To estimate the **Potential Peak Sales** for lifileucel (Amtagvi) in the indication of unresectable or metastatic melanoma 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 such as exact patient numbers, pricing, and market penetration may not be fully available, I will make reasonable assumptions based on publicly available information, epidemiology data, and industry standards for oncology drugs. Let's break this down step by step.

Step 1: Define the Indication and Patient Population

Lifileucel is approved for **unresectable or metastatic melanoma** (Stage III/IV) in patients previously treated with a PD-1 blocking antibody (and BRAF/MEK inhibitors if BRAF V600 positive). This is a second-line or later-line therapy for advanced melanoma patients who have progressed on prior therapies.

Epidemiology of Metastatic Melanoma

- **US**: Approximately 100,000 new melanoma cases are diagnosed annually, with ~8-10% being Stage IV at diagnosis, and a portion of Stage III progressing to Stage IV. Total prevalent cases of metastatic melanoma are estimated at ~20,000-25,000. Of these, ~50-60% may fail first-line PD-1 inhibitors (e.g., nivolumab, pembrolizumab) and become eligible for lifileucel (i.e., ~10,000-15,000 patients).

- **EU5**: The incidence of melanoma in Europe is ~150,000 annually, with a similar proportion of Stage IV cases. Prevalent metastatic melanoma cases are estimated at ~30,000-40,000, with ~15,000-20,000 eligible for second-line therapies like lifileucel.

- **China**: Melanoma incidence is lower in China due to lower UV exposure and genetic factors, with ~20,000 new cases annually. Prevalent metastatic cases are estimated at ~5,000-10,000, with ~2,500-5,000 eligible for lifileucel.

- **Japan**: Melanoma incidence is ~5,000-6,000 annually, with prevalent metastatic cases at ~1,500-2,000, and ~750-1,000 eligible for lifileucel.

Total Eligible Patients (Approximate):

- US: 12,500 (midpoint of 10,000-15,000)

- EU5: 17,500 (midpoint of 15,000-20,000)

- China: 3,750 (midpoint of 2,500-5,000)

- Japan: 875 (midpoint of 750-1,000)

- **Total**: ~34,625 eligible patients across these geographies.

Step 2: Market Share of Treated Patients

The problem assumes a **20%-30% share of treated patients**. This refers to the proportion of eligible patients who will receive lifileucel. Let’s calculate the number of treated patients at the midpoint of this range (25%):

- US: 12,500 × 25% = **3,125 patients**

- EU5: 17,500 × 25% = **4,375 patients**

- China: 3,750 × 25% = **938 patients**

- Japan: 875 × 25% = **219 patients**

- **Total Treated Patients**: ~8,657 patients annually at peak.

Step 3: Pricing of Lifileucel

Lifileucel is a tumor-infiltrating lymphocyte (TIL) therapy, a personalized cell therapy. Such therapies are expensive due to complex manufacturing and administration processes. Iovance has announced that the list price of lifileucel in the US is **$515,000 per patient** (based on public announcements following FDA approval in February 2024). Pricing in other regions is typically lower due to healthcare system negotiations and cost controls:

- **EU5**: Assume ~70% of US price = $360,500 per patient.

- **China**: Assume ~50% of US price = $257,500 per patient (due to lower affordability and pricing controls).

- **Japan**: Assume ~80% of US price = $412,000 per patient (Japan often has pricing closer to the US for innovative therapies).

Step 4: Calculate Potential Peak Sales

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

- **US**: 3,125 patients × $515,000 = **$1.61 billion**

- **EU5**: 4,375 patients × $360,500 = **$1.58 billion**

- **China**: 938 patients × $257,500 = **$0.24 billion**

- **Japan**: 219 patients × $412,000 = **$0.09 billion**

- **Total Peak Sales**: **$3.52 billion annually** (at 25% market share).

Range of Peak Sales (20%-30% market share):

- At 20% share: ~$2.82 billion

- At 30% share: ~$4.22 billion

Thus, **Potential Peak Sales** for lifileucel in this indication across the US, EU5, China, and Japan are estimated to be **$2.8 billion to $4.2 billion annually**, with a midpoint of ~$3.5 billion.

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 geography. Using the eligible patient numbers from Step 1:

- **US**: 12,500 × 1% = 125 patients × $515,000 = **$64.4 million**
- **EU5**: 17,500 × 1% = 175 patients × $360,500 = **$63.1 million**
- **China**: 3,750 × 1% = 37.5 patients × $257,500 = **$9.7 million**
- **Japan**: 875 × 1% = 8.75 patients × $412,000 = **$3.6 million**
- **Total Value of 1% Share**: **$140.8 million**

Thus, the **$ value of a 1% share of treated patients** across these geographies is approximately **$141 million**.

Final Answer

1. **Potential Peak Sales for lifileucel** in unresectable or metastatic melanoma (assuming 20%-30% market share):

- **US, EU5, China, Japan combined**: $2.8 billion to $4.2 billion annually (midpoint ~$3.5 billion).
- Breakdown:
- US: $1.29B (20%) to $1.93B (30%)
- EU5: $1.26B (20%) to $1.89B (30%)
- China: $0.19B (20%) to $0.29B (30%)
- Japan: $0.07B (20%) to $0.11B (30%)

2. **$ Value of 1% Share of Treated Patients**:

- **US**: $64.4 million
- **EU5**: $63.1 million
- **China**: $9.7 million
- **Japan**: $3.6 million
- **Total**: $140.8 million (~$141 million)

Note: These estimates are based on assumptions regarding patient population, market penetration, and pricing. Actual figures may vary depending on real-world adoption, reimbursement policies, competition (e.g., other immunotherapies or TIL therapies), and regional healthcare dynamics. Adjustments can be made if more precise data on patient numbers or pricing becomes available.