

To estimate the **Potential Peak Sales** for **daratumumab and hyaluronidase-fihj (Darzalex Faspro)** in the specified indication (newly diagnosed multiple myeloma [NDMM] eligible for autologous stem cell transplant [ASCT]) in the US, EU5 (Germany, France, 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 based on available data, assumptions, and market analysis. Since specific sales data or exact patient numbers might not be publicly available in real-time, I will use a combination of industry-standard approaches, epidemiology data, and reasonable assumptions. Let's break this down step-by-step.

Step 1: Define the Target Patient Population

The indication is for **newly diagnosed multiple myeloma (NDMM) patients eligible for ASCT** in combination with bortezomib, lenalidomide, and dexamethasone (VRd) for induction and consolidation.

Incidence of Multiple Myeloma (MM) and NDMM Eligible for ASCT

- **US:** The incidence of MM is approximately 7 per 100,000 people, with a population of ~330 million, leading to ~34,000 new cases annually (American Cancer Society, 2023). About 40-50% of NDMM patients are eligible for ASCT (based on age <65-70 years and comorbidities).

- NDMM eligible for ASCT: ~13,600 to 17,000 patients/year.

- **EU5:** The incidence of MM is similar, around 7-8 per 100,000, with a combined population of ~330 million, leading to ~26,000-28,000 new cases annually. ASCT eligibility is ~40-50%.

- NDMM eligible for ASCT: ~10,400 to 14,000 patients/year.

- **China:** Incidence is lower, ~1-2 per 100,000, with a population of ~1.4 billion, leading to ~14,000-28,000 new cases annually. ASCT eligibility is lower due to access and cost constraints, estimated at ~20-30%.

- NDMM eligible for ASCT: ~2,800 to 8,400 patients/year.

- **Japan:** Incidence is ~3-4 per 100,000, with a population of ~125 million, leading to ~3,750-5,000 new cases annually. ASCT eligibility is ~40-50%.

- NDMM eligible for ASCT: ~1,500 to 2,500 patients/year.

Total NDMM Eligible for ASCT Across Geographies:

- US: ~15,300 (midpoint)

- EU5: ~12,200 (midpoint)

- China: ~5,600 (midpoint)

- Japan: ~2,000 (midpoint)

- **Total:** ~35,100 patients/year

Treated Patients (Assuming 20-30% Market Share)

The problem states a 20-30% share of treated patients for Darzalex Faspro in this indication. Assuming "treated patients" refers to the eligible NDMM ASCT population who receive treatment:

- **20% share:** ~7,020 patients/year
- **30% share:** ~10,530 patients/year

Step 2: Estimate Annual Cost of Treatment per Patient

Darzalex Faspro is a high-cost biologic therapy. The annual cost of treatment depends on the dosing schedule (e.g., induction and consolidation phases for NDMM ASCT-eligible patients, typically 4-6 cycles pre-ASCT and 2-4 cycles post-ASCT).

- **US:** The annual cost of Darzalex (IV or SC) is approximately \$150,000–\$200,000 per patient for a full course in NDMM (based on reported costs and payer data). Let's assume ~\$175,000 as midpoint.
- **EU5:** Pricing is typically 30-50% lower due to healthcare system negotiations. Assume ~\$100,000–\$120,000 per patient (midpoint ~\$110,000).
- **China:** Pricing is further discounted due to market access challenges and local policies. Assume ~\$50,000–\$70,000 per patient (midpoint ~\$60,000).
- **Japan:** Pricing is closer to EU levels due to regulated markets. Assume ~\$100,000–\$120,000 per patient (midpoint ~\$110,000).

Weighted Average Cost per Patient (Approximate):

- Considering patient distribution and pricing differences, the average cost per patient across geographies is roughly ~\$120,000 (weighted by higher costs in the US and lower in China).

Step 3: Calculate Potential Peak Sales

Peak sales are typically achieved 5-7 years post-launch in an indication, assuming maximum market penetration (20-30% as given). Using the patient numbers and cost estimates:

At 20% Market Share (~7,020 patients/year)

- **US:** 15,300 patients * 20% = 3,060 patients * \$175,000 = **\$535.5 million**
- **EU5:** 12,200 patients * 20% = 2,440 patients * \$110,000 = **\$268.4 million**
- **China:** 5,600 patients * 20% = 1,120 patients * \$60,000 = **\$67.2 million**
- **Japan:** 2,000 patients * 20% = 400 patients * \$110,000 = **\$44.0 million**
- **Total Peak Sales (20% share): \$915.1 million/year**

At 30% Market Share (~10,530 patients/year)

- **US:** 15,300 patients * 30% = 4,590 patients * \$175,000 = **\$803.3 million**
- **EU5:** 12,200 patients * 30% = 3,660 patients * \$110,000 = **\$402.6 million**
- **China:** 5,600 patients * 30% = 1,680 patients * \$60,000 = **\$100.8 million**

- **Japan:** 2,000 patients * 30% = 600 patients * \$110,000 = **\$66.0 million**

- **Total Peak Sales (30% share): \$1,372.7 million/year**

Potential Peak Sales Range: \$915 million to \$1.37 billion annually across the US, EU5, China, and Japan for this indication.

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

A 1% share of treated patients corresponds to 1% of the total NDMM ASCT-eligible population (~35,100 patients/year = 351 patients/year).

Using the same per-patient cost estimates:

- **US:** 15,300 * 1% = 153 patients * \$175,000 = **\$26.8 million**

- **EU5:** 12,200 * 1% = 122 patients * \$110,000 = **\$13.4 million**

- **China:** 5,600 * 1% = 56 patients * \$60,000 = **\$3.4 million**

- **Japan:** 2,000 * 1% = 20 patients * \$110,000 = **\$2.2 million**

- **Total \$ Value of 1% Share: \$45.8 million/year**

Final Answer

- **Potential Peak Sales** for daratumumab and hyaluronidase-fihj (Darzalex Faspro) in NDMM ASCT-eligible patients (20-30% market share):

- **\$915 million to \$1.37 billion annually** across the US, EU5, China, and Japan.

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

- **\$45.8 million annually** across the US, EU5, China, and Japan.

Note: These estimates are based on assumptions regarding epidemiology, ASCT eligibility, market share, and pricing. Actual figures may vary based on real-world uptake, competition (e.g., other anti-CD38 therapies like isatuximab), payer dynamics, and regional access. For precise figures, primary market research or proprietary data from sources like EvaluatePharma or company reports would be needed.