

To estimate the **Potential Peak Sales** for **loncastuximab tesirine-lpyl (Zynlonta)** in the indication of relapsed or refractory (R/R) large B-cell lymphoma (specifically DLBCL and related subtypes after two or more lines of therapy) in the US, EU5 (France, Germany, 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 exact figures (e.g., pricing, patient population, or market penetration) may not be publicly available, I will outline the methodology and use realistic estimates grounded in oncology market trends and epidemiology.

Step 1: Define the Target Patient Population

The indication is for adult patients with R/R large B-cell lymphoma (including DLBCL) after two or more lines of systemic therapy. DLBCL is the most common subtype of non-Hodgkin lymphoma (NHL), and we will focus on estimating the eligible patient population in the specified geographies.

Incidence and Prevalence of DLBCL

- **DLBCL Incidence:** DLBCL accounts for approximately 30-40% of NHL cases. The incidence of NHL varies by region:
- **US:** ~74,000 new NHL cases/year (SEER data); ~25,000-30,000 DLBCL cases.
- **EU5:** ~60,000 new NHL cases/year; ~20,000-24,000 DLBCL cases.
- **China:** ~90,000 new NHL cases/year (due to large population); ~30,000-36,000 DLBCL cases.
- **Japan:** ~30,000 new NHL cases/year; ~10,000-12,000 DLBCL cases.
- **Relapsed/Refractory (R/R) DLBCL:** Approximately 30-40% of DLBCL patients relapse after first-line therapy (R-CHOP), and of those, a subset progresses to second-line and beyond. About 10-15% of initial DLBCL patients may reach third-line or later therapy.
- **US:** ~2,500-4,500 R/R DLBCL patients eligible for third-line therapy annually.
- **EU5:** ~2,000-3,600 eligible patients.
- **China:** ~3,000-5,400 eligible patients.
- **Japan:** ~1,000-1,800 eligible patients.

Total Eligible Patients (mid-range estimate):

- US: ~3,500 patients
- EU5: ~2,800 patients
- China: ~4,200 patients
- Japan: ~1,400 patients
- **Total across geographies:** ~12,000 patients annually.

Treated Patient Share (20%-30%)

Assuming a 20%-30% market share for loncastuximab tesirine-lpyl among eligible R/R DLBCL patients (considering competition from CAR-T therapies, other antibody-drug conjugates, and emerging

treatments):

- **US:** 700-1,050 patients treated (25% share = ~875).
- **EU5:** 560-840 patients treated (25% share = ~700).
- **China:** 840-1,260 patients treated (25% share = ~1,050).
- **Japan:** 280-420 patients treated (25% share = ~350).
- **Total treated patients (25% share):** ~2,975 patients annually.

Step 2: Estimate Drug Pricing and Treatment Cost

Loncastuximab tesirine-lpyl (Zynlonta) is a novel antibody-drug conjugate (ADC), and pricing for such therapies in oncology is typically high, especially for rare or niche indications like R/R DLBCL.

- **US Pricing:** Zynlonta's list price is approximately \$23,500 per vial, with a typical course of treatment requiring multiple vials over several cycles. A full treatment course may cost ~\$200,000-\$250,000 per patient (based on reported data and comparisons to other ADCs like Polivy).
- **EU5 Pricing:** Typically 60-70% of US pricing due to healthcare system negotiations; assume ~\$120,000-\$150,000 per patient.
- **China and Japan Pricing:** Likely lower due to pricing controls and market dynamics; assume ~\$80,000-\$100,000 per patient in China and ~\$100,000-\$120,000 in Japan.

Average Annual Cost per Patient (mid-range estimate):

- US: \$225,000
- EU5: \$135,000
- China: \$90,000
- Japan: \$110,000

Step 3: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of treated patients (at 20%-30% market share) by the average cost per patient in each geography.

Peak Sales at 25% Market Share (mid-point of 20%-30%)

- **US:** 875 patients × \$225,000 = **\$196.9 million**
- **EU5:** 700 patients × \$135,000 = **\$94.5 million**
- **China:** 1,050 patients × \$90,000 = **\$94.5 million**
- **Japan:** 350 patients × \$110,000 = **\$38.5 million**
- **Total Peak Sales (25% share):** **\$424.4 million annually**

Range of Peak Sales (20%-30% Market Share)

- **20% Share:**

- US: $700 \times \$225,000 = \157.5M

- EU5: $560 \times \$135,000 = \75.6M

- China: $840 \times \$90,000 = \75.6M

- Japan: $280 \times \$110,000 = \30.8M

- **Total: \$339.5 million**

- **30% Share:**

- US: $1,050 \times \$225,000 = \236.3M

- EU5: $840 \times \$135,000 = \113.4M

- China: $1,260 \times \$90,000 = \113.4M

- Japan: $420 \times \$110,000 = \46.2M

- **Total: \$509.3 million**

Potential Peak Sales Range: \$339.5 million to \$509.3 million annually, with a mid-point of ~\$424.4 million at 25% market share.

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

A 1% share of treated patients corresponds to 1% of the total eligible patient population in each geography.

- **US:** $3,500 \text{ patients} \times 1\% = 35 \text{ patients} \times \$225,000 = \$7.9 \text{ million}$

- **EU5:** $2,800 \text{ patients} \times 1\% = 28 \text{ patients} \times \$135,000 = \$3.8 \text{ million}$

- **China:** $4,200 \text{ patients} \times 1\% = 42 \text{ patients} \times \$90,000 = \$3.8 \text{ million}$

- **Japan:** $1,400 \text{ patients} \times 1\% = 14 \text{ patients} \times \$110,000 = \$1.5 \text{ million}$

- **Total \$ Value of 1% Share: \$17.0 million annually**

Final Answer

- **Potential Peak Sales for Loncastuximab Tesirine-Ipyl** (20%-30% market share) in R/R large B-cell lymphoma across the US, EU5, China, and Japan: **\$339.5 million to \$509.3 million annually** (mid-point: ~\$424.4 million at 25% share).

- **\$ Value of 1% Share of Treated Patients: \$17.0 million annually** across all geographies.

Note: These estimates are based on assumptions regarding patient population, market penetration, and pricing. Actual figures may vary depending on real-world uptake, competition (e.g., CAR-T therapies like Yescarta and Kymriah), reimbursement policies, and clinical trial outcomes for expanded indications or combinations. If you have specific data (e.g., exact pricing or patient numbers), I can refine the calculations further.