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Durability of Complete Responses in Patients From the ECHELON-3 Study

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Conclusions

- Patients with relapsed/refractory (R/R) diffuse large B-cell lymphoma (DLBCL) treated with brentuximab vedotin (BV) + lenalidomide (Len) + rituximab (R) were 3.3 times more likely to achieve a complete response (CR) than those treated with placebo+Len+R
- The CR rate was 40.2% in patients treated with BV+Len+R, compared with 18.6% in patients treated with placebo+Len+R
- Outcomes in patients with CR were durable; 93.3% of patients who achieved a CR with BV+Len+R did not receive any subsequent systemic anticancer therapy, compared with 77.3% of patients with a CR treated with placebo+Len+R
- Overall, BV+Len+R achieved a high rate of durable CRs, consistent with the observed survival benefit in the randomized, global, phase 3 ECHELON-3 study (NCT04404283), and is a promising option to achieve complete and durable responses in third- or later-line therapy for patients with R/R DLBCL

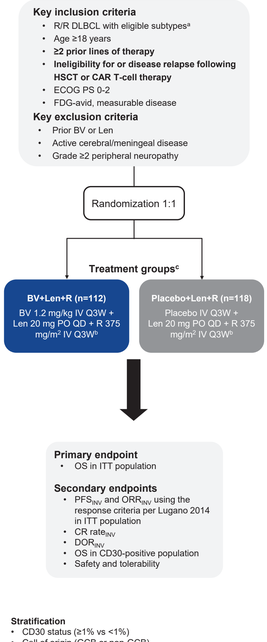
Introduction

- R/R DLBCL is very aggressive, with historically low CR rate (2%-15%)[1]
- Recent research has focused on achieving complete and durable responses in this population, which translate to improvements in overall survival (OS) and progression-free survival (PFS)[2]
- Results from the ECHELON-3 study demonstrated a statistically significant and clinically meaningful improvement in OS, PFS, and objective response rate (ORR) with BV+Len+R vs placebo+Len+R in patients with R/R DLBCL after ≥2 prior systemic therapies[3]
- Here, we present subgroup analyses in patients with a best overall response (BOR) of CR (n=67)

Methods

- Patients in the study were randomized (1:1) to receive BV (1.2 mg/kg) or placebo every 3 weeks (Q3W), in combination with R (375 mg/m^2) and Len (20 mg) once daily (QD) (**Figure 1**)
- In these subgroup analyses, eligible patients had a BOR of CR, and some ended study treatment and received subsequent anticancer therapy
  - BOR was assessed by investigators according to the Lugano 2014 classification
  - Duration of response was defined as the time from the start of the first documented CR to the first documented tumor progression per Lugano 2014 or death
- Patients who initiated a subsequent nonpalliative anticancer therapy were censored at the most recent prior response assessment
- Subsequent nonpalliative anticancer therapies were defined as any systemic therapy received after the end of study treatment
- *P* values are descriptive

Figure 1: ECHELON-3 study design



CAR-T, chimeric antigen receptor T-cell; DOR, duration of response; ECOG PS, Eastern Cooperative Oncology Group performance status; FDG, fluorodeoxyglucose; GCB, germinal center B cell; HSCT, hematopoietic stem cell transplant; INV, investigator; ITT, intention to treat; IV, intravenous; NOS, not otherwise specified; PO, oral.
[a]Eligible subtypes include but are not limited to transformed DLCBL, high-grade double/triple-hit lymphoma, and NOS.
[b]Starting with cycle 2, R can be administered intravenously or subcutaneously (1400 mg subcutaneously Q3W).
[c]Treatment was allowed to continue until disease progression or unacceptable toxicity.

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Results

- Patient demographics were mostly balanced between the BV+Len+R and placebo+Len+R groups (**Table 1**)
  - A greater proportion of patients in the BV+Len+R group (53.3%) had an ECOG PS of 1 than in the placebo+Len+R group (31.8%)
- Baseline disease characteristics were also mostly balanced between the 2 groups (**Table 2**)

Table 1: Patient demographics

Patients with a BOR of CR	BV+Len+R (n=45)	Placebo+Len+R (n=22)
Age, median (range), years	74.0 (40-87)	74.0 (39-81)
Age group, n (%)		
<65 years	9 (20)	7 (32)
≥65 years	36 (80)	15 (68)
Sex, n (%)		
Female	27 (60)	15 (68)
Male	18 (40)	7 (32)
Baseline ECOG PS, n (%)[a]		
0	21 (47)	14 (64)
1	24 (53)	7 (32)
2	0	1 (5)
Race, n (%)		
White	24 (53)	12 (55)
Asian	16 (36)	7 (32)
Other/not reportable	5 (11)	3 (14)
Ethnicity, n (%)		
Hispanic or Latino or of Spanish origin	0	1 (5)
Not Hispanic or Latino or of Spanish origin	40 (89)	19 (86)
Not reportable	5 (11)	2 (9)

[a]Values presented are the last nonmissing values on or before the first dose date. If a patient did not receive any dose, the randomization/enrollment date is used in place of the first dose date.

