To estimate the **Potential Peak Sales** for **naxitamab-gqgk (DANYELZA)** in the indication of relapsed or refractory high-risk neuroblastoma in the US, EU5 (France, Germany, Italy, Spain, UK), China, and Japan, as well as the **$ value of a 1% share of treated patients**, we need to follow a structured approach based on available data and reasonable assumptions. Since exact patient numbers, pricing, and market penetration can vary, I will outline the methodology and provide approximate figures based on publicly available information and typical market dynamics for rare diseases like neuroblastoma.

Step 1: Define the Target Patient Population

Neuroblastoma is a rare pediatric cancer, with a specific subset of patients having relapsed or refractory high-risk disease. The indication for naxitamab-gqgk is for pediatric and adult patients with relapsed/refractory high-risk neuroblastoma in the bone or bone marrow who have shown a partial response, minor response, or stable disease to prior therapy.

- **US**: Approximately 700-800 new cases of neuroblastoma are diagnosed annually, with about 50% being high-risk. Of these, a significant portion (around 40-50%) may relapse or become refractory. Assuming ~350 high-risk cases annually, with 40-50% relapsed/refractory, the eligible population could be ~140-175 patients per year. Considering prevalence (patients living with the disease over multiple years), the total addressable population may be higher (~500-700 patients).

- **EU5**: Incidence is similar to the US, adjusted for population. With a combined population of ~330 million (vs. ~330 million in the US), the annual new cases are ~600-700, with ~300 high-risk, and ~120-150 relapsed/refractory annually. Prevalence may be ~400-600 patients.

- **China**: With a population of ~1.4 billion, incidence scales up significantly. Assuming a slightly lower diagnosis rate due to healthcare access, ~2,000-2,500 new cases annually, with ~1,000-1,250 high-risk, and ~400-500 relapsed/refractory. Prevalence may be ~1,500-2,000 patients.

- **Japan**: Population of ~125 million, with ~250-300 new cases annually, ~125-150 high-risk, and ~50-75 relapsed/refractory. Prevalence may be ~150-200 patients.

Total Addressable Population (Prevalence Estimate for Treated Patients):

- US: ~600 patients

- EU5: ~500 patients

- China: ~1,750 patients

- Japan: ~175 patients

- **Total**: ~3,025 patients

Step 2: Market Penetration (20%-30% Share of Treated Patients)

The problem assumes a 20%-30% share of treated patients for naxitamab-gqgk. Given the rarity of the disease and the unmet need in relapsed/refractory high-risk neuroblastoma, this penetration rate is reasonable, especially as naxitamab is one of the few targeted therapies approved for this indication.

- **At 20% penetration**: ~605 patients treated annually (3,025 * 0.2)

- **At 30% penetration**: ~908 patients treated annually (3,025 * 0.3)

Breakdown by Geography (at 20%-30% penetration):

- US: 120-180 patients

- EU5: 100-150 patients

- China: 350-525 patients

- Japan: 35-53 patients

Step 3: Pricing of Naxitamab-gqgk

Naxitamab is a high-cost therapy due to its orphan drug status and targeted indication. Based on available information:

- In the US, the cost of naxitamab is approximately **$20,000 per vial**, with a typical treatment course requiring multiple vials over several cycles. A full course of treatment may cost ~$500,000-$1,000,000 per patient annually, depending on dosing and duration.

- In EU5 and Japan, pricing may be slightly lower due to healthcare system negotiations (~70%-80% of US price, or ~$350,000-$800,000 per patient).

- In China, pricing is often significantly lower due to market access and affordability constraints (~30%-50% of US price, or ~$150,000-$500,000 per patient).

Assumed Average Annual Cost per Patient:

- US: $750,000

- EU5: $600,000

- Japan: $600,000

- China: $300,000

Step 4: Calculate Potential Peak Sales

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

At 20% Penetration:

- **US**: 120 patients * $750,000 = **$90 million**

- **EU5**: 100 patients * $600,000 = **$60 million**

- **China**: 350 patients * $300,000 = **$105 million**

- **Japan**: 35 patients * $600,000 = **$21 million**

- **Total Peak Sales (20%)**: $90M + $60M + $105M + $21M = **$276 million**

At 30% Penetration:

- **US**: 180 patients * $750,000 = **$135 million**

- **EU5**: 150 patients * $600,000 = **$90 million**

- **China**: 525 patients * $300,000 = **$157.5 million**

- **Japan**: 53 patients * $600,000 = **$31.8 million**

- **Total Peak Sales (30%)**: $135M + $90M + $157.5M + $31.8M = **$414.3 million**

Potential Peak Sales Range: **$276 million to $414 million annually**

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

A 1% share of treated patients corresponds to 1% of the total addressable population (~3,025 patients), which is ~30 patients.

Value of 1% Share (30 patients):

- **US**: (600 * 0.01) = 6 patients * $750,000 = **$4.5 million**

- **EU5**: (500 * 0.01) = 5 patients * $600,000 = **$3 million**

- **China**: (1,750 * 0.01) = 17.5 patients * $300,000 = **$5.25 million**

- **Japan**: (175 * 0.01) = 1.75 patients * $600,000 = **$1.05 million**

- **Total Value of 1% Share**: $4.5M + $3M + $5.25M + $1.05M = **$13.8 million**

Final Answer:

1. **Potential Peak Sales for Naxitamab-gqgk (20%-30% penetration)**:

- Range: **$276 million to $414 million annually** across the US, EU5, China, and Japan.

- Breakdown:

- US: $90M - $135M

- EU5: $60M - $90M

- China: $105M - $157.5M

- Japan: $21M - $31.8M

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

- Total: **$13.8 million annually**

- Breakdown:

- US: $4.5M

- EU5: $3M

- China: $5.25M

- Japan: $1.05M

Note: These estimates are based on assumptions about patient population, pricing, and market penetration. Actual figures may vary based on real-world data, reimbursement policies, competition, and market access challenges, especially in China. For more precise calculations, detailed epidemiology data, pricing agreements, and market research would be required.