

To calculate the **Potential Peak Sales** for **daratumumab and hyaluronidase-fihj (Darzalex Faspro)** in the indication of newly diagnosed light chain (AL) amyloidosis 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. Since specific data on patient populations, pricing, and market dynamics may not be fully available, I will outline the methodology and provide a reasoned estimate based on publicly available information and logical assumptions. Please note that exact figures would require proprietary data from sources like company reports, market research, or healthcare databases.

Step 1: Indication and Market Context

- **Indication:** Daratumumab and hyaluronidase-fihj (Darzalex Faspro) in combination with bortezomib, cyclophosphamide, and dexamethasone (VCd) for newly diagnosed light chain (AL) amyloidosis.
- **Approval:** Granted accelerated approval by the FDA in January 2021 for this indication.
- **Disease Overview:** AL amyloidosis is a rare disease caused by abnormal plasma cells producing amyloid proteins that deposit in organs. Incidence is approximately 8-12 per million people per year, with a prevalence of ~30,000-45,000 patients in the US and EU combined. Newly diagnosed patients are a subset of this population.

Step 2: Estimate Treated Patient Population

Since the question assumes a **20% to 30% share of treated patients**, we first need to estimate the total number of newly diagnosed AL amyloidosis patients eligible for treatment in each geography.

Incidence of AL Amyloidosis (Newly Diagnosed Cases per Year)

- **US:** Incidence is ~8-12 per million. With a population of ~330 million, this translates to ~2,640-3,960 new cases per year.
- **EU5:** Combined population of ~320 million. Using the same incidence rate, ~2,560-3,840 new cases per year.
- **China:** Population of ~1.4 billion. Incidence data is less clear, but assuming a similar or slightly lower rate (due to underdiagnosis), ~8,400-12,600 new cases per year.
- **Japan:** Population of ~125 million. Incidence of ~1,000-1,500 new cases per year.

Total newly diagnosed patients annually (midpoint estimate):

- US: 3,300
- EU5: 3,200
- China: 10,500
- Japan: 1,250
- **Total:** ~18,250 patients per year.

Treated Patient Share

Assuming **20%-30% market share** for Darzalex Faspro in this indication (as per the question), the number of treated patients per year would be:

- **20% share:** $18,250 * 0.2 = 3,650$ patients

- **30% share:** $18,250 * 0.3 = 5,475$ patients

Breaking this down by geography (proportional to incidence):

- **US (18% of total patients):**

- 20% share: $3,300 * 0.2 = 660$ patients

- 30% share: $3,300 * 0.3 = 990$ patients

- **EU5 (17.5% of total patients):**

- 20% share: $3,200 * 0.2 = 640$ patients

- 30% share: $3,200 * 0.3 = 960$ patients

- **China (57.5% of total patients):**

- 20% share: $10,500 * 0.2 = 2,100$ patients

- 30% share: $10,500 * 0.3 = 3,150$ patients

- **Japan (7% of total patients):**

- 20% share: $1,250 * 0.2 = 250$ patients

- 30% share: $1,250 * 0.3 = 375$ patients

Step 3: Estimate Annual Treatment Cost per Patient

Darzalex Faspro pricing varies by region due to differences in healthcare systems, reimbursement, and pricing negotiations. Based on available data for Darzalex (IV formulation) and Faspro:

- **US:** Annual cost of Darzalex Faspro is ~\$150,000-\$200,000 per patient (based on multiple myeloma indication; AL amyloidosis may be similar or slightly lower due to combination therapy and dosing schedule).

- **EU5:** Pricing is typically 30%-50% lower than the US due to price controls. Estimate ~\$80,000-\$120,000 per patient annually.

- **China:** Pricing is significantly lower due to market access challenges and generics competition. Estimate ~\$30,000-\$50,000 per patient annually.

- **Japan:** Pricing is closer to EU levels, ~\$80,000-\$120,000 per patient annually.

Using midpoint estimates for annual cost per patient:

- US: \$175,000

- EU5: \$100,000

- China: \$40,000

- Japan: \$100,000

Step 4: Calculate Potential Peak Sales

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

At 20% Market Share

- **US:** 660 patients * \$175,000 = **\$115.5 million**
- **EU5:** 640 patients * \$100,000 = **\$64 million**
- **China:** 2,100 patients * \$40,000 = **\$84 million**
- **Japan:** 250 patients * \$100,000 = **\$25 million**
- **Total Peak Sales at 20% Share:** \$115.5M + \$64M + \$84M + \$25M = **\$288.5 million**

At 30% Market Share

- **US:** 990 patients * \$175,000 = **\$173.25 million**
- **EU5:** 960 patients * \$100,000 = **\$96 million**
- **China:** 3,150 patients * \$40,000 = **\$126 million**
- **Japan:** 375 patients * \$100,000 = **\$37.5 million**
- **Total Peak Sales at 30% Share:** \$173.25M + \$96M + \$126M + \$37.5M = **\$432.75 million**

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

A 1% share of treated patients corresponds to 1% of the total newly diagnosed patients (18,250 * 0.01 = 182.5 patients). Breaking this down by geography and multiplying by the annual cost per patient:

- **US:** 3,300 * 0.01 = 33 patients * \$175,000 = **\$5.775 million**
- **EU5:** 3,200 * 0.01 = 32 patients * \$100,000 = **\$3.2 million**
- **China:** 10,500 * 0.01 = 105 patients * \$40,000 = **\$4.2 million**
- **Japan:** 1,250 * 0.01 = 12.5 patients * \$100,000 = **\$1.25 million**
- **Total \$ Value of 1% Share:** \$5.775M + \$3.2M + \$4.2M + \$1.25M = **\$14.425 million**

Final Answer

- **Potential Peak Sales for Darzalex Faspro in AL Amyloidosis (20%-30% Share):**

- At 20% share: **\$288.5 million**
- At 30% share: **\$432.75 million**

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

- US: **\$5.775 million**
- EU5: **\$3.2 million**
- China: **\$4.2 million**
- Japan: **\$1.25 million**

- Total: **\$14.425 million**

Notes and Caveats

1. These estimates are based on assumptions for incidence, pricing, and market share. Real-world figures may differ due to factors like reimbursement, competition, and uptake rates.
2. Peak sales assume steady-state market penetration, which may take several years post-launch to achieve.
3. AL amyloidosis is a rare disease, and the small patient pool limits overall sales potential compared to other indications for Darzalex (e.g., multiple myeloma).
4. Pricing in China is particularly uncertain due to government policies and potential inclusion in the National Reimbursement Drug List (NRDL), which could lower costs further.
5. If more precise data on patient numbers, pricing, or market dynamics is available, these estimates can be refined.