

To estimate the **Potential Peak Sales** for belzutifan (Welireg) in the indication of advanced renal cell carcinoma (RCC) 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 (e.g., exact patient numbers, pricing, or market penetration) is not provided, I will outline the methodology and make reasonable assumptions based on publicly available information and industry standards. The final numbers will be illustrative and should be validated with real-world data.

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## **Step 1: Define the Target Patient Population**

Belzutifan is approved for advanced RCC patients who have progressed after a PD-1/PD-L1 inhibitor and a VEGF-TKI. This is typically a second- or third-line treatment setting for advanced/metastatic RCC.

### #### Estimated RCC Patient Population

- **US:** Approximately 76,000 new RCC cases annually (American Cancer Society, 2023). About 30-40% are diagnosed with advanced/metastatic disease (~25,000 patients). Of these, ~50-60% may progress to second- or third-line therapy (~12,500-15,000 patients).
- **EU5:** Incidence is ~115,000 new cases annually (combined). Advanced/metastatic cases are ~35,000, with ~17,500-21,000 progressing to later lines.
- **China:** Incidence is ~66,000 new cases annually. Advanced cases are ~20,000-25,000, with ~10,000-15,000 progressing to later lines.
- **Japan:** Incidence is ~30,000 new cases annually. Advanced cases are ~9,000-12,000, with ~4,500-7,000 progressing to later lines.

### **Total Target Population (Eligible for Belzutifan):**

- US: ~12,500-15,000
- EU5: ~17,500-21,000
- China: ~10,000-15,000
- Japan: ~4,500-7,000
- **Total:** ~44,500-58,000 patients annually across these geographies.

### #### Treated Patient Share (20%-30%) Assumption

Given the 20%-30% share of treated patients:

- **Low End (20%):** ~8,900-11,600 patients treated with belzutifan.
- **High End (30%):** ~13,350-17,400 patients treated with belzutifan.

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## **Step 2: Estimate Drug Pricing**

Belzutifan (Welireg) pricing varies by region due to differences in healthcare systems and purchasing power. Based on available data:

- **US:** Annual cost of therapy is approximately \$240,000-\$300,000 (based on reported costs for similar targeted therapies and initial pricing data for Welireg).
- **EU5:** Pricing is typically 50%-60% of US prices due to negotiations and health technology assessments (HTA). Estimated at \$120,000-\$180,000 annually.
- **Japan:** Pricing is often aligned with EU levels or slightly higher, ~\$120,000-\$180,000 annually.
- **China:** Pricing is significantly lower due to market access programs and local pricing policies, ~\$30,000-\$50,000 annually.

**Weighted Average Annual Cost per Patient (Assumption):**

- US: \$270,000
- EU5: \$150,000
- Japan: \$150,000
- China: \$40,000

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### **Step 3: Calculate Potential Peak Sales**

Peak sales are calculated by multiplying the number of treated patients by the annual cost per patient in each region.

#### Patient Distribution Across Geographies (Rough Estimate Based on Population Above)

- US: ~25% of total treated patients
- EU5: ~35% of total treated patients
- China: ~25% of total treated patients
- Japan: ~15% of total treated patients

#### Low-End Peak Sales (20% Share)

- Total treated patients: ~8,900-11,600
- US: ~2,225-2,900 patients \* \$270,000 = **\$600M - \$783M**
- EU5: ~3,115-4,060 patients \* \$150,000 = **\$467M - \$609M**
- China: ~2,225-2,900 patients \* \$40,000 = **\$89M - \$116M**
- Japan: ~1,335-1,740 patients \* \$150,000 = **\$200M - \$261M**
- **Total Peak Sales (Low End): ~\$1.36B - \$1.77B**

#### High-End Peak Sales (30% Share)

- Total treated patients: ~13,350-17,400

- US: ~3,338-4,350 patients \* \$270,000 = **\$901M - \$1.17B**
- EU5: ~4,673-6,090 patients \* \$150,000 = **\$701M - \$914M**
- China: ~3,338-4,350 patients \* \$40,000 = **\$134M - \$174M**
- Japan: ~2,003-2,610 patients \* \$150,000 = **\$300M - \$392M**
- **Total Peak Sales (High End): ~\$2.04B - \$2.65B**

**Potential Peak Sales Range: \$1.36B - \$2.65B annually** across US, EU5, China, and Japan.

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## **Step 4: Calculate \$ Value of 1% Share of Treated Patients**

A 1% share corresponds to 1% of the total target population (44,500-58,000), i.e., ~445-580 patients.

#### Value per Region for 1% Share

- US: ~111-145 patients \* \$270,000 = **\$30M - \$39M**
- EU5: ~156-203 patients \* \$150,000 = **\$23M - \$30M**
- China: ~111-145 patients \* \$40,000 = **\$4.4M - \$5.8M**
- Japan: ~67-87 patients \* \$150,000 = **\$10M - \$13M**
- **Total \$ Value of 1% Share: ~\$67.4M - \$87.8M**

**\$ Value of 1% Share of Treated Patients: \$67M - \$88M annually** across these geographies.

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## **Summary of Results**

1. **Potential Peak Sales for Belzutifan (20%-30% Share): \$1.36B - \$2.65B annually** across US, EU5, China, and Japan.
2. **\$ Value of 1% Share of Treated Patients: \$67M - \$88M annually** across the same geographies.

## **Caveats and Assumptions**

- Patient numbers are estimates based on epidemiology data and may vary based on real-world treatment patterns.
- Pricing is assumed based on similar therapies and regional pricing differences; actual pricing for belzutifan may differ.
- Market share (20%-30%) is an assumption; actual uptake depends on competition (e.g., other RCC therapies like cabozantinib, lenvatinib + pembrolizumab), physician adoption, and payer dynamics.
- Peak sales assume steady-state penetration and do not account for patent cliffs or generic entry.

- Currency fluctuations and local market access policies (especially in China) may impact final numbers.

For more accurate figures, primary data on patient numbers, real-world pricing, and market share forecasts from sources like EvaluatePharma, GlobalData, or company reports should be consulted. If you have specific data points, I can refine the calculations accordingly.