To estimate the **Potential Peak Sales** for retifanlimab-dlwr (Zynyz) in the indication of inoperable locally recurrent or metastatic squamous cell carcinoma of the anal canal (SCAC) 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 exact patient numbers, pricing, and penetration rates are not publicly available in full detail, I will outline the methodology and provide an estimate based on typical industry benchmarks and epidemiology data.

Step 1: Define the Target Patient Population

SCAC is a rare cancer, and the target population for retifanlimab-dlwr includes:

- **First-line treatment**: Adults with inoperable locally recurrent or metastatic SCAC (in combination with carboplatin and paclitaxel).

- **Second-line treatment**: Adults with locally recurrent or metastatic SCAC who have disease progression on or intolerance to platinum-based chemotherapy (as a single agent).

Epidemiology of SCAC

- **Incidence**: SCAC accounts for approximately 1-2% of all anal cancers, with an incidence of ~1-2 cases per 100,000 people annually in most regions. However, only a subset of these patients will have inoperable locally recurrent or metastatic disease.

- **Prevalence of Advanced/Metastatic SCAC**: Approximately 20-30% of SCAC patients present with or progress to metastatic disease.

- **Geographic Breakdown (Estimated Annual Incidence of SCAC)**:

- **US**: ~8,000 new cases of anal cancer annually; ~2,000-2,400 metastatic or locally recurrent inoperable cases.

- **EU5**: ~12,000 new cases of anal cancer annually (combined); ~3,000-3,600 metastatic or locally recurrent inoperable cases.

- **China**: ~5,000 new cases of anal cancer annually (lower incidence due to demographics); ~1,200-1,500 metastatic or locally recurrent inoperable cases.

- **Japan**: ~2,500 new cases of anal cancer annually; ~600-750 metastatic or locally recurrent inoperable cases.

- **Total Eligible Patients**: ~6,800-8,250 patients annually across these geographies for first-line and second-line treatment combined.

Treated Patients

- Not all eligible patients receive treatment due to comorbidities, access issues, or other factors. Assuming 70-80% of eligible patients are treated:

- **US**: ~1,400-1,900 treated patients.

- **EU5**: ~2,100-2,900 treated patients.

- **China**: ~800-1,200 treated patients.

- **Japan**: ~400-600 treated patients.

- **Total Treated Patients**: ~4,700-6,600 annually.

Market Share Assumption

- As per the query, assuming a **20-30% market share** for retifanlimab-dlwr among treated patients:

- **US**: ~280-570 patients.

- **EU5**: ~420-870 patients.

- **China**: ~160-360 patients.

- **Japan**: ~80-180 patients.

- **Total Patients on Retifanlimab-dlwr**: ~940-1,980 annually.

Step 2: Estimate Drug Pricing

Retifanlimab-dlwr is a PD-1 inhibitor, and pricing for such drugs typically aligns with other immunotherapies like pembrolizumab (Keytruda) or nivolumab (Opdivo). Pricing varies by region due to healthcare systems and negotiations:

- **US**: ~$150,000-$200,000 per patient per year.

- **EU5**: ~$80,000-$120,000 per patient per year (lower due to price negotiations and reimbursement structures).

- **China**: ~$50,000-$80,000 per patient per year (lower due to cost sensitivity and local pricing policies).

- **Japan**: ~$100,000-$150,000 per patient per year (similar to EU but with some premium pricing).

Average Annual Cost per Patient (Assumed Midpoint):

- **US**: $175,000.

- **EU5**: $100,000.

- **China**: $65,000.

- **Japan**: $125,000.

Step 3: Calculate Potential Peak Sales

Peak sales are calculated by multiplying the number of patients treated with retifanlimab-dlwr (based on 20-30% market share) by the average annual cost per patient in each region.

Peak Sales at 20% Market Share

- **US**: 280 patients x $175,000 = **$49 million**.

- **EU5**: 420 patients x $100,000 = **$42 million**.

- **China**: 160 patients x $65,000 = **$10.4 million**.

- **Japan**: 80 patients x $125,000 = **$10 million**.

- **Total Peak Sales (20% share)**: **$111.4 million**.

Peak Sales at 30% Market Share

- **US**: 570 patients x $175,000 = **$99.75 million**.

- **EU5**: 870 patients x $100,000 = **$87 million**.

- **China**: 360 patients x $65,000 = **$23.4 million**.

- **Japan**: 180 patients x $125,000 = **$22.5 million**.

- **Total Peak Sales (30% share)**: **$232.65 million**.

Potential Peak Sales Range

- **Range**: **$111.4 million to $232.65 million annually** across the US, EU5, China, and Japan, assuming a 20-30% market share.

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

A 1% share of treated patients corresponds to 1% of the total treated patient population in each region. Using the midpoint of the treated patient range:

- **US**: 1,650 treated patients x 1% = 16.5 patients x $175,000 = **$2.89 million**.

- **EU5**: 2,500 treated patients x 1% = 25 patients x $100,000 = **$2.5 million**.

- **China**: 1,000 treated patients x 1% = 10 patients x $65,000 = **$0.65 million**.

- **Japan**: 500 treated patients x 1% = 5 patients x $125,000 = **$0.625 million**.

- **Total $ Value of 1% Share**: **$6.665 million annually**.

Final Answer

1. **Potential Peak Sales for Retifanlimab-dlwr** in the indication of inoperable locally recurrent or metastatic SCAC (20-30% market share):

- **US, EU5, China, and Japan Combined**: **$111.4 million to $232.65 million annually**.

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

- **US**: ~$2.89 million.

- **EU5**: ~$2.5 million.

- **China**: ~$0.65 million.

- **Japan**: ~$0.625 million.

- **Total**: ~**$6.665 million annually**.

Notes and Assumptions

- These estimates are based on approximate epidemiology data for SCAC and typical pricing for PD-1 inhibitors. Actual patient numbers and pricing may vary.

- Market share assumptions (20-30%) are based on the query and typical penetration rates for new oncology drugs in rare indications.

- Peak sales assume steady-state adoption, which may take 3-5 years post-launch, depending on competition, reimbursement, and clinical uptake.

- The analysis does not account for potential off-label use, additional indications, or changes in treatment paradigms. If more specific data (e.g., exact patient numbers or pricing) is available, these estimates can be refined.