## Polivy™ (polatuzumab vedotin-piiq) – New orphan drug approval

- On June 10, 2019, the FDA announced the approval of Genentech's Polivy (polatuzumab vedotin-piiq), in combination with bendamustine and a rituximab product (eg, Rituxan®), for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), not otherwise specified, after at least two prior therapies.
    - Accelerated approval was granted for this indication based on complete response (CR) rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial.
- DLBCL is the most common form of non-Hodgkin's lymphoma (NHL), accounting for about one in three cases of NHL. DLBCL is an aggressive (fast-growing) type of NHL, which is generally responsive to treatment in the frontline. However, as many as 40% of patients will relapse. In the U.S. it is estimated that nearly 25,000 new cases of DLBCL will be diagnosed in 2019.
- Polivy is a first-in-class anti-CD79b antibody-drug conjugate. The CD79b protein is expressed specifically in the majority of B-cells. Polivy binds to CD79b and destroys these B-cells through the delivery of an anti-cancer agent (monomethyl auristatin E), which is thought to minimize the effects on normal cells.
- The efficacy of Polivy was evaluated in an open-label study that included a cohort of 80 patients with relapsed or refractory DLBCL. Patients were randomized to receive either Polivy in combination with bendamustine and a rituximab product (BR) or BR alone for six 21-day cycles. Efficacy was based on CR rate at the end of treatment and duration of response (DOR).
    - At the end of treatment, the CR rate was 40% with Polivy plus BR vs. 18% with BR alone (difference in CR rate of 22; 95% CI: 3, 41).
    - Of the 25 patients who achieved a partial or complete response to Polivy plus BR, 16 (64%) had a DOR of at least six months and 12 (48%) had a DOR of at least 12 months.
- Warnings and precautions for Polivy include peripheral neuropathy, infusion-related reactions, myelosuppression, serious and opportunistic infections, progressive multifocal leukoencephalopathy, tumor lysis syndrome, hepatotoxicity, and embryo-fetal toxicity.
- The most common adverse reactions (≥ 20%) with Polivy use were neutropenia, thrombocytopenia, anemia, peripheral neuropathy, fatigue, diarrhea, pyrexia, decreased appetite, and pneumonia.
- The recommended dose of Polivy is 1.8 mg/kg administered as an intravenous (IV) infusion every 21 days for 6 cycles in combination with BR. Polivy, bendamustine, and rituximab product should be administered in any order on day 1 of each cycle.
    - The recommended dose of bendamustine is 90 mg/m$^2$/day IV on day 1 and 2 when administered with Polivy and a rituximab product. The recommended dose of rituximab product is 375 mg/m$^2$ IV on Day 1 of each cycle.
    - Refer to the Polivy, bendamustine, and rituximab drug labels for additional dosing and administration recommendations.

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- Genentech’s launch plans for Polivy are pending. Polivy will be available as a 140 mg lyophilized powder in a single-dose vial.