

To estimate the **Potential Peak Sales** for zanubrutinib (Brukinsa) in the indication of Waldenström's macroglobulinemia (WM) 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 follow a structured approach. Since specific data on patient numbers, pricing, and market dynamics may not be fully available, I will outline the methodology and provide reasonable assumptions based on available information and industry standards. Note that exact figures would require access to proprietary data (e.g., from BeiGene, market research reports, or databases like EvaluatePharma or GlobalData).

Step 1: Understanding Waldenström's Macroglobulinemia (WM)

- **WM Overview:** WM is a rare type of non-Hodgkin lymphoma characterized by the overproduction of IgM antibodies. It primarily affects older adults.
- **Epidemiology:** WM has an incidence of approximately 3-5 per million people per year in Western countries. Prevalence is higher due to its indolent nature (patients live with the disease for many years).
- **Treatment Landscape:** Treatments include BTK inhibitors (like ibrutinib and zanubrutinib), chemotherapy, and rituximab-based regimens. Zanubrutinib is a second-generation BTK inhibitor with potentially better efficacy and safety compared to ibrutinib.

Step 2: Estimating the Treated Patient Population

Since WM is rare, the total number of treated patients is limited. Below are approximate prevalence and treated patient estimates for each geography based on available epidemiology data and assumptions:

- **US:** Prevalence of WM is ~6,000-10,000 patients. Assuming 50-60% of patients are treated annually (due to indolent nature), ~3,000-6,000 patients are treated.
- **EU5:** Combined prevalence is ~8,000-12,000 patients (based on population size and similar incidence). Assuming 50-60% treated, ~4,000-7,000 patients.
- **China:** Prevalence is harder to estimate due to underdiagnosis, but with a population of 1.4 billion and lower reported incidence, assume ~5,000-8,000 prevalent cases. Assuming 30-40% treated (lower access to advanced therapies), ~1,500-3,000 patients.
- **Japan:** Prevalence is ~1,000-2,000 patients (smaller population, similar incidence to Western countries). Assuming 50-60% treated, ~500-1,200 patients.

Total treated patients across geographies: ~9,000-17,200.

Step 3: Market Share Assumption (20%-30%)

Given the query's assumption of a 20%-30% share of treated patients for zanubrutinib, we calculate the number of patients treated with zanubrutinib:

- **US:** 20%-30% of 3,000-6,000 = 600-1,800 patients.
- **EU5:** 20%-30% of 4,000-7,000 = 800-2,100 patients.
- **China:** 20%-30% of 1,500-3,000 = 300-900 patients.
- **Japan:** 20%-30% of 500-1,200 = 100-360 patients.
- **Total:** 1,800-5,160 patients treated with zanubrutinib.

Step 4: Drug Pricing and Annual Cost per Patient

Pricing for zanubrutinib varies by region due to healthcare systems, negotiations, and market access:

- **US:** Annual cost of BTK inhibitors like zanubrutinib is ~\$150,000-\$200,000 per patient (based on pricing for similar drugs like ibrutinib).
- **EU5:** Annual cost is typically lower due to price negotiations, ~\$80,000-\$120,000 per patient.
- **China:** Pricing is significantly lower due to government negotiations and local manufacturing, ~\$30,000-\$50,000 per patient.
- **Japan:** Pricing is similar to EU5, ~\$80,000-\$120,000 per patient.

Step 5: Potential Peak Sales Calculation

Peak sales are calculated as (number of patients treated with zanubrutinib) × (annual cost per patient). Using mid-range estimates for patient numbers and pricing:

- **US:** 1,200 patients (midpoint of 600-1,800) × \$175,000 = ~\$210 million.
- **EU5:** 1,450 patients (midpoint of 800-2,100) × \$100,000 = ~\$145 million.
- **China:** 600 patients (midpoint of 300-900) × \$40,000 = ~\$24 million.
- **Japan:** 230 patients (midpoint of 100-360) × \$100,000 = ~\$23 million.
- **Total Peak Sales:** \$210M (US) + \$145M (EU5) + \$24M (China) + \$23M (Japan) = ~\$402 million.

Range for Peak Sales (using low and high ends of patient numbers and pricing):

- Low end: ~\$180 million (lower patient numbers and pricing).
- High end: ~\$650 million (higher patient numbers and pricing).

Step 6: \$ Value of 1% Share of Treated Patients

A 1% share of treated patients represents the revenue generated from treating 1% of the total treated patient population in each geography.

- **US:** 1% of 3,000-6,000 = 30-60 patients × \$175,000 = ~\$5.25M-\$10.5M.
- **EU5:** 1% of 4,000-7,000 = 40-70 patients × \$100,000 = ~\$4M-\$7M.
- **China:** 1% of 1,500-3,000 = 15-30 patients × \$40,000 = ~\$0.6M-\$1.2M.
- **Japan:** 1% of 500-1,200 = 5-12 patients × \$100,000 = ~\$0.5M-\$1.2M.
- **Total \$ Value of 1% Share:** ~\$10.35M-\$19.9M.

Using midpoints for simplicity:

- **US:** ~\$7.9M.
- **EU5:** ~\$5.5M.
- **China:** ~\$0.9M.

- **Japan:** ~\$0.85M.
- **Total:** ~\$15.15M.

Final Answer

- Potential Peak Sales for Zanubrutinib in WM (20%-30% market share):

- US: ~\$210 million.
- EU5: ~\$145 million.
- China: ~\$24 million.
- Japan: ~\$23 million.
- **Total:** ~\$402 million (range: \$180M-\$650M).

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

- US: ~\$7.9 million.
- EU5: ~\$5.5 million.
- China: ~\$0.9 million.
- Japan: ~\$0.85 million.
- **Total:** ~\$15.15 million (range: \$10.35M-\$19.9M).

Caveats

- These estimates are based on assumptions and publicly available data. Real-world figures may differ due to pricing negotiations, market access, competition (e.g., ibrutinib, acalabrutinib), and patient uptake.

- WM is a small indication for zanubrutinib; the drug is also approved for other indications (e.g., mantle cell lymphoma, chronic lymphocytic leukemia), which could contribute to higher overall sales.

- Peak sales typically occur several years after launch, factoring in market penetration and patent exclusivity.

If you have access to specific data (e.g., exact patient numbers, pricing, or market share projections), I can refine these calculations further.