LETTER TO THE EDITOR

The phase III DUO trial of PI3K inhibitor duvelisib *versus* ofatumumab in relapsed/refractory chronic lymphocytic leukemia/small lymphocytic lymphoma: final analysis including overall survival

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The phase III DUO trial of PI3K inhibitor duvelisib *versus* ofatumumab in relapsed/ refractory chronic lymphocytic leukemia/small lymphocytic lymphoma: final analysis including overall survival

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DUO Supplemental tables and figures

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Table S1. Serious adverse events (SAEs) in ≥2% of patients and adverse events of special interest (AESIs) in patients treated with duvelisib in the DUO trial[1]

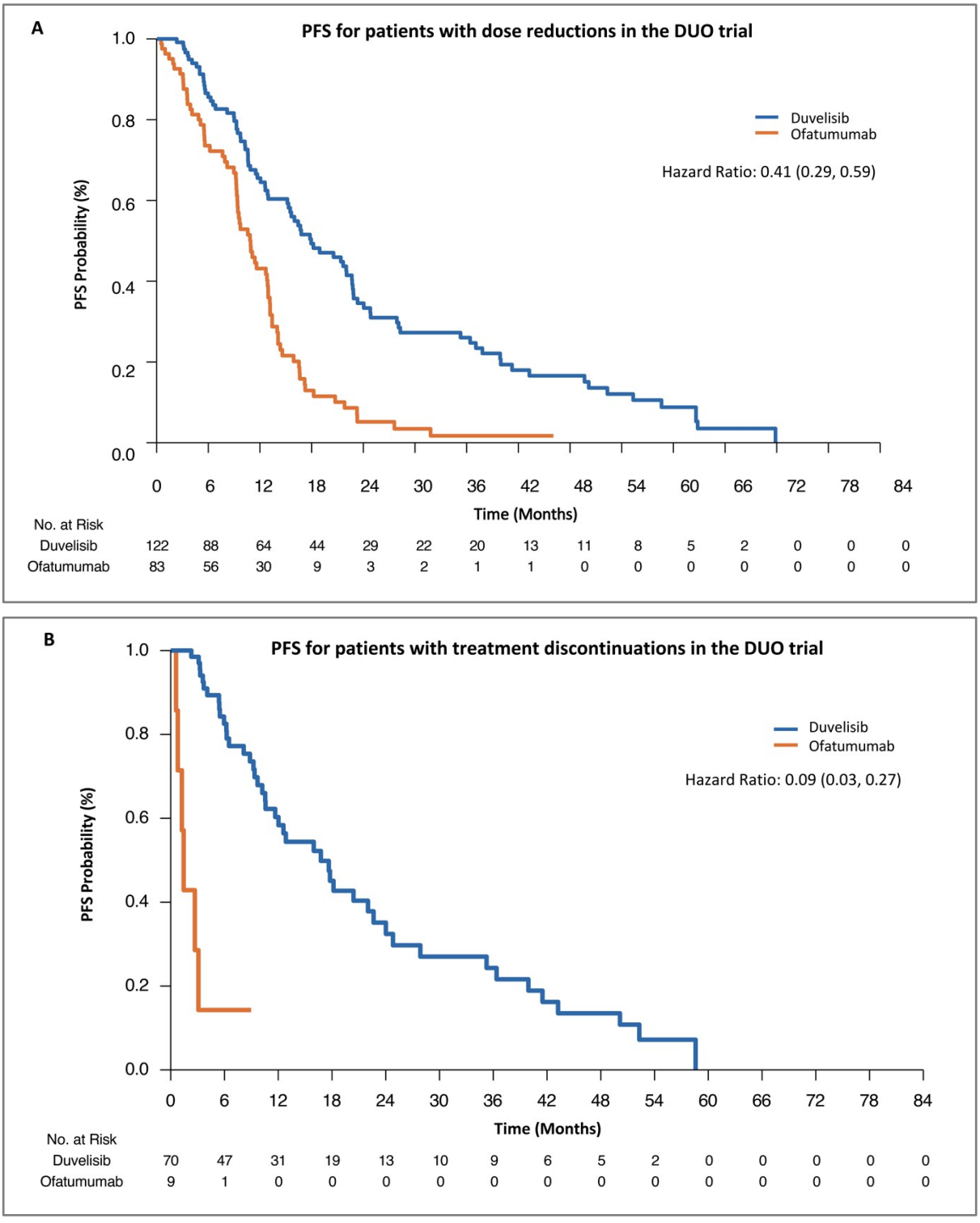
	Duvelisib (N=158) n (%)
Patients with ≥1 SAE	124 (78.5)
Blood and lymphatic system disorders	**18 (11.4)**
Febrile neutropenia	10 (6.3)
Gastrointestinal disorders	**50 (31.6)**
Colitis	20 (12.7)
Diarrhea	18 (11.4)
General disorders; administration site conditions	**16 (10.1)**
Pyrexia	7 (4.4)
General physical health deterioration	4 (2.5)
Infections and infestations	**63 (39.9)**
Pneumonia	25 (15.8)
Bronchitis	5 (3.2)
Gastroenteritis	4 (2.5)
Renal and urinary disorders	**7 (4.4)**
Renal failure, acute	4 (2.5)
Respiratory, thoracic, mediastinal disorders	**19 (12.0)**
Pneumonitis	6 (3.8)
Skin and subcutaneous tissue disorders	**12 (7.6)**
Toxic skin eruption	4 (2.5)
Patients with ≥1 AESI	113 (71.5)
Infection (Grade ≥3, including pneumonia)	56 (35.4)
Diarrhea (Grade ≥3) or Colitis (Grade ≥2)	46 (29.1)
Neutropenia (Grade ≥4)	32 (20.3)
Severe Cutaneous Reaction (Grade ≥3)	20 (12.7)
Transaminase Elevation (Grade ≥3 hepatoxicity)	10 (6.3)
Non-Infectious Pneumonitis (Grade ≥2)	9 (5.7)

