Safety Profile and Management of Adverse Events Associated With Duvelisib in Patients With Advanced Hematologic Malignancies

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INTRODUCTION

• Duvelisib (DUV), a first-in-class, oral, dual inhibitor of PI3K-δ, -ε, targets key pathways in malignancies and in normal tissues that promote the growth and survival of hematologic malignancies (Figure 1).

Figure 1. Mechanism of Action of DUV, a Dual Inhibitor of PI3K-δ, -ε

RESULTS

• Summary of AEIs associated with DUV is presented in Table 1 – The most frequent SAEs ranged from 0.7 to 18%, except infection, which occurred in 31% of patients – The AEIs of diarrhea or colitis resulted in discontinuations in 10% of patients. No other AEI resulted in rates of discontinuations of > 6% – Diarrhea/collitis was the AE that most commonly caused a decrease in median duration of treatment in 6% of patients (Table 1, Figure 4).

Table 1. Safety With DUV 25 mg BID in Patients With R/R CLL, SLL, or FL

Objective

• To present an overview of the safety profile of DUV 25 mg BID in patients primarily with R/R CLL, SLL, or FL from a pooled analysis of 4 clinical trials,14 highlighting adverse events of special interest (AEIS) and key aspects of AE management relevant to oncology nurses

METHODS

• Safety data from 442 patients primarily with R/R CLL, SLL, or FL treated with DUV 25 mg BID monotherapy across 4 studies were evaluated in a pooled analysis (Figure 5).

• Treatment-emergent AEs were defined as AEs that occurred from the time that the first DUV dose was administered to 30 days after the last dose.

• AEs and laboratory values were coded using the Medical Dictionary for Regulatory Activities (MedDRA) version 18.1.

• AE severity was assessed by investigators according to the National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events version 4.03

OBJECTIVE

Figure 2. DUV Improves PFS (Kaplan-Meier estimates) in Patients With R/R CLL or SLL Who Had Received ≥ 2 Prior Therapies in the DUO trial

Table 2. Recommended Management of AEIs

Table 3. Dose Modification Levels

CONCLUSIONS

• DUV is a novel oral treatment option for patients with R/R CLL, SLL, or FL, with the potential for durable responses and good tolerability over time.

• In this heavily pretreated population of patients with advanced hematologic malignancies, DUV demonstrated a manageable safety profile – AEIs were generally reversible, often managed through dose modifications, and, in most cases, did not lead to treatment discontinuation.

• Nurses play a pivotal role in patient education, AE monitoring, early intervention, and communication to optimize patient outcomes.

• Early identification and intervention are critical for effective management and resolution of most AEIs, which may result in low rates of discontinuation, improved patient quality of care, and enhanced adherence to therapy

REFERENCES


Table 2. Recommended Management of AEIS

Table 3. Dose Modification Levels

ACKNOWLEDGMENTS

Oncology Nursing Society Congress; Anaheim, CA; April 11-14, 2019

Figure 4. Median Time to Onset of and Discontinuations Due to AEIs With DUV 25 mg BID

Figure 3. Overview of Patients Included in the Pooled Safety Analysis

Figure 5. Nursing Considerations for Patient Education and Monitoring AEIs in Patients Receiving DUV

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