

To estimate the **Potential Peak Sales** for **daratumumab and hyaluronidase-fihj (Darzalex Faspro)** in the indication of multiple myeloma (MM) in combination with pomalidomide and dexamethasone for patients with at least one prior line of therapy, as well as the **\$ value of a 1% share of treated patients** in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, we need to follow a structured approach. Since specific data (e.g., exact patient numbers, pricing, or market penetration rates) is not provided, I will outline the methodology and make reasonable assumptions based on publicly available information and market trends for multiple myeloma treatments. All figures are approximate and should be validated with up-to-date data.

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

Daratumumab and hyaluronidase-fihj (Darzalex Faspro) is approved for adult patients with multiple myeloma who have received at least one prior line of therapy, including lenalidomide and a proteasome inhibitor. This targets a relapsed/refractory multiple myeloma (RRMM) population in the second-line or later (2L+) setting.

Estimated MM Patient Population (Incident and Prevalent Cases):

- **US:** ~35,000 new cases of MM per year (American Cancer Society, 2023). Prevalent cases (living with MM) are ~150,000. For RRMM (2L+), approximately 50-60% of prevalent cases may be eligible (~75,000-90,000 patients).
- **EU5:** ~40,000 new cases per year across EU5. Prevalent cases are ~160,000. For RRMM (2L+), ~80,000-96,000 patients.
- **China:** ~20,000-25,000 new cases per year (due to lower incidence rates compared to Western countries). Prevalent cases are ~80,000-100,000. For RRMM (2L+), ~40,000-50,000 patients.
- **Japan:** ~7,000-8,000 new cases per year. Prevalent cases are ~30,000-35,000. For RRMM (2L+), ~15,000-18,000 patients.

Total eligible RRMM patients (2L+):

- US: ~85,000 (midpoint)
- EU5: ~88,000 (midpoint)
- China: ~45,000 (midpoint)
- Japan: ~16,500 (midpoint)
- **Total across geographies:** ~234,500 patients.

Treated Patient Share (Assumption):

Not all eligible patients receive treatment due to access, cost, or clinical decisions. Assume ~70-80% of eligible RRMM patients are treated in the US and EU5, ~50-60% in China, and ~60-70% in Japan:

- US: ~60,000 treated patients
- EU5: ~62,000 treated patients
- China: ~25,000 treated patients
- Japan: ~11,000 treated patients

- **Total treated patients:** ~158,000.

Market Share Assumption (20-30% as per query):

Given the 20-30% share of treated patients, let's calculate the number of patients treated with Darzalex Faspro:

- US: 20-30% of 60,000 = 12,000-18,000 patients
- EU5: 20-30% of 62,000 = 12,400-18,600 patients
- China: 20-30% of 25,000 = 5,000-7,500 patients
- Japan: 20-30% of 11,000 = 2,200-3,300 patients
- **Total patients treated with Darzalex Faspro:** 31,600-47,400 (midpoint ~39,500).

****Step 2: Estimate Drug Pricing****

Darzalex Faspro's pricing varies by geography due to healthcare systems, negotiations, and purchasing power. The cost is typically based on a yearly treatment cost per patient (often involving multiple cycles):

- **US:** Annual cost ~\$150,000-\$180,000 per patient (based on Darzalex IV pricing and reports of Faspro being similarly priced).
- **EU5:** Annual cost ~\$80,000-\$100,000 per patient (lower due to price negotiations and health system discounts).
- **China:** Annual cost ~\$40,000-\$60,000 per patient (adjusted for lower pricing and market access challenges).
- **Japan:** Annual cost ~\$90,000-\$110,000 per patient (similar to EU5 but with slight variations).

Using midpoint pricing:

- US: \$165,000
- EU5: \$90,000
- China: \$50,000
- Japan: \$100,000

****Step 3: Calculate Potential Peak Sales****

Peak sales are calculated by multiplying the number of treated patients (at 20-30% share) by the annual cost per patient in each geography.

At 20% Share:

- US: 12,000 patients * \$165,000 = **\$1.98 billion**

- EU5: 12,400 patients * \$90,000 = **\$1.12 billion**
- China: 5,000 patients * \$50,000 = **\$0.25 billion**
- Japan: 2,200 patients * \$100,000 = **\$0.22 billion**
- **Total Peak Sales (20% share): \$3.57 billion**

At 30% Share:

- US: 18,000 patients * \$165,000 = **\$2.97 billion**
- EU5: 18,600 patients * \$90,000 = **\$1.67 billion**
- China: 7,500 patients * \$50,000 = **\$0.38 billion**
- Japan: 3,300 patients * \$100,000 = **\$0.33 billion**
- **Total Peak Sales (30% share): \$5.35 billion**

Range of Potential Peak Sales: \$3.57 billion to \$5.35 billion (midpoint ~\$4.46 billion).

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

A 1% share of treated patients corresponds to 1% of the total treated patient population in each geography. Multiply this by the annual cost per patient.

- **US:** 1% of 60,000 = 600 patients * \$165,000 = **\$99 million**
- **EU5:** 1% of 62,000 = 620 patients * \$90,000 = **\$55.8 million**
- **China:** 1% of 25,000 = 250 patients * \$50,000 = **\$12.5 million**
- **Japan:** 1% of 11,000 = 110 patients * \$100,000 = **\$11 million**
- **Total \$ Value of 1% Share Across Geographies: \$178.3 million**

****Final Answer****

1. **Potential Peak Sales for Darzalex Faspro** in the specified indication (multiple myeloma, 2L+ in combination with pomalidomide and dexamethasone) at 20-30% share of treated patients:

- **Range: \$3.57 billion to \$5.35 billion** annually across the US, EU5, China, and Japan.
- **Midpoint: ~\$4.46 billion.**

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

- **US: \$99 million**
- **EU5: \$55.8 million**

- China: **\$12.5 million**
- Japan: **\$11 million**
- **Total: \$178.3 million** annually.

****Caveats and Notes****

- These estimates are based on assumptions about patient populations, treatment rates, market share, and pricing. Real-world figures may differ due to competition (e.g., other anti-CD38 therapies like isatuximab), reimbursement policies, and market access.
- Peak sales typically occur several years after launch as market penetration grows, and sales may decline with patent expiry or biosimilar competition.
- For more precise figures, consult specific epidemiology data, payer policies, and company reports (e.g., Janssen's financials for Darzalex sales). Darzalex (IV and Faspro combined) already generates over \$8 billion annually globally across all indications, so this estimate for one indication aligns with a subset of total revenue.