NEWEVIDENCE

Activity of idelalisib in high-risk follicular lymphoma with early relapse following front-line immunochemotherapy

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Background

- FL is the most common iNHL
- A high-risk cohort of patients with FL, POD at ≤24 months, and median survival of ~5 years following initiation of R-CHOP was recently identified
- **Objective:** to assess potential activity of idelalisib in this high-risk patient population

FL = follicular lymphoma; iNHL = indolent non-Hodgkin lymphoma; POD = progression of disease; R-CHOP = rituximab, cyclophosphamide, doxorubicin, prednisone

Study Design

- Study 101-09 was a single-group, open-label, phase II study of 125 patients with iNHL refractory to both rituximab and an alkylating agent, who were treated with a starting dose of 150 mg of idelalisib bid
- A subset of 46 patients enrolled in Study 101-09 were diagnosed with FL and received first-line immunochemotherapy, of which 37 experienced early POD
  - Demographics, baseline characteristics, and intertreatment intervals were summarized
  - PFS and OS were calculated using Kaplan-Meier estimates

biid = twice a day; FL = follicular lymphoma; iNHL = indolent non-Hodgkin lymphoma; OS = overall survival; POD = progression of disease; PFS = progression-free survival

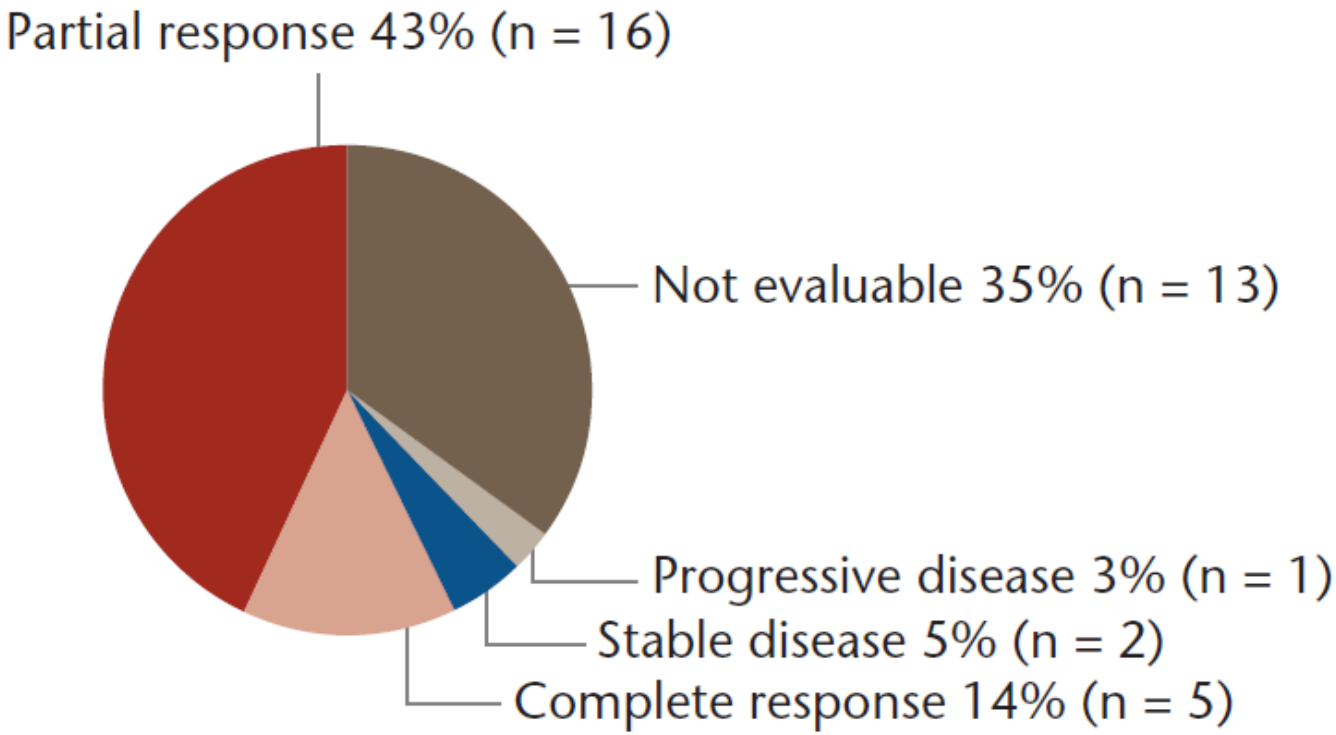
Baseline Characteristics

		Early POD (n = 37)
Median age, years (range)		64 (33–84)
Female, n (%)		18 (49)
Histologic grade, n (%)	1 or 2 3A	33 (89) 4 (11)
FLIPI score ≥3, n (%)		21 (57)
Mean number of prior therapies (SD; range)		3.4 (1.4; 2–8)
Prior therapy, n (%)	R-CHOP BR R-CVP	21 (57) 7 (19) 5 (14)
Mean intertreatment interval, months (SD)	1st and 2nd line 2nd and 3rd line 3rd and 4th line 4th and 5th line	12.5 (6.1) 9.7 (9.3) 11.9 (12.0)* 11.8 (7.6)†
Median time to initiation of idelalisib, months (range)‡		30.3 (8.9–94.7)

