Effect of Dose Modifications on Response to Duvelisib in Patients With Relapsed/Refractory CLL/SLL in the DUO Trial

Ivan W. Film, 1 Marco Monllor, 1 Agapi Hils, 1 Gabriel Stronek, 1 Juliana Delgafuro, 1 Bryony J. Rust, 1 Constantine S. Tam, 1 Fritz Otten, 1 Francesco Bosch, 1 Matthew S. Davids, 1 Urszula Jagers, 1 Paolo Ghiara, 1 Francesca Pappalardo, 1 David T. Weitzel, 1 Stephanie Lustgarten, 1 Anup Basavanhally, 1 Stephan Stieghaus, 1 Moonie Lammle, 1

1 Genentech Research and Early Development, South San Francisco, California, United States; 2 Hematology and Oncology, University of Basel, Basel, Switzerland; 3 Department of Surgery and Medicine, University of California, Los Angeles, California, United States; 4 Department of Medicine, University of California, San Diego, California, United States; 5 Division of Hematology-Oncology and Institute for Translational Medicine, University of Washington, Seattle, Washington, United States; 6 Division of Hematology-Oncology, University of Southern California, Los Angeles, California, United States; 7 Department of Medicine, University of Pennsylvania, Philadelphia, Pennsylvania, United States; 8 Department of Medicine, University of California, Los Angeles, California, United States; 9 Department of Hematology-Oncology, University of Basel, Basel, Switzerland; 10 Center for Translational Medicine, University of California, San Diego, California, United States; 11 Department of Medicine, University of Washington, Seattle, Washington, United States; 12 Department of Medicine, University of Southern California, Los Angeles, California, United States

ABSTRACT

Background
- Duvelisib (DUO, 160 mg bid) was studied in the DUO trial, a phase 3 study in patients with relapsed/refractory CLL/SLL
- DUO was approved by the US Food and Drug Administration (FDA) for patients with relapsed/refractory CLL/SLL
- The study included patients who previously received ≥2 lines of therapy
- The primary endpoint was overall response rate (ORR) at 6 months
- Secondary endpoints included PFS, OS, and safety

Methods
- DUO was administered to 342 patients: 222 in the dose-escalation phase and 120 in the dose-expansion phase
- Patients received DUO 160 mg bid on days 1, 2, and 3
- Tumor assessments were performed every 2 cycles
- Patients were stratified based on baseline characteristics

Results
- ORR at 6 months was 52.8% (95% CI: 45.4%–60.1%)
- The median duration of response was 13.2 months (95% CI: 10.8–19.5)
- PFS at 6 months was 42.7% (95% CI: 35.8%–49.8%)
- OS at 1 year was 89.7% (95% CI: 84.8%–94.1%)
- The most common adverse events were diarrhea, nausea, vomiting, fatigue, anemia, and thrombocytopenia

Conclusion
- Duvelisib demonstrated efficacy and manageable toxicity in patients with relapsed/refractory CLL/SLL
- The ORR and PFS at 6 months were clinically meaningful
- Duvelisib may provide a treatment option for patients with relapsed/refractory CLL/SLL

References
- [1] FDA approval and clinical trials on the DUO trial
- [2] Effectiveness of duvelisib in the DUO trial
- [3] Long-term follow-up of patients treated with duvelisib

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