To estimate the **Potential Peak Sales** for "daratumumab + hyaluronidase-fihj" (Darzalex Faspro) in the indication of relapsed or refractory multiple myeloma (RRMM) in adult patients who have received 1 to 3 prior lines of therapy, as well as the **$ value of a 1% share of treated patients** in the US, EU5 (France, Germany, 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 therapies. The final numbers are illustrative and should be validated with real-world data.

Step 1: Define the Target Patient Population

The target population is adult patients with relapsed or refractory multiple myeloma (RRMM) who have received 1 to 3 prior lines of therapy. We need to estimate the number of eligible patients in each geography (US, EU5, China, Japan).

Incidence and Prevalence of Multiple Myeloma

- **US**: Approximately 35,000 new cases of multiple myeloma are diagnosed annually, with a prevalence of ~130,000 patients. RRMM patients in 1-3 prior lines of therapy account for ~40-50% of treated patients (as many are newly diagnosed or in later lines).

- **EU5**: Combined incidence is ~40,000 new cases annually, with a prevalence of ~150,000 patients. Similar proportion (~40-50%) in 1-3 prior lines.

- **China**: Incidence is lower due to underdiagnosis but growing; ~20,000 new cases annually, prevalence ~80,000. RRMM proportion assumed at ~40%.

- **Japan**: Incidence ~9,000 new cases annually, prevalence ~30,000. RRMM proportion ~40-50%.

Eligible Patients (RRMM, 1-3 Prior Lines)

Assuming 40-50% of prevalent patients are in the target group:

- **US**: ~52,000-65,000 patients

- **EU5**: ~60,000-75,000 patients

- **China**: ~32,000-40,000 patients

- **Japan**: ~12,000-15,000 patients

Total eligible patients across all geographies: ~156,000-195,000.

Treated Patients

Not all eligible patients receive active treatment due to access, comorbidities, or other factors. Assuming 80% of eligible patients are treated:

- **US**: ~42,000-52,000

- **EU5**: ~48,000-60,000

- **China**: ~26,000-32,000

- **Japan**: ~10,000-12,000

Total treated patients: ~126,000-156,000.

Step 2: Market Share Assumption

The problem states a **20-30% share of treated patients** for daratumumab + hyaluronidase-fihj. This is a reasonable assumption given Darzalex's established position in the RRMM market and the convenience of subcutaneous administration (Faspro). We will use the midpoint of 25% for calculations.

Treated patients with 25% market share:

- **US**: ~10,500-13,000
- **EU5**: ~12,000-15,000
- **China**: ~6,500-8,000
- **Japan**: ~2,500-3,000

Total patients on drug: ~31,500-39,000.

Step 3: Pricing per Patient

Daratumumab (Darzalex/Darzalex Faspro) pricing varies by region due to healthcare systems, negotiations, and access programs. Approximate annual cost per patient (based on historical data for Darzalex and typical RRMM treatment duration):

- **US**: ~$150,000-$200,000 per year
- **EU5**: ~$80,000-$120,000 per year (lower due to price controls)
- **China**: ~$50,000-$80,000 per year (discounts and local pricing)
- **Japan**: ~$100,000-$150,000 per year (similar to US but slightly lower)

Using midpoint values for simplicity:

- **US**: $175,000
- **EU5**: $100,000
- **China**: $65,000
- **Japan**: $125,000

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as: (Number of treated patients at 25% market share) × (Annual cost per patient).

- **US**: 11,750 patients × $175,000 = **$2.06 billion**

- **EU5**: 13,500 patients × $100,000 = **$1.35 billion**

- **China**: 7,250 patients × $65,000 = **$0.47 billion**

- **Japan**: 2,750 patients × $125,000 = **$0.34 billion**

Total Potential Peak Sales (at 25% market share): **$4.22 billion**

If we consider the range of 20-30% market share:

- At 20%: ~$3.38 billion

- At 30%: ~$5.06 billion

Thus, **Potential Peak Sales Range**: **$3.4-$5.1 billion annually**.

Step 5: 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. Using the midpoint of treated patients:

- **US**: 47,000 patients × 1% = 470 patients × $175,000 = **$82.25 million**

- **EU5**: 54,000 patients × 1% = 540 patients × $100,000 = **$54 million**

- **China**: 29,000 patients × 1% = 290 patients × $65,000 = **$18.85 million**

- **Japan**: 11,000 patients × 1% = 110 patients × $125,000 = **$13.75 million**

Total $ Value of 1% Share: **$168.85 million**

Final Answer

1. **Potential Peak Sales for daratumumab + hyaluronidase-fihj** in the indication of relapsed or refractory multiple myeloma (1-3 prior lines of therapy) across the US, EU5, China, and Japan, assuming a 20-30% market share:

- **Range**: $3.4 billion to $5.1 billion annually

- **Midpoint (25% share)**: $4.2 billion annually

Breakdown by geography (at 25% share):

- US: $2.06 billion

- EU5: $1.35 billion

- China: $0.47 billion

- Japan: $0.34 billion

2. **$ Value of 1% Share of Treated Patients** across these geographies:

- **Total**: $168.85 million

- Breakdown:

- US: $82.25 million

- EU5: $54 million

- China: $18.85 million

- Japan: $13.75 million

Note: These estimates are based on assumptions about patient numbers, treatment rates, market share, and pricing. Real-world data (e.g., from Janssen's financial reports, market research, or epidemiology studies) should be used to refine these figures. Factors such as competition (e.g., other anti-CD38 therapies, BCMA-targeted therapies), payer dynamics, and patent cliffs could also impact peak sales.