

To estimate the **Potential Peak Sales** for asciminib (Scemblix) in the indication of newly diagnosed Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in chronic phase (CP) 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 exact data on patient populations, pricing, and market penetration may not be publicly available, I will outline the methodology and provide reasonable assumptions based on available data and industry standards. The final numbers are illustrative and should be validated with primary data.

Step 1: Key Assumptions

1. Indication and Patient Population:

- Asciminib is approved for newly diagnosed Ph+ CML in chronic phase (CP).
- Ph+ CML accounts for ~15% of leukemias, with the majority in chronic phase at diagnosis.
- Incidence of CML is approximately 1-2 cases per 100,000 people annually, with prevalence higher due to chronic nature and improved survival with tyrosine kinase inhibitors (TKIs).
- Estimated newly diagnosed Ph+ CML-CP patients per year (based on literature and epidemiology data):
 - US: ~5,000-6,000
 - EU5: ~5,000-6,000 (combined)
 - China: ~7,000-10,000 (higher population base)
 - Japan: ~1,000-1,500
- Total: ~18,000-23,500 newly diagnosed patients annually across these regions.

2. Market Share:

- Assuming asciminib captures **20%-30% of treated patients** in this indication, as per the query.
- Current standard of care includes other TKIs (e.g., imatinib, dasatinib, nilotinib, bosutinib), so asciminib will compete in a crowded market but may have a niche due to its novel mechanism (STAMP inhibitor) and efficacy in resistant/intolerant patients.

3. Treatment Cost:

- Annual cost of asciminib in the US is estimated at ~\$200,000-\$250,000 per patient (based on pricing of similar TKIs and Novartis announcements).
- Costs in EU5 and Japan are typically 50%-70% of US pricing due to healthcare system negotiations (~\$100,000-\$175,000).
- Costs in China are lower due to pricing controls and generics (~\$50,000-\$75,000).

4. Treatment Duration:

- CML-CP is a chronic condition, and patients often remain on therapy for many years. For peak sales calculation, we assume an average of **5-10 years of treatment** per patient, but annual sales are based on the number of patients treated in a given year (incident + prevalent treated patients).

5. Prevalence Adjustment:

- Peak sales will include not only newly diagnosed patients but also a portion of prevalent patients switching to asciminib due to resistance or intolerance to other TKIs.
- Estimated prevalent treated patients (based on survival and epidemiology):
- US: ~20,000-25,000
- EU5: ~20,000-25,000
- China: ~25,000-30,000
- Japan: ~5,000-7,000
- Total prevalent treated: ~70,000-87,000.
- Assume asciminib captures 20%-30% of both incident and prevalent treated patients over time.

Step 2: Estimate Treated Patients for Peak Sales

- **Total treated patients (incident + prevalent)** eligible for asciminib at peak:
- US: 25,000-31,000 (5,000 incident + 20,000-25,000 prevalent)
- EU5: 25,000-31,000
- China: 32,000-40,000
- Japan: 6,000-8,500
- Total: ~88,000-110,500 treated patients.
- **Asciminib market share (20%-30%):**
- US: 5,000-9,300 patients
- EU5: 5,000-9,300 patients
- China: 6,400-12,000 patients
- Japan: 1,200-2,550 patients
- Total treated with asciminib: 17,600-33,150 patients.

Step 3: Estimate Peak Sales

Using the annual treatment cost per patient and the number of treated patients with asciminib:

- **US:**
- Patients: 5,000-9,300
- Cost per patient: \$225,000 (midpoint of \$200K-\$250K)

- Peak Sales: $5,000 \times \$225,000 = \1.13B (low end); $9,300 \times \$225,000 = \2.09B (high end)

- **Range: \$1.1B - \$2.1B**

- **EU5:**

- Patients: 5,000-9,300

- Cost per patient: \$137,500 (midpoint of \$100K-\$175K)

- Peak Sales: $5,000 \times \$137,500 = \0.69B ; $9,300 \times \$137,500 = \1.28B

- **Range: \$0.7B - \$1.3B**

- **China:**

- Patients: 6,400-12,000

- Cost per patient: \$62,500 (midpoint of \$50K-\$75K)

- Peak Sales: $6,400 \times \$62,500 = \0.40B ; $12,000 \times \$62,500 = \0.75B

- **Range: \$0.4B - \$0.8B**

- **Japan:**

- Patients: 1,200-2,550

- Cost per patient: \$137,500 (similar to EU5)

- Peak Sales: $1,200 \times \$137,500 = \0.17B ; $2,550 \times \$137,500 = \0.35B

- **Range: \$0.2B - \$0.4B**

- **Total Peak Sales** (across all regions):

- Low end: $\$1.1\text{B (US)} + \$0.7\text{B (EU5)} + \$0.4\text{B (China)} + \$0.2\text{B (Japan)} = \mathbf{\$2.4B}$

- High end: $\$2.1\text{B (US)} + \$1.3\text{B (EU5)} + \$0.8\text{B (China)} + \$0.4\text{B (Japan)} = \mathbf{\$4.6B}$

- **Potential Peak Sales Range: \$2.4B - \$4.6B**

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

- **Total treated patients (across regions):** 88,000-110,500

- **1% of treated patients:** 880-1,105 patients

- Calculate revenue per 1% share using weighted average cost across regions:

- US: 1% of 25,000-31,000 = 250-310 patients $\times \$225,000 = \$56\text{M}-\$70\text{M}$

- EU5: 1% of 25,000-31,000 = 250-310 patients $\times \$137,500 = \$34\text{M}-\$43\text{M}$

- China: 1% of 32,000-40,000 = 320-400 patients $\times \$62,500 = \$20\text{M}-\$25\text{M}$

- Japan: 1% of 6,000-8,500 = 60-85 patients $\times \$137,500 = \$8\text{M}-\$12\text{M}$

- **Total \$ value of 1% share:**

- Low end: \$56M (US) + \$34M (EU5) + \$20M (China) + \$8M (Japan) = **\$118M**

- High end: \$70M (US) + \$43M (EU5) + \$25M (China) + \$12M (Japan) = **\$150M**

- **Range: \$118M - \$150M per 1% share of treated patients**

Final Answer

1. **Potential Peak Sales for Asciminib** (20%-30% market share) in the indication of newly diagnosed Ph+ CML-CP across US, EU5, China, and Japan:

- **\$2.4 billion to \$4.6 billion annually**

2. **\$ Value of 1% Share of Treated Patients** across these geographies:

- **\$118 million to \$150 million**

Note: These estimates are based on assumptions about patient numbers, pricing, and market share. Actual figures may vary depending on real-world data, competition, reimbursement policies, and market access. For precise calculations, primary data from Novartis, healthcare databases, or market research reports (e.g., EvaluatePharma, GlobalData) should be consulted.