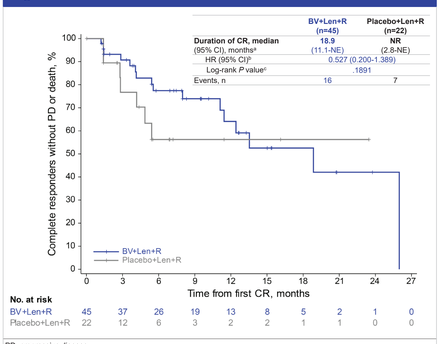
Table 2: Baseline disease characteristics

	BV+Len+R (n=45)	Placebo+Len+R (n=22)
Disease diagnosis, n (%)		
DLBCL, NOS	39 (87)	17 (77)
Double/triple-hit lymphoma[a]	4 (9)	2 (9)
EBV-positive DLBCL, NOS	1 (2)	2 (9)
Primary mediastinal large B-cell lymphoma	1 (2)	0
Primary cutaneous DLBCL, leg type	0	1 (5)
Transformed DLBCL, n (%)	9 (20)	5 (23)
Cell of origin, n (%)[b]		
GCB	19 (42)	11 (50)
Non-GCB	26 (58)	11 (50)
CD30 status, n (%)[c]		
≥1%	14 (31)	10 (45)
<1%	31 (69)	12 (55)
Extranodal disease involvement at study entry, n (%)		
No involvement	11 (24)	7 (32)
1 Site	19 (42)	9 (41)
>1 Site	15 (33)	6 (27)
Time from initial DLBCL diagnosis to randomization/enrollment, median (range), months	28.5 (7-187)	49.7 (12-219)
Elevated lactate dehydrogenase at study entry, n (%)	25 (56)	7 (32)
Bulky disease at study entry, n (%)[d]	2 (4)	4 (18)
Other disease characteristics, n (%)		
Ann Arbor stage III at study entry	8 (18)	7 (32)
Ann Arbor stage IV at study entry	25 (56)	11 (50)
IPI score ≥3 at time of enrollment	23 (51)	9 (41)
Primary refractory[e]	19 (42)	6 (27)
Refractory to last prior DLBCL therapy[e]	34 (76)	11 (50)
Patients with any prior systemic therapy, n (%)	45 (100)	22 (100)
Prior lines of systemic therapy received in DLBCL setting, median (range)	2 (0-5)	3 (2-5)
Prior anti-CD20 antibody, n (%)	45 (100)	22 (100)
Prior anthracycline, n (%)	44 (98)	21 (95)
Prior CAR-T therapy, n (%)	12 (27)	4 (18)
Prior HSCT, n (%)	5 (11)	7 (32)
Prior bispecific, n (%)	2 (4)	5 (23)

EBV, Epstein-Barr virus; IPI, International Prognostic Index.
[a]High-grade B-cell lymphoma with translocations of *MYC, BCL2,* and/or *BCL6.*
[b]Based on postrandomization corrected values.
[c]CD30 status per central result. When central result is not available, local result is used.
[d]Bulky disease is defined as ≥1 target lesion with longest diameter >7.5 cm by investigator assessment.
[e]Refractory status is derived from prior therapy data. Refractory was defined as no response or a response lasting <6 months from the last treatment end date.

- Of the 112 patients in the BV+Len+R group, 45 (40.2%) had a BOR of CR. Of the 118 patients in the placebo+Len+R group, 22 (18.6%) had a BOR of CR
- The median time to first CR was 1.6 months (range, 1.2-7.3 months) with BV+Len+R and 1.6 months (range, 0.7-4.6 months) with placebo+Len+R
- In a logistic regression model, the odds of achieving a CR in the BV+Len+R group were 3.3 (95% CI, 1.7-6.4) times that in the placebo+Len+R group, after adjusting for baseline prognostic factors
  - Prognostic factors include age, sex, double- or triple-hit lymphoma, transformed status, Ann Arbor stage, ECOG PS, prior CAR-T therapy, cell of origin (GCB vs non-GCB), and CD30 (≥1% vs <1%)
- The median duration of CR was 18.9 months with BV+Len+R vs not reached (NR) with placebo+Len+R (hazard ratio [HR], 0.527; 95% CI, 0.200-1.389; P=.1891) (**Figure 2**)

