Zenocutuzumab-zbco (Bizengri) is a bispecific antibody developed by Merus N.V. that targets NRG1 fusion-positive cancers, a rare genetic alteration associated with various solid tumors. On [insert date if available, or note as "recently" if specific date is unknown], the U.S. Food and Drug Administration (FDA) granted accelerated approval to zenocutuzumab-zbco for the treatment of adults with unresectable or metastatic NRG1 fusion-positive solid tumors who have progressed on or after prior systemic therapy or who have no satisfactory alternative treatment options. This approval marks a significant milestone for patients with this rare cancer subtype.

To estimate the **Potential Peak Sales** for zenocutuzumab-zbco in the specified indication (NRG1 fusion-positive solid tumors) in the US, EU5 (Germany, France, Italy, Spain, UK), China, and Japan, as well as the **$ value of a 1% share of treated patients** in these geographies, we need to make several assumptions due to the rarity of the indication and limited publicly available data. The analysis will be based on epidemiology, market penetration, pricing, and treatment duration. Below is a step-by-step estimation:

Key Assumptions and Methodology

1. **Indication and Patient Population**:

- NRG1 fusion-positive solid tumors are rare, occurring in approximately 0.2%–0.5% of all solid tumors. Common tumor types include non-small cell lung cancer (NSCLC), pancreatic cancer, and others.

- Estimated annual incidence of solid tumors in the geographies:

- US: ~1.7 million new cancer cases/year.

- EU5: ~1.5 million new cancer cases/year.

- China: ~4.5 million new cancer cases/year.

- Japan: ~1.0 million new cancer cases/year.

- Assuming 0.3% of these are NRG1 fusion-positive, we estimate the eligible patient population.

2. **Market Penetration**:

- Given the 20%–30% share of treated patients as per the query, we will calculate peak sales at both ends of this range.

- Zenocutuzumab-zbco targets a rare, unmet need, so uptake could be high among diagnosed patients, though diagnosis rates may be limited due to the need for genetic testing.

3. **Pricing**:

- As a targeted therapy for a rare cancer, pricing is likely to be high, similar to other orphan drugs or bispecific antibodies (e.g., $150,000–$200,000 per patient per year in the US). We will use a conservative estimate of $180,000/year in the US, with adjustments for other regions based on healthcare system pricing (e.g., 60%–80% of US price in EU5 and Japan, 30%–40% in China).

4. **Treatment Duration**:

- Assuming an average treatment duration of 12 months for metastatic patients (based on progression-free survival in rare cancers).

5. **Diagnosis Rate**:

- Not all patients are tested for NRG1 fusions. We assume a diagnosis rate of 50% initially, growing over time with increased awareness and testing.

Step 1: Estimate Eligible Patient Population

Using the 0.3% prevalence for NRG1 fusions and a 50% diagnosis rate:

- **US**: 1.7M new cancer cases × 0.003 × 0.5 = ~2,550 diagnosed patients/year.
- **EU5**: 1.5M new cancer cases × 0.003 × 0.5 = ~2,250 diagnosed patients/year.
- **China**: 4.5M new cancer cases × 0.003 × 0.5 = ~6,750 diagnosed patients/year.
- **Japan**: 1.0M new cancer cases × 0.003 × 0.5 = ~1,500 diagnosed patients/year.

Total diagnosed patients across geographies: ~13,050/year.

Step 2: Estimate Treated Patients (20%–30% Market Share)

- **20% Share**:
- US: 2,550 × 0.2 = 510 patients.
- EU5: 2,250 × 0.2 = 450 patients.
- China: 6,750 × 0.2 = 1,350 patients.
- Japan: 1,500 × 0.2 = 300 patients.
- Total: 2,610 patients.
- **30% Share**:
- US: 2,550 × 0.3 = 765 patients.
- EU5: 2,250 × 0.3 = 675 patients.
- China: 6,750 × 0.3 = 2,025 patients.
- Japan: 1,500 × 0.3 = 450 patients.
- Total: 3,915 patients.

Step 3: Estimate Pricing per Patient per Year

- **US**: $180,000/year.

- **EU5**: $126,000/year (70% of US price).

- **Japan**: $144,000/year (80% of US price).

- **China**: $54,000/year (30% of US price).

Step 4: Calculate Potential Peak Sales

Peak sales are calculated as (number of treated patients) × (price per patient per year).

At 20% Market Share:

- **US**: 510 patients × $180,000 = $91.8 million.

- **EU5**: 450 patients × $126,000 = $56.7 million.

- **China**: 1,350 patients × $54,000 = $72.9 million.

- **Japan**: 300 patients × $144,000 = $43.2 million.

- **Total Peak Sales (20% share)**: $91.8M + $56.7M + $72.9M + $43.2M = **$264.6 million**.

At 30% Market Share:

- **US**: 765 patients × $180,000 = $137.7 million.

- **EU5**: 675 patients × $126,000 = $85.1 million.

- **China**: 2,025 patients × $54,000 = $109.4 million.

- **Japan**: 450 patients × $144,000 = $64.8 million.

- **Total Peak Sales (30% share)**: $137.7M + $85.1M + $109.4M + $64.8M = **$397.0 million**.

Potential Peak Sales Range: **$264.6 million to $397.0 million** annually across the US, EU5, China, and Japan for this indication.

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

A 1% share corresponds to 1% of the diagnosed patients being treated with zenocutuzumab-zbco.

- **US**: 2,550 patients × 0.01 = 25.5 patients × $180,000 = **$4.59 million**.

- **EU5**: 2,250 patients × 0.01 = 22.5 patients × $126,000 = **$2.84 million**.

- **China**: 6,750 patients × 0.01 = 67.5 patients × $54,000 = **$3.65 million**.

- **Japan**: 1,500 patients × 0.01 = 15 patients × $144,000 = **$2.16 million**.

- **Total Value of 1% Share**: $4.59M + $2.84M + $3.65M + $2.16M = **$13.24 million**.

$ Value of 1% Share of Treated Patients: **$13.24 million** annually across the US, EU5, China, and Japan.

Final Answer

- **Potential Peak Sales for zenocutuzumab-zbco** in the indication of NRG1 fusion-positive solid tumors, assuming a 20%–30% share of treated patients:

- **$264.6 million to $397.0 million** annually across the US, EU5, China, and Japan.

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

- **$13.24 million** annually across the US, EU5, China, and Japan.

Note: These estimates are based on assumptions about epidemiology, diagnosis rates, pricing, and market penetration. Actual figures may vary depending on real-world diagnosis rates, reimbursement policies, competition, and clinical trial outcomes (e.g., confirmatory trials for accelerated approval). Adjustments may be needed as more data becomes available. If you have specific data on pricing, patient numbers, or other parameters, I can refine the calculations further.