* n = 24 (65%).
† n = 15 (41%).
‡ Measured from time of initiation of first-line therapy; no patient received idelalisib as second-line therapy.

BR = bendamustine, rituximab; FLIPI = Follicular Lymphoma International Prognostic Index; POD = progression of disease; R-CHOP = rituximab, cyclophosphamide, doxorubicin, prednisone; R-CVP = rituximab, cyclophosphamide, prednisone; SD = standard deviation

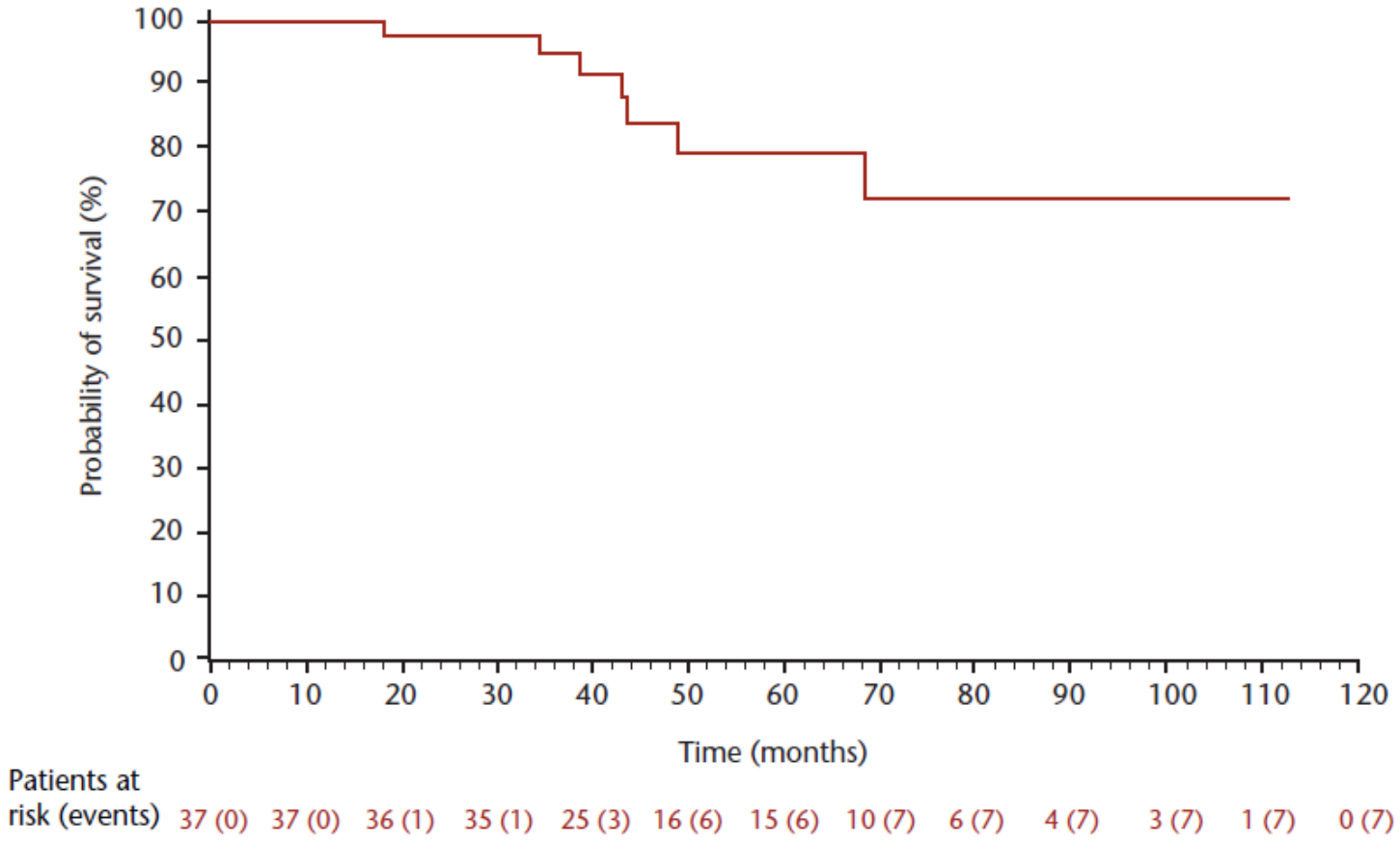
Best Overall Response to Treatment with Idelalisib



