To estimate the **Potential Peak Sales** for abemaciclib (Verzenio) in the adjuvant treatment of HR-positive, HER2-negative, node-positive early breast cancer with a high risk of recurrence and Ki-67 score ≥20% 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 real-time, I will outline the methodology and provide reasonable assumptions based on available information and market trends. Please note that these are illustrative calculations, and actual figures may vary based on proprietary data, market dynamics, and pricing strategies.

Step 1: Define the Target Patient Population

The indication is for **HR-positive, HER2-negative, node-positive early breast cancer at high risk of recurrence with Ki-67 score ≥20%**. We need to estimate the number of eligible patients in each geography.

1. **US**:

- Approximately 280,000 new breast cancer cases are diagnosed annually in the US (American Cancer Society, 2023).

- About 70% are HR-positive, HER2-negative (~196,000 cases).

- Of these, ~30-40% are node-positive (~58,800–78,400 cases).

- High risk of recurrence and Ki-67 ≥20% may apply to ~20-30% of node-positive cases (~11,760–23,520 patients annually).

- Let's assume ~17,500 eligible patients annually as a midpoint.

2. **EU5 (Germany, France, Italy, Spain, UK)**:

- Combined annual breast cancer incidence in EU5 is ~250,000 (based on GLOBOCAN and EU cancer statistics).

- Using similar proportions: 70% HR+/HER2- (~175,000), 30-40% node-positive (~52,500–70,000), and 20-30% high risk with Ki-67 ≥20% (~10,500–21,000).

- Assume ~15,750 eligible patients annually.

3. **China**:

- Breast cancer incidence is ~420,000 annually (GLOBOCAN 2020).

- HR+/HER2- (~294,000), node-positive (~88,200–117,600), high risk with Ki-67 ≥20% (~17,640–35,280).

- Assume ~26,500 eligible patients annually.

4. **Japan**:

- Breast cancer incidence is ~90,000 annually.

- HR+/HER2- (~63,000), node-positive (~18,900–25,200), high risk with Ki-67 ≥20% (~3,780–7,560).

- Assume ~5,670 eligible patients annually.

Total Eligible Patients Annually (across all geographies): ~17,500 (US) + 15,750 (EU5) + 26,500 (China) + 5,670 (Japan) = **65,420 patients**.

Step 2: Estimate Treated Patient Share

The query assumes a **20% to 30% share of treated patients** for abemaciclib in this indication. This accounts for competition (e.g., other CDK4/6 inhibitors like palbociclib and ribociclib, though abemaciclib is the first approved for adjuvant use), physician adoption, and payer dynamics.

- **Low-end (20%)**: 65,420 * 0.20 = **13,084 treated patients annually**.

- **High-end (30%)**: 65,420 * 0.30 = **19,626 treated patients annually**.

Step 3: Estimate Annual Treatment Cost per Patient

Abemaciclib pricing varies by region due to healthcare systems, negotiations, and discounts. Based on available data for metastatic breast cancer (prior indication), we can estimate costs for adjuvant use (assuming a 2-year treatment duration as per clinical trials like monarchE):

1. **US**: Annual cost ~$150,000–$160,000 per patient (based on list price before discounts).

- Assume ~$155,000/year.

2. **EU5**: Prices are lower due to negotiations; assume ~$80,000–$100,000/year.

- Assume ~$90,000/year.

3. **China**: Significantly lower due to pricing controls and local competition; assume ~$20,000–$30,000/year.

- Assume ~$25,000/year.

4. **Japan**: Pricing similar to EU5; assume ~$80,000–$100,000/year.

- Assume ~$90,000/year.

For simplicity, calculate weighted average cost based on patient distribution (or use region-specific costs for precision).

Step 4: Calculate Potential Peak Sales

Peak sales occur when the drug reaches maximum market penetration, typically a few years after launch. Using the 20% and 30% treated patient share, and applying region-specific costs:

Low-end (20% share):

- **US**: 17,500 * 0.20 = 3,500 patients * $155,000 = **$542.5 million**.

- **EU5**: 15,750 * 0.20 = 3,150 patients * $90,000 = **$283.5 million**.

- **China**: 26,500 * 0.20 = 5,300 patients * $25,000 = **$132.5 million**.

- **Japan**: 5,670 * 0.20 = 1,134 patients * $90,000 = **$102.1 million**.

- **Total Peak Sales (20%)**: $542.5M + $283.5M + $132.5M + $102.1M = **$1,060.6 million (~$1.06 billion)**.

High-end (30% share):

- **US**: 17,500 * 0.30 = 5,250 patients * $155,000 = **$813.8 million**.

- **EU5**: 15,750 * 0.30 = 4,725 patients * $90,000 = **$425.3 million**.

- **China**: 26,500 * 0.30 = 7,950 patients * $25,000 = **$198.8 million**.

- **Japan**: 5,670 * 0.30 = 1,701 patients * $90,000 = **$153.1 million**.

- **Total Peak Sales (30%)**: $813.8M + $425.3M + $198.8M + $153.1M = **$1,591.0 million (~$1.59 billion)**.

Potential Peak Sales Range: **$1.06 billion to $1.59 billion annually** across the US, EU5, China, and Japan for this indication.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population (65,420 patients) being treated with abemaciclib.

- **1% of eligible patients**: 65,420 * 0.01 = **654 patients**.

Now, apply region-specific costs based on patient distribution:

- **US**: (17,500 / 65,420) * 654 ≈ 175 patients * $155,000 = **$27.1 million**.

- **EU5**: (15,750 / 65,420) * 654 ≈ 157 patients * $90,000 = **$14.1 million**.

- **China**: (26,500 / 65,420) * 654 ≈ 265 patients * $25,000 = **$6.6 million**.

- **Japan**: (5,670 / 65,420) * 654 ≈ 57 patients * $90,000 = **$5.1 million**.

- **Total $ Value of 1% Share**: $27.1M + $14.1M + $6.6M + $5.1M = **$53.0 million**.

$ Value of 1% Share of Treated Patients: **$53 million annually**.

Summary

1. **Potential Peak Sales for Abemaciclib** in the adjuvant treatment of HR-positive, HER2-negative, node-positive early breast cancer (20%–30% treated patient share):

- **$1.06 billion to $1.59 billion annually** across the US, EU5, China, and Japan.

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

- **$53 million annually** across the same geographies.

Caveats and Assumptions

- Patient population estimates are based on general breast cancer epidemiology and assumed proportions for the specific indication.

- Pricing is approximate and may vary due to discounts, rebates, and regional policies.

- Market share assumptions (20%–30%) account for competition and adoption rates but could differ based on real-world uptake.

- Peak sales assume steady-state penetration and do not account for patent expiry or generic entry.

- Treatment duration is assumed to be annualized; actual costs may depend on the duration of therapy (e.g., 2 years in the monarchE trial).

For more precise figures, access to proprietary market research (e.g., EvaluatePharma, IQVIA) or company guidance from Eli Lilly would be necessary. Would you like me to refine any specific part of this analysis or explore additional factors (e.g., competition, pricing sensitivity)?