

To estimate the **Potential Peak Sales** for temozolomide (Temodar) with updated labeling in the specified indication across 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 and follow a structured approach. Since specific data on the indication, patient population, pricing, and market penetration for temozolomide under the updated labeling are not provided, I will outline a general methodology and provide illustrative figures based on reasonable assumptions. For precise numbers, real-world data on epidemiology, pricing, and market dynamics would be required.

Temozolomide is primarily used for the treatment of glioblastoma multiforme (GBM) and anaplastic astrocytoma, which are types of brain cancer. The updated labeling under Project Renewal likely improves clarity or expands usage within these or related indications, potentially increasing market access or physician confidence in prescribing. For this analysis, I will assume the indication remains focused on brain cancers, particularly GBM, as it is the primary use.

Step 1: Key Assumptions

1. **Indication and Patient Population:** Assuming the updated labeling pertains to glioblastoma multiforme (GBM), the most common and aggressive primary brain tumor, as the primary indication.

2. **Market Share:** As per the query, we assume a 20% to 30% share of treated patients for temozolomide in this indication.

3. **Pricing:** Pricing varies by region due to differences in healthcare systems and purchasing power. Approximate annual treatment costs for temozolomide are assumed as follows (based on historical data and general oncology drug pricing):

- US: \$50,000 per patient per year
- EU5: \$30,000 per patient per year (average across countries)
- China: \$15,000 per patient per year (lower due to pricing controls and generics)
- Japan: \$40,000 per patient per year (similar to developed markets)

4. **Incident Cases of GBM (Treated Population):** Using approximate annual incidence rates for GBM and assuming a high treatment rate due to limited therapeutic options:

- US: ~12,000 new cases/year
- EU5: ~15,000 new cases/year (combined)
- China: ~30,000 new cases/year (larger population, though diagnosis rates may be lower)
- Japan: ~3,000 new cases/year

Total treated population: ~60,000 patients/year across these geographies.

5. **Peak Sales Timing:** Peak sales are typically reached 3-5 years after a label update or market expansion, assuming no major competitive disruptions (e.g., new therapies or generics). Temozolomide is already generic in many markets, which may cap peak sales potential compared to a novel drug.

Step 2: Estimate Potential Peak Sales

Using the above assumptions, we calculate the potential peak sales at 20% and 30% market share of treated patients.

Total Treated Patients by Region (Assumed):

- US: 12,000 patients
- EU5: 15,000 patients
- China: 30,000 patients
- Japan: 3,000 patients
- **Total: 60,000 patients**

At 20% Market Share:

- US: 2,400 patients \times \$50,000 = **\$120 million**
- EU5: 3,000 patients \times \$30,000 = **\$90 million**
- China: 6,000 patients \times \$15,000 = **\$90 million**
- Japan: 600 patients \times \$40,000 = **\$24 million**
- **Total Peak Sales (20% share): \$324 million**

At 30% Market Share:

- US: 3,600 patients \times \$50,000 = **\$180 million**
- EU5: 4,500 patients \times \$30,000 = **\$135 million**
- China: 9,000 patients \times \$15,000 = **\$135 million**
- Japan: 900 patients \times \$40,000 = **\$36 million**
- **Total Peak Sales (30% share): \$486 million**

Thus, the **Potential Peak Sales** for temozolomide with updated labeling in this indication across the US, EU5, China, and Japan are estimated to be in the range of **\$324 million to \$486 million** annually, assuming a 20% to 30% share of treated patients.

Step 3: \$ Value of 1% Share of Treated Patients

A 1% share corresponds to 1% of the total treated population (60,000 patients) = **600 patients**.

Revenue from 1% Share by Region:

- US: 120 patients (1% of 12,000) \times \$50,000 = **\$6 million**
- EU5: 150 patients (1% of 15,000) \times \$30,000 = **\$4.5 million**
- China: 300 patients (1% of 30,000) \times \$15,000 = **\$4.5 million**
- Japan: 30 patients (1% of 3,000) \times \$40,000 = **\$1.2 million**
- **Total \$ Value of 1% Share: \$16.2 million**

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$16.2 million** annually.

Step 4: Considerations and Limitations

- **Generic Competition:** Temozolomide is off-patent in most markets, with generics widely available. The updated labeling may not significantly increase market share unless it expands the indication or improves reimbursement. This could lower the assumed pricing or market share.
- **Epidemiology Variability:** The number of treated patients is an estimate. Actual numbers may vary based on diagnosis rates, access to care, and treatment guidelines.
- **Pricing Differences:** Pricing assumptions are illustrative. Actual costs may differ due to discounts, rebates, or government negotiations (especially in China and EU5).
- **Competition:** New therapies for GBM (e.g., immunotherapies, targeted therapies) could reduce temozolomide's market share over time.
- **Updated Labeling Impact:** The impact of the labeling update (e.g., new indication, dosing clarity) is unknown. If it significantly expands the eligible patient population, peak sales could be higher.

Final Answer

- **Potential Peak Sales** for temozolomide with updated labeling in the US, EU5, China, and Japan (assuming 20% to 30% share of treated patients): **\$324 million to \$486 million annually.**
- **\$ Value of 1% Share of Treated Patients** in these geographies: **\$16.2 million annually.**

For more accurate estimates, specific data on the indication, updated labeling impact, current market share, and regional pricing would be necessary. If you have additional details, I can refine the analysis further.