- Median duration of response for patients with complete or partial response was 11.8 months (95% CI: 3.8–not evaluable)
- Estimated probability of survival (± SE) at 5 years following initiation of first-line treatment was 79% ± 8%

CI = confidence interval; SE = standard error

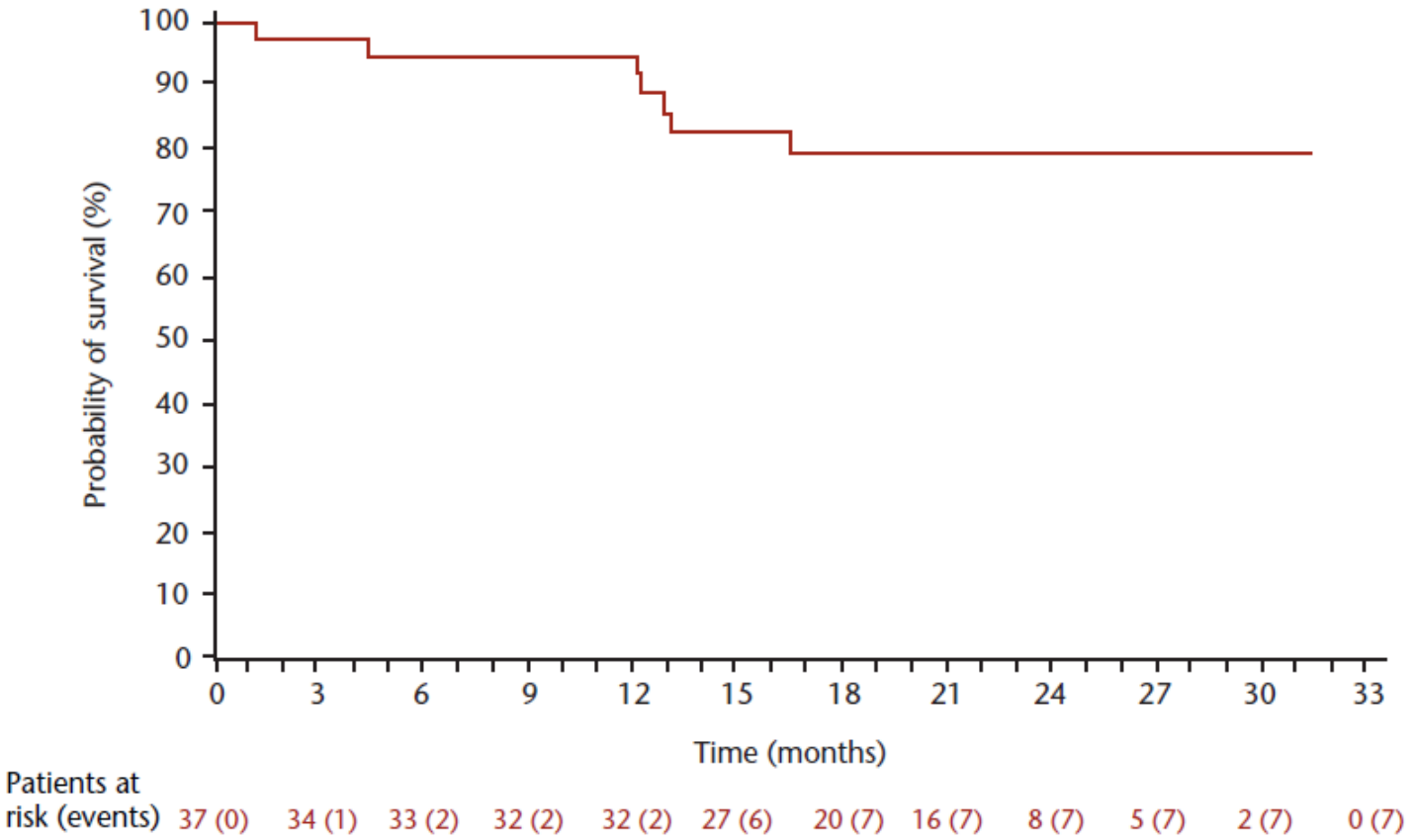
Overall Survival from Initiation of First-line Treatment



- Median OS following initiation of first-line immunochemotherapy was not reached during the course of the study

