The final numbers are illustrative and should be refined with more precise data if available.

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

Abatacept is approved for the prophylaxis of aGVHD in patients undergoing hematopoietic stem cell transplantation (HSCT) from matched or 1 allele-mismatched unrelated donors, for adults and pediatric patients aged 2 years and older. We need to estimate the number of eligible patients in each geography.

#### Incidence of HSCT and aGVHD Risk

- **HSCT Procedures:** The number of HSCT procedures varies by region. According to data from the Center for International Blood and Marrow Transplant Research (CIBMTR) and other sources:

- **US:** ~8,000-10,000 allogeneic HSCTs annually.

- **EU5:** ~15,000-18,000 allogeneic HSCTs annually (combined across the 5 countries).

- **Japan:** ~3,000-4,000 allogeneic HSCTs annually.

- **China:** ~5,000-7,000 allogeneic HSCTs annually (growing rapidly due to increasing healthcare access).

- **aGVHD Risk:** Approximately 30-50% of allogeneic HSCT patients develop aGVHD, depending on donor match and other factors. Since abatacept is for prophylaxis in matched or 1 allele-mismatched unrelated donor HSCTs, we assume ~50-60% of allogeneic HSCTs fall into this category.

- **Eligible Patients:** For simplicity, assume 50% of allogeneic HSCT patients are eligible for abatacept prophylaxis.

#### Estimated Eligible Patients for Prophylaxis

- US: 8,000 HSCTs x 50% = **4,000 patients**.

- EU5: 16,000 HSCTs x 50% = **8,000 patients**.

- Japan: 3,500 HSCTs x 50% = **1,750 patients**.

- China: 6,000 HSCTs x 50% = **3,000 patients**.

- **Total Eligible Patients:** 4,000 (US) + 8,000 (EU5) + 1,750 (Japan) + 3,000 (China) = **16,750 patients annually**.

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

The problem assumes a 20-30% share of treated patients. This represents the proportion of eligible patients who will receive abatacept. We will calculate for both ends of this range:

- **20% Penetration:**  $16,750 \times 0.20 = 3,350$  treated patients.

- **30% Penetration:**  $16,750 \times 0.30 = 5,025$  treated patients.

#### Breakdown by Geography (at 20% and 30% Penetration)

- **US:**  $4,000 \times 20\% = 800$  patients;  $4,000 \times 30\% = 1,200$  patients.

- **EU5:**  $8,000 \times 20\% = 1,600$  patients;  $8,000 \times 30\% = 2,400$  patients.

- **Japan:**  $1,750 \times 20\% = 350$  patients;  $1,750 \times 30\% = 525$  patients.

- **China:**  $3,000 \times 20\% = 600$  patients;  $3,000 \times 30\% = 900$  patients.

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### **Step 3: Pricing of Abatacept**

Abatacept (Orencia) is a biologic drug, and pricing varies by region due to healthcare systems, reimbursement policies, and market dynamics. For aGVHD prophylaxis, the treatment regimen may involve multiple doses over a short period (likely 4-6 doses based on clinical trial data, e.g., the ABA2 trial). We assume an annual or per-treatment course cost based on existing pricing for other indications (e.g., rheumatoid arthritis) adjusted for this acute use.

#### Estimated Cost per Treatment Course

- **US:** ~\$50,000 per treatment course (biologics for rare indications often carry high prices).

- **EU5:** ~\$30,000 per treatment course (lower due to price controls and negotiations).

- **Japan:** ~\$35,000 per treatment course (similar to EU but with some premium pricing).

- **China:** ~\$15,000 per treatment course (lower due to cost sensitivity and local pricing dynamics).

These are rough estimates and may vary based on actual dosing schedules and negotiated prices.

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

Peak sales are calculated as:

**Peak Sales = Number of Treated Patients x Cost per Treatment Course**

#### At 20% Penetration

- **US:**  $800 \text{ patients} \times \$50,000 = \$40 \text{ million}$ .

- **EU5:**  $1,600 \text{ patients} \times \$30,000 = \$48 \text{ million}$ .

- **Japan:**  $350 \text{ patients} \times \$35,000 = \$12.25 \text{ million}$ .

- **China:**  $600 \text{ patients} \times \$15,000 = \$9 \text{ million}$ .

- **Total Peak Sales (20%):** \$40M + \$48M + \$12.25M + \$9M = **\$109.25 million.**

#### At 30% Penetration

- **US:** 1,200 patients x \$50,000 = **\$60 million.**

- **EU5:** 2,400 patients x \$30,000 = **\$72 million.**

- **Japan:** 525 patients x \$35,000 = **\$18.375 million.**

- **China:** 900 patients x \$15,000 = **\$13.5 million.**

- **Total Peak Sales (30%):** \$60M + \$72M + \$18.375M + \$13.5M = **\$163.875 million.**

#### Range of Potential Peak Sales

- **Potential Peak Sales for Abatacept in aGVHD Prophylaxis: \$109.25 million to \$163.875 million annually** across the US, EU5, Japan, and China, assuming 20-30% market penetration.

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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 eligible patient population being treated with abatacept.

#### Eligible Patients per 1% Share

- Total Eligible Patients = 16,750.

- 1% Share = 16,750 x 0.01 = **167.5 patients.**

#### Breakdown by Geography (1% Share)

- **US:** 4,000 x 0.01 = 40 patients.

- **EU5:** 8,000 x 0.01 = 80 patients.

- **Japan:** 1,750 x 0.01 = 17.5 patients.

- **China:** 3,000 x 0.01 = 30 patients.

#### Revenue from 1% Share

- **US:** 40 patients x \$50,000 = **\$2 million.**

- **EU5:** 80 patients x \$30,000 = **\$2.4 million.**

- **Japan:** 17.5 patients x \$35,000 = **\$0.6125 million.**

- **China:** 30 patients x \$15,000 = **\$0.45 million.**

- **Total \$ Value of 1% Share:** \$2M + \$2.4M + \$0.6125M + \$0.45M = **\$5.4625 million.**

#### Summary of \$ Value of 1% Share

- **\$ Value of 1% Share of Treated Patients: \$5.46 million annually** across the US, EU5, Japan, and China.

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## **Final Answer**

1. **Potential Peak Sales for Abatacept in aGVHD Prophylaxis** (assuming 20-30% market penetration):

- **\$109.25 million to \$163.88 million annually** across the US, EU5, Japan, and China.

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

- **\$5.46 million annually** across the US, EU5, Japan, and China.

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## **Notes and Assumptions**

- The patient numbers for HSCT and aGVHD eligibility are approximate and based on publicly available data. Actual numbers may vary.

- Pricing assumptions are illustrative and based on typical costs for biologics in rare disease indications. Real-world pricing for abatacept in aGVHD prophylaxis may differ.

- Market penetration of 20-30% assumes competition, reimbursement challenges, and physician adoption rates. Abatacept being the first approved drug for aGVHD prophylaxis may lead to higher initial uptake, but this is speculative.

- These calculations do not account for potential growth in HSCT procedures, changes in pricing, or additional indications for abatacept.

If more specific data (e.g., exact HSCT numbers, dosing regimens, or regional pricing) is available, the estimates can be refined further.