To estimate the **Potential Peak Sales** for **daratumumab and hyaluronidase-fihj (DARZALEX FASPRO)** in the specified indication (newly diagnosed or relapsed/refractory multiple myeloma) across the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, and to calculate the **$ value of a 1% share of treated patients** in these geographies, we need to follow a structured approach. Since exact data (e.g., patient population, pricing, or market share) isn't provided, I'll outline the methodology using reasonable assumptions based on publicly available information and industry standards. You can adjust the numbers based on more specific data if available.

Step 1: Key Assumptions and Methodology

1. **Indication**: Newly diagnosed or relapsed/refractory multiple myeloma (MM).

2. **Market Share**: Assuming 20% to 30% share of treated patients as given.

3. **Geographies**: US, EU5 (aggregate), China, and Japan.

4. **Patient Population**: Estimated based on epidemiology data for MM.

5. **Pricing**: Annual cost per patient for DARZALEX FASPRO (subcutaneous daratumumab) based on publicly reported figures or analogs.

6. **Peak Sales**: Calculated as (Eligible Patient Population) × (Market Share) × (Annual Cost per Patient).

7. **1% Share Value**: Calculated as (Peak Sales at 100% market share) × (1%).

Step 2: Estimating Patient Population for Multiple Myeloma

Using approximate incidence and prevalence data for MM (sourced from cancer statistics and reports like Globocan, SEER, and others):

- **US**: ~35,000 new cases/year; prevalence ~130,000 patients.

- **EU5**: ~40,000 new cases/year; prevalence ~150,000 patients.

- **China**: ~20,000 new cases/year; prevalence ~70,000 patients.

- **Japan**: ~8,000 new cases/year; prevalence ~30,000 patients.

For treatment-eligible patients (newly diagnosed or relapsed/refractory), we assume a significant portion of prevalent cases and incident cases are eligible. Let’s estimate **treated patient population** as follows (considering not all patients receive active treatment):

- **US**: ~50,000 treated patients.

- **EU5**: ~60,000 treated patients.

- **China**: ~30,000 treated patients.

- **Japan**: ~15,000 treated patients.

- **Total**: ~155,000 treated patients across geographies.

Step 3: Pricing Assumption

The annual cost of daratumumab-based therapy varies by region due to healthcare systems and pricing negotiations:

- **US**: ~$150,000–$200,000 per patient per year (based on DARZALEX IV pricing and reports).
- **EU5**: ~$80,000–$120,000 per patient per year (lower due to price controls).
- **China**: ~$50,000–$70,000 per patient per year (emerging market pricing).
- **Japan**: ~$100,000–$150,000 per patient per year (similar to US but slightly discounted).

For simplicity, let's use midpoint estimates:

- **US**: $175,000/year.
- **EU5**: $100,000/year.
- **China**: $60,000/year.
- **Japan**: $125,000/year.

Step 4: Potential Peak Sales Calculation (20%–30% Market Share)

Peak sales are calculated as:

Peak Sales = Treated Patients × Market Share × Annual Cost per Patient

At 20% Market Share:

- **US**: 50,000 × 20% × $175,000 = **$1.75 billion**
- **EU5**: 60,000 × 20% × $100,000 = **$1.2 billion**
- **China**: 30,000 × 20% × $60,000 = **$0.36 billion**
- **Japan**: 15,000 × 20% × $125,000 = **$0.375 billion**
- **Total at 20%**: **$3.685 billion**

At 30% Market Share:

- **US**: 50,000 × 30% × $175,000 = **$2.625 billion**
- **EU5**: 60,000 × 30% × $100,000 = **$1.8 billion**
- **China**: 30,000 × 30% × $60,000 = **$0.54 billion**
- **Japan**: 15,000 × 30% × $125,000 = **$0.5625 billion**
- **Total at 30%**: **$5.5275 billion**

Potential Peak Sales Range: **$3.7 billion to $5.5 billion** across the US, EU5, China, and Japan.

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

The value of a 1% market share is calculated as the total addressable market (100% share) divided by 100.

Total Addressable Market (100% Share):

- **US**: 50,000 × $175,000 = **$8.75 billion**

- **EU5**: 60,000 × $100,000 = **$6.0 billion**

- **China**: 30,000 × $60,000 = **$1.8 billion**

- **Japan**: 15,000 × $125,000 = **$1.875 billion**

- **Total**: **$18.425 billion**

Value of 1% Share:

- **US**: $8.75 billion ÷ 100 = **$87.5 million**

- **EU5**: $6.0 billion ÷ 100 = **$60 million**

- **China**: $1.8 billion ÷ 100 = **$18 million**

- **Japan**: $1.875 billion ÷ 100 = **$18.75 million**

- **Total**: $18.425 billion ÷ 100 = **$184.25 million**

Final Answer

1. **Potential Peak Sales for daratumumab and hyaluronidase-fihj** in the indication (newly diagnosed or relapsed/refractory multiple myeloma) across the US, EU5, China, and Japan, assuming 20%–30% market share:

$3.7 billion to $5.5 billion annually.

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

- **US**: $87.5 million

- **EU5**: $60 million

- **China**: $18 million

- **Japan**: $18.75 million

- **Total**: $184.25 million

Notes

- These estimates are based on assumptions for patient populations, pricing, and treatment rates. Actual figures may vary based on real-world data, competition (e.g., other MM therapies), market access, and pricing negotiations.

- DARZALEX FASPRO’s subcutaneous administration may drive higher adoption compared to IV daratumumab due to convenience, potentially impacting market share positively.

- If you have specific data on patient numbers, pricing, or market dynamics, I can refine the calculations accordingly.