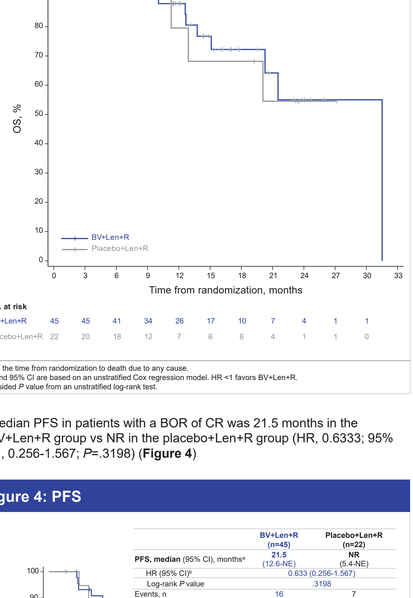
Figure 2: Duration of CR



PD, progressive disease.
[a]Duration of CR is the time from first CR per Lugano 2014 to earliest occurrence of PD or death.
[b]HR and 95% CI are based on a stratified Cox regression model with the stratification factors cell of origin (GCB, non-GCB) and CD30 status (≥1%, <1%) at randomization. HR <1 favors BV+Len+R.
[c]Two-sided *P* value from a stratified log-rank test based on the stratification factors cell of origin (GCB, non-GCB) and CD30 status (≥1%, <1%) at randomization.

- The median duration of treatment was 9.8 months (range, 3.5-26.4 months) with BV+Len+R and 6.8 months (range, 2.1-26.6 months) with placebo+Len+R
- The median number of dosed cycles was 12.0 (range, 3-34) with BV+Len+R and 8.5 (range, 3-37) with placebo+Len+R
- With a median follow-up of 14.3 months, the median OS in patients with a BOR of CR was 31.5 months in the BV+Len+R group vs NR in the placebo+Len+R group (HR, 1.044; 95% CI, 0.331-3.298; *P*=.9407) (**Figure 3**)

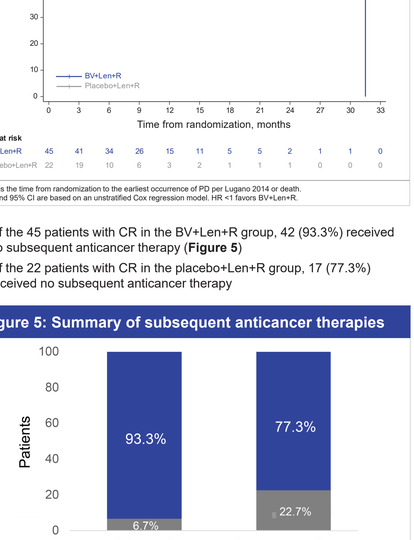
Figure 3: OS



[a]OS is the time from randomization to death due to any cause.
[b]HR and 95% CI are based on an unstratified Cox regression model. HR <1 favors BV+Len+R.
[c]Two-sided *P* value from an unstratified log-rank test.

- Median PFS in patients with a BOR of CR was 21.5 months in the BV+Len+R group vs NR in the placebo+Len+R group (HR, 0.6333; 95% CI, 0.256-1.567; *P*=.3198) (**Figure 4**)

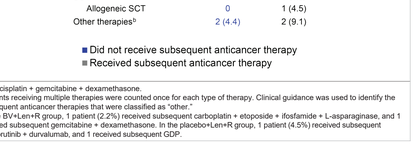
Figure 4: PFS



[a]PFS is the time from randomization to the earliest occurrence of PD per Lugano 2014 or death.
[b]HR and 95% CI are based on an unstratified Cox regression model. HR <1 favors BV+Len+R.

- Of the 45 patients with CR in the BV+Len+R group, 42 (93.3%) received no subsequent anticancer therapy (**Figure 5**)
- Of the 22 patients with CR in the placebo+Len+R group, 17 (77.3%) received no subsequent anticancer therapy

Figure 5: Summary of subsequent anticancer therapies



Patients with subsequent anticancer therapy, n (%)[a]	BV+Len+R (n=3)	Placebo+Len+R (n=5)
Anti-CD20 antibody	0	2 (9.1)
Azacitidine + R-GDP	0	1 (4.5)
R + etoposide + ifosfamide	0	1 (4.5)
Bispecific	0	2 (9.1)
CAR T-cell therapy	1 (2.2)	1 (4.5)
SCT	0	1 (4.5)
Allogeneic SCT	0	1 (4.5)
Other therapies[b]	2 (4.4)	2 (9.1)

■ Did not receive subsequent anticancer therapy
■ Received subsequent anticancer therapy

GDP, cisplatin + gemcitabine + dexamethasone.
[a]Patients receiving multiple therapies were counted once for each type of therapy. Clinical guidance was used to identify the subsequent anticancer therapies that were classified as "other."
[b]In the BV+Len+R group, 1 patient (2.2%) received subsequent carboplatin + etoposide + ifosfamide + L-asparaginase, and 1 received subsequent gemcitabine + dexamethasone. In the placebo+Len+R group, 1 patient (4.5%) received subsequent acalabrutinib + durvalumab, and 1 received subsequent GDP.