OS = overall survival

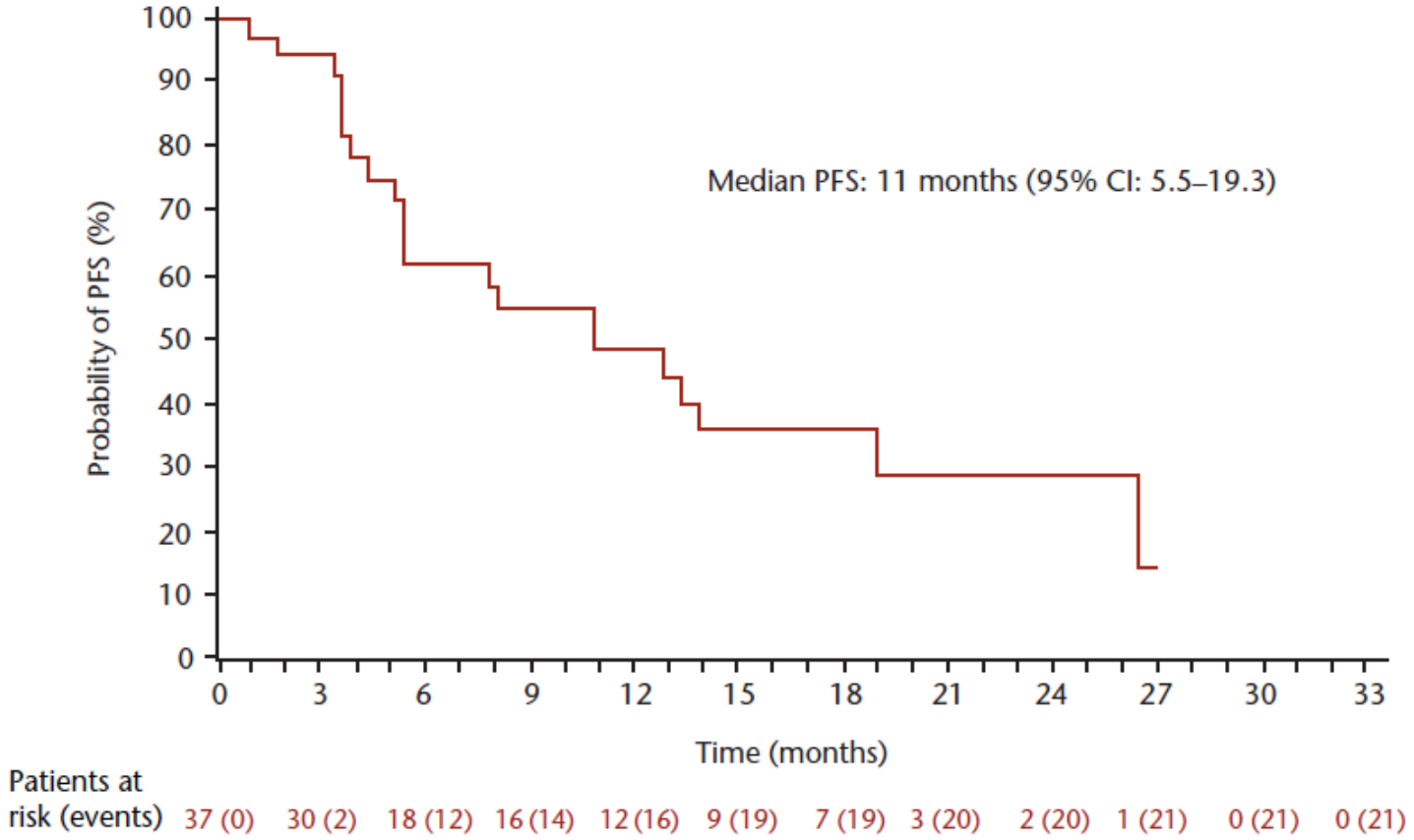
Overall Survival from Initiation of Idelalisib



- Estimated probability of survival (± SE) at 2 years following initiation of idelalisib was 79% ± 7%
- Median OS following initiation of idelalisib was not reached during the course of the study

OS = overall survival; SE = standard error

Progression-free Survival from Initiation of Idelalisib



- Estimated probability of PFS (± SE) at 2 years following initiation of idelalisib was 29% ± 10%

CI = confidence interval; PFS = progression-free survival; SE = standard error

Summary and Conclusion

- Idelalisib may have significant clinical activity in high-risk patients with FL and early relapse following first-line immunochemotherapy
- Given the limited sample size of the present analysis, further study in a larger population is warranted to ensure the generalizability of these findings
- Further consideration of investigational protocols featuring targeted therapies used both as monotherapy and in combination in high-risk patients with FL is also warranted

FL = follicular lymphoma