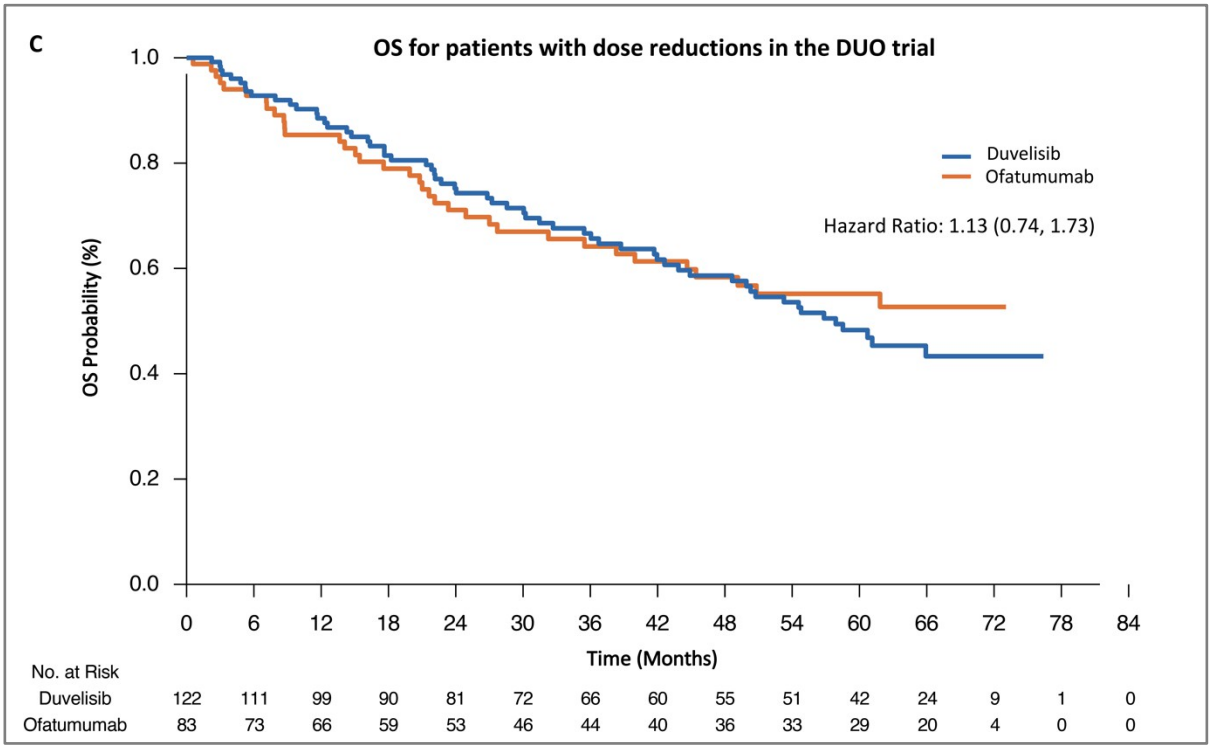
Table S2. Patients with treatment emergent adverse events (TEAEs; all causality) resulting in death for patients treated with duvelisib in the DUO trial[1]

