RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Beleodaq (belinostat) is used in the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL). Beleodaq is a histone deacetylase (HDAC) inhibitor which catalyzes acetyl group removal from protein lysine residues (of histone and some nonhistone proteins). Inhibition of histone deacetylase results in accumulation of acetyl groups, leading to cell cycle arrest and apoptosis (1).

Regulatory Status

FDA-approved indications: Beleodaq is a histone deacetylase inhibitor indicated for the treatment of patients with relapsed or refractory peripheral T-cell lymphoma (PTCL). (1).

Recommended dosage of Beleodaq is 1,000 mg/m^2 administered over 30 minutes by intravenous infusion once daily on days 1-5 of a 21-day cycle. Cycles can be repeated until disease progression or unacceptable toxicity. Beleodaq treatment discontinuation or interruption with or without dosage reductions by 25% may be needed to manage adverse reactions (1).

Beleodaq can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and/or anemia. Physicians are cautioned to monitor blood counts weekly during treatment in order to determine whether dosage modification is necessary. Absolute neutrophil count (ANC) should be greater than or equal to 1.0 x 10^9/L and the platelet count should be greater than or equal to 50 x 10^9/L prior to the start of each cycle and prior to resuming treatment following toxicity. Beleodaq should be discontinued in patients who have recurrent ANC nadirs less than 0.5 x 10^9/L and/or recurrent platelet count nadirs less than 25 x 10^9/L after two dosage reductions (1).

Beleodaq can cause hepatotoxicity therefore the physician is cautioned to monitor liver function tests before treatment and at the start of each cycle in order to omit or modify dosage based on his or her medical judgment. Patients with advanced stage disease and/or high tumor burden should be monitored for tumor lysis syndrome (1).

Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with Beleodaq. Beleodaq should not be administered to patients with an active infection (1).

The safety and effectiveness of Beleodaq in pediatric patients less than 18 years of age have not

been established (1).

Summary

Beleodaq (belinostat) is used in the treatment of relapsed or refractory peripheral T-cell lymphoma (PTCL). Beleodaq is a histone deacetylase (HDAC) inhibitor which catalyzes acetyl group removal from protein lysine residues (of histone and some nonhistone proteins). Inhibition of histone deacetylase results in accumulation of acetyl groups, leading to cell cycle arrest and apoptosis. Beleodaq can cause thrombocytopenia, leukopenia (neutropenia and lymphopenia), and/or anemia. Physicians are cautioned to monitor blood counts weekly during treatment. Beleodaq can cause hepatotoxicity therefore the physician is cautioned to monitor liver function tests before treatment and at the start of each cycle. Serious and sometimes fatal infections, including pneumonia and sepsis, have occurred with Beleodaq. Beleodaq should not be administered to patients with an active infection. The safety and effectiveness of Beleodaq in pediatric patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Beleodaq while maintaining optimal therapeutic outcomes.

References

1. Beleodaq [package insert]. East Windsor, NJ: Acrotech Biopharma LLC; November 2024.
2. NCCN Drugs & Biologics Compendium® Belinostat 2025. National Comprehensive Cancer Network, Inc. Accessed on January 21, 2025.