Polivy® (polatuzumab vedotin-piiq) – New indication

- On April 19, 2023, Genentech announced the FDA approval of Polivy (polatuzumab vedotin-piiq), in combination with a rituximab product, cyclophosphamide, doxorubicin and prednisone (R-CHP), for the treatment of adult patients who have previously untreated diffuse large B-cell lymphoma (DLBCL), not otherwise specified (NOS) or high-grade B-cell lymphoma (HGBL) and who have an International Prognostic Index (IPI) score of two or greater.

- In addition to the approval of Polivy plus R-CHP for the treatment of DLBCL, the FDA has granted full (traditional) approval for Polivy in combination with bendamustine and a rituximab product for the treatment of adult patients with relapsed or refractory DLBCL, NOS, after at least two prior therapies.

    — This indication was previously approved via the accelerated approval pathway.

- The approval of Polivy for the new indication was based on POLARIX, a randomized, double-blind, placebo-controlled study in 879 patients with previously untreated large B-cell lymphoma. Patients were randomized to Polivy plus R-CHP or to receive R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone) for six 21-day cycles followed by two additional cycles of rituximab alone in both arms. Efficacy was based on progression-free survival (PFS).

    — The risk of disease progression, relapse or death was reduced by 27% with Polivy plus R-CHP compared with R-CHOP (hazard ratio 0.73; 95% CI: 0.57, 0.95; $p < 0.02$).

- The most common adverse reactions (≥ 20%) in patients with large B-cell lymphoma treated with Polivy in combination with R-CHP, excluding laboratory abnormalities, were peripheral neuropathy, nausea, fatigue, diarrhea, constipation, alopecia, and mucositis.

    — Grade 3 to 4 laboratory abnormalities (≥ 10%) are lymphopenia, neutropenia, hyperuricemia, and anemia.

- The recommended dose of Polivy for previously untreated DLBCL, NOS or HGBL is 1.8 mg/kg administered as an intravenous infusion every 21 days for 6 cycles in combination with a rituximab product, cyclophosphamide, doxorubicin, and prednisone.

    — Polivy, cyclophosphamide, doxorubicin, and a rituximab product may be administered in any order on Day 1 after the administration of prednisone. Prednisone is administered on Days 1 to 5 of each cycle.
    — Refer to the Polivy drug label for dosing for relapsed or refractory DLBCL, NOS.