

To estimate the **Potential Peak Sales** for ciltacabtagene autoleucel (Carvykti) in the indication of relapsed or refractory multiple myeloma (RRMM) after four or more prior lines of therapy 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 based on available data and reasonable assumptions. Since specific data on patient populations, pricing, and market penetration may not be fully public, I will outline the methodology and provide an estimation based on industry norms and publicly available information as of my last update in October 2023. Note that exact figures may vary based on real-world data, updates in pricing, or market dynamics.

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

Ciltacabtagene autoleucel (Carvykti) is a CAR-T cell therapy approved for adult patients with relapsed or refractory multiple myeloma (RRMM) after four or more prior lines of therapy, including a proteasome inhibitor (PI), an immunomodulatory agent (IMiD), and an anti-CD38 monoclonal antibody. This is often referred to as "triple-class refractory" or "penta-refractory" patients in later lines of therapy (4L+).

### **#### Estimated Patient Population for RRMM (4L+):**

- **US:** Approximately 160,000 people are living with multiple myeloma in the US. Of these, about 10-15% are in later lines of therapy (4L+), and a subset of these are triple-class refractory. Based on studies and reports, the eligible population for CAR-T therapies in RRMM (4L+) is estimated at **5,000-7,000 patients per year** (incident cases).

- **EU5:** The prevalence of multiple myeloma in Europe is similar per capita to the US. Scaling for population (EU5 population ~330 million vs. US ~330 million), the eligible population is also estimated at **5,000-7,000 patients per year**.

- **Japan:** Japan has a smaller population (~125 million) and a lower incidence of multiple myeloma compared to the US and EU. The eligible population is estimated at **1,500-2,000 patients per year**.

- **China:** China has a much larger population (~1.4 billion), but lower diagnosis rates and access to advanced therapies. The incidence of multiple myeloma is lower per capita, and access to CAR-T therapies is limited due to cost and infrastructure. The eligible population is estimated at **3,000-5,000 patients per year**, though actual treated numbers may be lower due to access barriers.

### **Total Eligible Patients (Annual Incident Cases):**

- US: ~6,000

- EU5: ~6,000

- Japan: ~1,750

- China: ~4,000

- **Total: ~17,750 patients per year**

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## **\*\*Step 2: Estimate Market Penetration (20%-30% Share of Treated Patients)\*\***

The problem assumes a 20%-30% share of treated patients. This reflects the proportion of eligible patients who actually receive Carvykti, considering factors like:

- Competition from other CAR-T therapies (e.g., idecabtagene vicleucel [Abecma]) and other novel therapies.
- Access to treatment centers (CAR-T therapies require specialized facilities).
- Payer reimbursement and affordability.
- Patient and physician preference.

**Assumed Penetration Rate:** Let's take the midpoint of 25% for calculation purposes.

**Treated Patients with Carvykti (at 25% Penetration):**

- US:  $6,000 * 25\% = 1,500$  patients
- EU5:  $6,000 * 25\% = 1,500$  patients
- Japan:  $1,750 * 25\% = 438$  patients
- China:  $4,000 * 25\% = 1,000$  patients
- **Total: ~4,438 patients per year**

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**\*\*Step 3: Estimate Pricing per Patient\*\***

Carvykti is a one-time CAR-T therapy, and pricing varies by region due to healthcare systems, reimbursement policies, and market dynamics.

- **US:** The list price for Carvykti is approximately **\$465,000 per patient** (based on public announcements and industry reports as of 2023). Actual net price may be lower due to discounts/rebates, but we'll use list price for peak sales estimation.
- **EU5:** Pricing in Europe is typically 20-30% lower than in the US due to stricter pricing controls. Estimated price: **~\$350,000 per patient**.
- **Japan:** Pricing in Japan is often aligned with or slightly below European levels, estimated at **~\$350,000 per patient**.
- **China:** Pricing in China is significantly lower due to affordability constraints and local competition (e.g., domestic CAR-T therapies). Estimated price: **~\$200,000 per patient**.

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**\*\*Step 4: Calculate Potential Peak Sales\*\***

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

- **US:**  $1,500 \text{ patients} * \$465,000 = \$697.5 \text{ million}$

- **EU5:** 1,500 patients \* \$350,000 = **\$525 million**
- **Japan:** 438 patients \* \$350,000 = **\$153.3 million**
- **China:** 1,000 patients \* \$200,000 = **\$200 million**
- **Total Peak Sales:** \$697.5M + \$525M + \$153.3M + \$200M = **~\$1,575.8 million (or ~\$1.58 billion) per year**

**Range of Peak Sales (20%-30% Penetration):**

- At 20% penetration: ~\$1.26 billion
- At 30% penetration: ~\$1.89 billion
- **Midpoint (25% penetration): ~\$1.58 billion**

Thus, the **Potential Peak Sales** for Carvykti in this indication across the US, EU5, China, and Japan is approximately **\$1.5-\$1.9 billion per year**, with a midpoint of **\$1.58 billion**.

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

A 1% share of treated patients refers to 1% of the eligible patient population in each region being treated with Carvykti.

**1% of Eligible Patients:**

- US: 6,000 \* 1% = **60 patients**
- EU5: 6,000 \* 1% = **60 patients**
- Japan: 1,750 \* 1% = **17.5 patients**
- China: 4,000 \* 1% = **40 patients**

**\$ Value of 1% Share:**

- US: 60 patients \* \$465,000 = **\$27.9 million**
- EU5: 60 patients \* \$350,000 = **\$21 million**
- Japan: 17.5 patients \* \$350,000 = **\$6.1 million**
- China: 40 patients \* \$200,000 = **\$8 million**
- **Total \$ Value of 1% Share:** \$27.9M + \$21M + \$6.1M + \$8M = **\$63 million**

Thus, the **\$ value of a 1% share of treated patients** across these geographies is approximately **\$63 million per year**.

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**\*\*Final Answer\*\***

1. **Potential Peak Sales for Ciltacabtagene Autoleucel (Carvykti)** in the indication of relapsed or refractory multiple myeloma (4L+) in the US, EU5, China, and Japan, assuming a 20%-30% share of treated patients:

- Range: **\$1.26 billion to \$1.89 billion per year**
- Midpoint (25% penetration): **~\$1.58 billion per year**

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

- **~\$63 million per year**

**Note:** These estimates are based on assumptions regarding patient populations, market penetration, and pricing. Real-world figures may differ due to changes in competition, reimbursement policies, access to CAR-T therapy centers, or updated clinical data. For more precise figures, consult primary market research or company financial reports.