

Final results and overall survival data from a phase II study of acalabrutinib monotherapy in patients with relapsed/refractory mantle cell lymphoma, including those with poor prognostic factors

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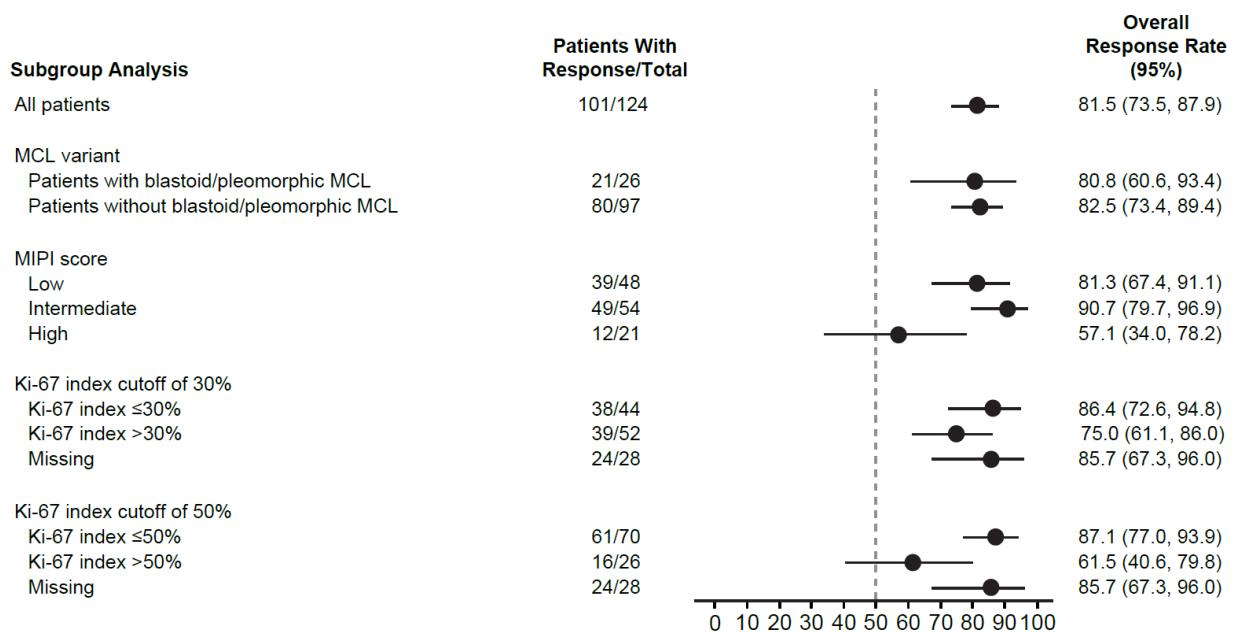
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Supplemental Figure 1. Forest plot of overall response rates by subgroup.



Supplemental Table 1. Patient disposition

| | All Patients (N=124) |
|--|----------------------|
| Follow-up, median (range), months | 38.1 (0.3–68.8) |
| Discontinued acalabrutinib, n (%) | |
| Disease progression | 77 (62.1) |
| AE | 15 (12.1) |
| Initiation of subsequent anticancer therapy | 6 (4.8) |
| Investigator's discretion not related to AE/SAE | 3 (2.4) |
| Withdrawal of consent | 2 (1.6) |
| Death | 1 (0.8) |
| Lost to follow-up | 1 (0.8) |
| Other | 1 (0.8) |
| Patients on treatment at time of data cutoff, n (%) | 18 (14.5) |
| Relative dose intensity, median % (range)^a | 98.6 (27.1–100) |
| Treatment exposure, median (range), months | 17.5 (0.1–65.3) |

^aRelative dose intensity is the ratio of the actual cumulative dose to the planned cumulative dose through the drug exposure period. AE, adverse event; SAE, serious adverse event.

Supplemental Table 2. Most common AEs (reported in ≥10% of patients)

| All Patients (N=124) | | | | | |
|--------------------------|-----------|---------|---------|---------|---------|
| AE Preferred Term, n (%) | Any Grade | Grade 1 | Grade 2 | Grade 3 | Grade 4 |
| Headache | 48 (39) | 30 (24) | 16 (13) | 2 (2) | 0 |
| Diarrhea | 47 (38) | 25 (20) | 17 (14) | 5 (4) | 0 |
| Fatigue | 37 (30) | 26 (21) | 8 (6) | 2 (2) | 0 |
| Cough | 29 (23) | 24 (19) | 5 (4) | 0 | 0 |
| Myalgia | 27 (22) | 19 (15) | 6 (5) | 2 (2) | 0 |
| Nausea | 27 (22) | 14 (11) | 11 (9) | 2 (2) | 0 |
| Asthenia | 22 (18) | 15 (12) | 5 (4) | 2 (2) | 0 |
| Constipation | 20 (16) | 15 (12) | 5 (4) | 0 | 0 |
| URTI | 20 (16) | 4 (3) | 14 (11) | 2 (2) | 0 |
| Dyspnea | 19 (15) | 13 (10) | 3 (2) | 2 (2) | 1 (0.8) |
| Pyrexia | 19 (15) | 13 (10) | 6 (5) | 0 | 0 |
| Vomiting | 19 (15) | 10 (8) | 6 (5) | 3 (2) | 0 |
| Anemia | 18 (15) | 1 (0.8) | 3 (2) | 12 (10) | 2 (2) |
| Dizziness | 18 (15) | 15 (12) | 3 (2) | 0 | 0 |
| Rash | 18 (15) | 9 (7) | 7 (6) | 2 (2) | 0 |
| Contusion | 16 (13) | 14 (11) | 2 (2) | 0 | 0 |
| Sinusitis | 16 (13) | 4 (3) | 12 (10) | 0 | 0 |
| Abdominal pain | 15 (12) | 5 (4) | 8 (6) | 2 (2) | 0 |
| Pneumonia | 15 (12) | 1 (0.8) | 5 (4) | 9 (7) | 0 |
| Back pain | 14 (11) | 11 (9) | 3 (2) | 0 | 0 |
| Neutropenia | 14 (11) | 0 | 0 | 7 (6) | 7 (6) |

| | | | | | |
|-------------------|---------|-------|-------|---|---|
| Arthralgia | 13 (10) | 7 (6) | 6 (5) | 0 | 0 |
|-------------------|---------|-------|-------|---|---|

Four patients (3.2%) reported grade 5 treatment-emergent AEs (aortic stenosis, non-small cell lung cancer, pulmonary embolism, and suicide attempt; none were treatment related). AE, adverse event; URTI, upper respiratory tract infection.