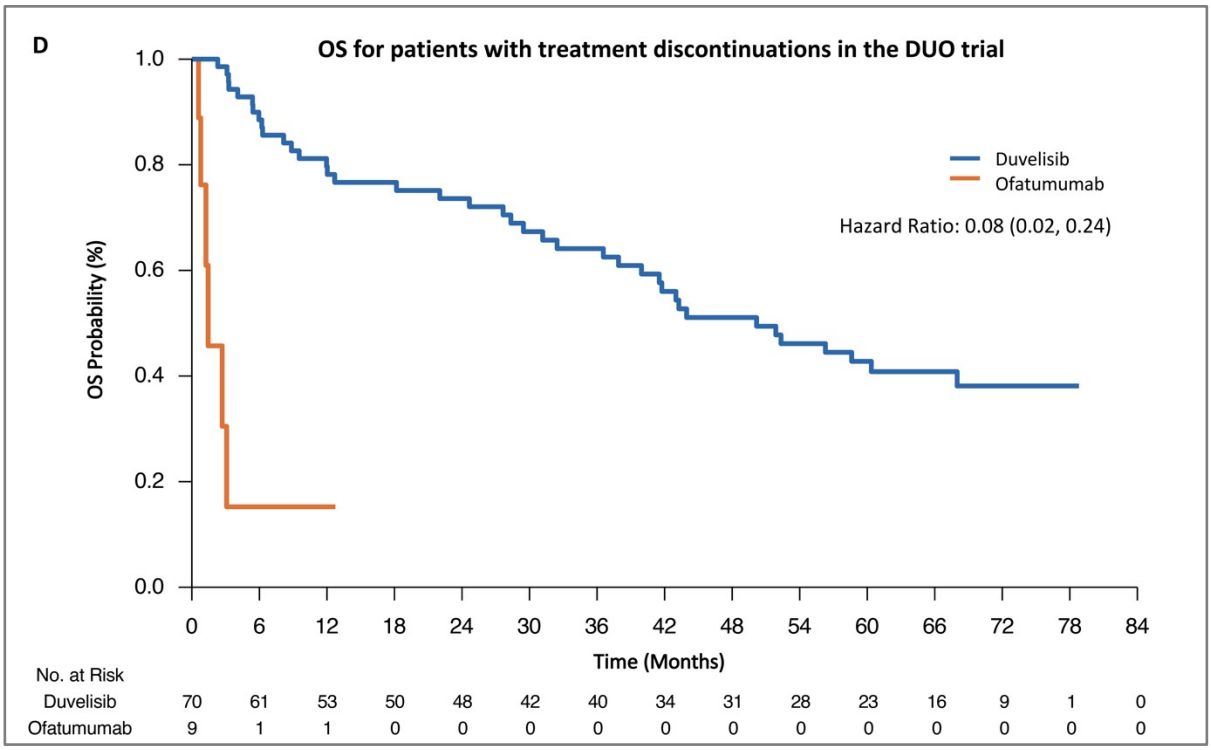
	Duvelisib (N=158) n (%)
Patients with ≥1 TEAE resulting in death*	24 (15.2)
Cardiac disorders	**1 (0.6)**
Cardiac failure	1 (0.6)
General disorders and administration site conditions	**5 (3.2)**
Unknown cause	2 (1.3)
General physical health deterioration	1 (0.6)
Multi-organ failure	1 (0.6)
Sudden death, cause unknown	1 (0.6)
Infections and infestations	**11 (7.0)**
Aspergillus infection	1 (0.6)
Bronchitis	1 (0.6)
Bronchopulmonary aspergillosis	1 (0.6)
Enterococcal sepsis	1 (0.6)
Escherichia sepsis	1 (0.6)
Infection	1 (0.6)
Pneumonia bacterial	1 (0.6)
Pneumonia *Pseudomonas aeruginosa*	1 (0.6)
Pseudomonal sepsis	1 (0.6)
Sepsis	1 (0.6)
Septic shock	1 (0.6)
Pneumonia staphylococcal	2 (1.3)
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	**2 (1.3)**
Intestinal adenocarcinoma	1 (0.6)
Neuroendocrine tumor	1 (0.6)
Nervous system disorders	**3 (1.9)**
Hemorrhagic stroke	2 (1.3)
Mental impairment	1 (0.6)
Respiratory, thoracic, and mediastinal disorders	**2 (1.3)**
Acute respiratory failure	1 (0.6)
Chronic obstructive pulmonary disease	1 (0.6)

*There were 4 fatal TEAEs in the duvelisib arm considered related to treatment: 2 caused by staphylococcal pneumonia probably related to treatment, and 1 each caused by general physical health deterioration and sepsis possibly related to treatment. TEAEs with a relationship of possible, probable, or definite per investigator are considered related to study treatment.

Figure S1. Dose reductions and treatment discontinuations due to adverse events (AEs) in the DUO trial: (A) Progression free survival (PFS) results for patients with dose reductions; (B) PFS results for patients with treatment discontinuations due to AEs; (C) Overall survival (OS) results for patients with dose reductions; (D) OS results for patients with treatment discontinuations due to AEs[1]







References

1. Data on File, Secura Bio, Inc. Las Vegas, NV.