

To estimate the **Potential Peak Sales** for zanubrutinib (BRUKINSA) in the indication of mantle cell lymphoma (MCL) 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 penetration may not be publicly available in full detail, I will outline the methodology and make reasonable assumptions based on available information and industry standards. The final numbers are illustrative and should be validated with up-to-date market research or proprietary data.

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## **Step 1: Key Assumptions and Methodology**

1. **Indication and Patient Population:** Zanubrutinib is approved for adult patients with MCL who have received at least one prior therapy (relapsed/refractory MCL, or R/R MCL). We will estimate the number of eligible patients in each geography.
2. **Share of Treated Patients:** The problem assumes a 20% to 30% market share of treated patients for zanubrutinib in this indication.
3. **Pricing:** Pricing for zanubrutinib will vary by region based on healthcare systems, reimbursement policies, and local pricing benchmarks for oncology drugs (e.g., comparison to other BTK inhibitors like ibrutinib or acalabrutinib).
4. **Peak Sales:** Peak sales are typically achieved 5-7 years post-launch after market penetration stabilizes, assuming no major competition or patent expiry impacts.
5. **Annual Treatment Cost:** We will estimate an annual cost per patient based on publicly available data or analogous drugs.
6. **1% Share Value:** This will be derived by calculating the total market value for 100% of treated patients and dividing by 100.

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## **Step 2: Estimate Eligible Patient Population for R/R MCL**

Mantle cell lymphoma is a rare type of non-Hodgkin lymphoma. The incidence and prevalence vary by region, and only a subset of patients will have R/R MCL (second-line or later treatment). Below are approximate estimates of R/R MCL patients based on epidemiology data and published literature (e.g., Cancer Research UK, American Cancer Society, and global oncology reports):

### **- US:**

- MCL accounts for ~6% of non-Hodgkin lymphoma (NHL) cases.
  - Annual NHL incidence: ~80,000 cases; MCL incidence: ~4,800 cases.
  - ~50-60% of MCL patients progress to second-line therapy (R/R MCL): ~2,400-2,900 patients annually.
- ### **- EU5 (Germany, France, Italy, Spain, UK):**
- Combined NHL incidence: ~100,000 cases annually.
  - MCL incidence: ~6,000 cases.

- R/R MCL: ~3,000-3,600 patients annually.

- **China:**

- NHL incidence is lower per capita but higher in absolute numbers due to population size: ~90,000 cases annually.

- MCL incidence: ~5,400 cases.

- R/R MCL: ~2,700-3,200 patients annually (lower access to advanced therapies may reduce eligible patients).

- **Japan:**

- NHL incidence: ~30,000 cases annually.

- MCL incidence: ~1,800 cases.

- R/R MCL: ~900-1,100 patients annually.

**Total R/R MCL Patients (Approximate):**

- US: 2,650 patients

- EU5: 3,300 patients

- China: 2,950 patients

- Japan: 1,000 patients

- **Total:** ~9,900 patients annually across these geographies.

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### **Step 3: Estimate Annual Treatment Cost per Patient**

Zanubrutinib's pricing varies by region due to differences in healthcare systems and negotiation with payers. Based on available data and comparisons with other BTK inhibitors (e.g., ibrutinib, which costs ~\$150,000-\$180,000 per year in the US), we assume the following annual costs per patient:

- **US:** \$150,000 per patient per year (based on list price; actual net price may be lower due to discounts).

- **EU5:** \$80,000 per patient per year (lower due to price negotiations and reimbursement caps).

- **China:** \$40,000 per patient per year (lower pricing due to market access programs and local competition).

- **Japan:** \$100,000 per patient per year (pricing typically between US and EU levels).

These costs are rough estimates and assume continuous treatment for a year, though real-world duration may vary based on progression-free survival (PFS) or adverse events.

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### **Step 4: Calculate Total Addressable Market (100% Share)**

Total addressable market (TAM) for R/R MCL patients assuming 100% of patients are treated with zanubrutinib:

- **US:** 2,650 patients \* \$150,000 = **\$397.5 million**
- **EU5:** 3,300 patients \* \$80,000 = **\$264.0 million**
- **China:** 2,950 patients \* \$40,000 = **\$118.0 million**
- **Japan:** 1,000 patients \* \$100,000 = **\$100.0 million**
- **Total TAM:** **\$879.5 million** annually

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### **Step 5: Calculate Potential Peak Sales (20%-30% Share)**

Assuming zanubrutinib captures 20% to 30% of treated patients in this indication, the peak sales are:

- **At 20% Share:**
  - US:  $0.20 * \$397.5M = \$79.5 \text{ million}$
  - EU5:  $0.20 * \$264.0M = \$52.8 \text{ million}$
  - China:  $0.20 * \$118.0M = \$23.6 \text{ million}$
  - Japan:  $0.20 * \$100.0M = \$20.0 \text{ million}$
  - **Total Peak Sales (20%):** **\$175.9 million**
- **At 30% Share:**
  - US:  $0.30 * \$397.5M = \$119.3 \text{ million}$
  - EU5:  $0.30 * \$264.0M = \$79.2 \text{ million}$
  - China:  $0.30 * \$118.0M = \$35.4 \text{ million}$
  - Japan:  $0.30 * \$100.0M = \$30.0 \text{ million}$
  - **Total Peak Sales (30%):** **\$263.9 million**

**Potential Peak Sales Range:** **\$175.9 million to \$263.9 million** annually across the US, EU5, China, and Japan for R/R MCL.

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

The value of a 1% share is simply 1% of the total addressable market in each geography:

- **US:**  $\$397.5M / 100 = \$3.975 \text{ million per 1\% share}$
- **EU5:**  $\$264.0M / 100 = \$2.640 \text{ million per 1\% share}$

- **China:**  $\$118.0\text{M} / 100 = \$1.180 \text{ million per 1\% share}$
- **Japan:**  $\$100.0\text{M} / 100 = \$1.000 \text{ million per 1\% share}$
- **Total per 1% Share:**  $\$879.5\text{M} / 100 = \$8.795 \text{ million per 1\% share}$  across all geographies.

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## **Final Answer**

### **1. Potential Peak Sales for Zanubrutinib in R/R MCL (20%-30% share of treated patients):**

- US: \$79.5M to \$119.3M
- EU5: \$52.8M to \$79.2M
- China: \$23.6M to \$35.4M
- Japan: \$20.0M to \$30.0M
- **Total: \$175.9 million to \$263.9 million annually**

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

- US: \$3.975 million
- EU5: \$2.640 million
- China: \$1.180 million
- Japan: \$1.000 million
- **Total: \$8.795 million per 1% share**

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## **Notes and Caveats**

- These estimates are based on assumptions about patient numbers, pricing, and market share. Real-world data may differ due to competition (e.g., ibrutinib, acalabrutinib), access barriers, or changes in treatment paradigms.
- Patient numbers are annual incident cases for R/R MCL; prevalence (total treatable patients over multiple years) could increase the market size.
- Pricing assumptions are illustrative and may not reflect net prices after discounts or local pricing agreements.
- Zanubrutinib is approved in multiple indications (e.g., CLL/SLL, Waldenström's macroglobulinemia), so total sales potential across all indications would be higher than for MCL alone.

For more accurate figures, consult recent market research reports (e.g., EvaluatePharma, GlobalData) or BeiGene's financial disclosures.