

Highlights in aggressive lymphoma

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SUMMARY

EHA 2019 featured several eagerly awaited presentations on Hodgkin lymphoma (HL). This included 3-year follow-up data of the ECHELON-1 trial in patients with high-risk features and longer follow-up data of CheckMate 2015 evaluating nivolumab plus doxorubicin, vinblastine, and dacarbazine in newly diagnosed advanced HL. In a third interesting HL abstract it was shown that foregoing radiotherapy in PET-negative patients with early-stage HL increases the risk of disease progression. In non-Hodgkin lymphoma (NHL), data were presented indicating that there is no benefit of rituximab maintenance beyond two years in patients with relapsed or refractory indolent NHL. In addition to this, interesting data were presented on the use of an obinutuzumab + DHAP combination in patients with untreated mantle cell lymphoma, with polatuzumab vedotin + obinutuzumab + lenalidomide in relapsed/refractory follicular lymphoma (FL) and with the anti-CD47 antibody Hu5F9-G4 in patients with refractory lymphoma.

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HODGKIN LYMPHOMA

TWO-YEAR FOLLOW-UP OF CHECKMATE 205: NIVOLUMAB PLUS DOXORUBICIN, VINBLASTINE, AND DACARBAZINE IN NEWLY DIAGNOSED ADVANCED-STAGE CHL

The current multi-agent chemotherapy regimens lead to sub-optimal results in newly diagnosed patients with advanced-stage cHL. However, the use of nivolumab, an anti-PD-1 checkpoint inhibitor, followed by N-AVD (nivolumab, doxorubicin, vinblastine, and dacarbazine) has shown promising activity in this patient population, as indicated by the 9-month follow-up of the CheckMate 205 that was presented last year at EHA.¹ This year, *Dr Domingo-Domènech* provided an update on the study results after a 2-year follow-up of the patient cohort.²

In the study at hand, patients received monotherapy with nivolumab (four doses; 240mg intravenously every two weeks) for approximately eight weeks, followed by N-AVD combination therapy (12 doses) for approximately 22 weeks. Overall, 49 out of 51 patients (96%) completed the monotherapy phase of the study and 45/50 (90%) completed the N-AVD combination therapy. The median follow-up of the presented analysis was 25.3 months.

The median age of the patients enrolled in the trial was 37 years, 63% was male and a quarter of patients had an IPSS score of 4 or more at diagnosis. Eighty percent of patients had B symptoms at diagnosis, 31% had bulky disease and 20%, 24% and 57% of patients had respectively stage II, III or IV disease at diagnosis. Progression-free survival (PFS) at 21 months by investigator assessment was 83% (95%CI: 69-91). Combination therapy improved response rates, with the majority of patients achieving a complete response (CR) (69%) or complete metabolic response (CMR) (75%) at the end of therapy. Two patients died after the last dose of N-AVD. One patient (68 years old), treated for 175 days, died 38 days after the last dose due to the study drug toxicity (acute respiratory failure). The second patient (85 years old) was treated for 209 days and died 451 days after the last dose due to disease progression.¹ The most common grade 3/4 adverse event (AE) was neutropenia (41%), with grade 3/4 febrile neutropenia in 10% of patients.

In summary, nivolumab followed by N-AVD offered benefit to patients with newly diagnosed, advanced stage cHL, leading to high ORR (86%) and CMR (75%), as well as prolonged PFS (83% at 21 months). The therapy was also well tolerated.

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TABLE 1. 3-year PFS by PET2 status and in patients <60 years of age in the phase III ECHELON-1 trial.³

	A+AVD N=664	ABVD N= 670	Difference at 3-years	HR (95% CI)	p-value
All patients	83.1%	76%	7.1%	0.70 (0.55-0.90)	0.005
PET2-	N= 577 85.8%	N=573 79.5%	6.3%	0.69 (0.52-0.91)	0.009
PET2+	N= 58 67.7%	N=63 51.5%	16.2%	0.59 (0.33-1.07)	0.077
Patients <60 yrs	N= 580 84.9%	N= 568 81.0%	7.1%	0.69 (0.52-0.91)	0.008
<60, PET2-	N= 512 87.2%	N= 489 81.0%	6.2%	0.71 (0.51-0.98)	0.034
<60, PET2+	N= 51 69.2%	N= 54 54.7%	14.5%	0.60 (0.32-1.15)	0.117

FRONTLINE BRENTUXIMAB VEDOTIN + AVD PROVIDES DURABLE BENEFIT OVER ABVD IN PATIENTS WITH STAGE 3/4 HODGKIN'S LYMPHOMA

Previously, the phase 3 ECHELON-1 study demonstrated that brentuximab vedotin + doxorubicin, vinblastine and dacarbazine (A+AVD) was superior to doxorubicin, bleomycin, vinblastine, and dacarbazine (ABVD) as frontline treatment for stage 3/4 cHL in terms of modified PFS (mPFS) per independent review and per investigator. During EHA 2019, 3-year follow-up data of the ECHELON-1 trial were presented. In this study, 1,334 patients with untreated stage III/IV cHL patients were randomized (1:1) to A+AVD or ABVD. At the end of cycle 2 a PET scan was conducted (Deauville 1-3 PET-negative; Deauville 4-5 PET-positive) after which patients with a Deauville score of 5 were allowed to switch to an alternative therapy.³

At 3 years, the PFS rate in the A+AVD arm was 83.1% as compared to 76.0% with ABVD (Table 1). This PFS benefit was seen in all investigated subgroups, irrespective of age, IPSS score, baseline lymphoma stage, ECOG performance status and the number of baseline extra nodal sites. Interestingly, the PFS benefit at 3 years was also seen irrespective of the PET2 result. In PET2-negative patients the difference in 3-year PFS rate was 7.1% in favour of A+AVD (85.8% vs. 79.5%; HR[95%CI]: 0.69[0.52-0.91]; p= 0.009). In PET2-positive patients this difference was even more pronounced with a 3-year PFS rate of 67.7% with A+AVD as compared to

51.5% with ABVD (difference 16.2%; HR[95%CI]: 0.59[0.33-1.07]; p= 0.077). Also in patients younger than 60 years of age A+AVD was superior to ABVD with a 3-year PFS rate of 84.9% with A+AVD and 77.8% with ABVD (HR[95%CI]: 0.69[0.52-0.91]; p= 0.008). In patients younger than 60 with a positive PET2, the 3-year PFS rate was 69.2% with A+AVD vs. 54.7% with ABVD (difference of 14.5%; HR[95%CI]: 0.60[0.32-1.15], p= 0.117) (Table 1). At the primary analysis 67% of patients in the A+AVD arm and 43% in the ABVD arm had peripheral neuropathy (PN). After 3 years of follow-up, 78% of PN cases in the A+AVD arm and 83% of PN cases in the ABVD arm were completely resolved or improved significantly. Of the remaining PN events in the A+AVD arm, 89% were grade 1/2. The median time to complete resolution of PN in the A+AVD arm was 28 weeks.³

FOREGOING RADIOTHERAPY IN PET-NEGATIVE PATIENTS WITH EARLY-STAGE HODGKIN LYMPHOMA INCREASES THE RISK OF DISEASE PROGRESSION

Having a negative PET following two cycles of ABVD chemotherapy is no reason to eliminate radiation therapy among patients with early-stage favorable Hodgkin lymphoma, according to the HD16 study.⁴ In this randomized, parallel-group, phase III trial, 1150 patients (age 18-75 years) with newly diagnosed, early-stage, favorable Hodgkin lymphoma were randomized to receive standard combined-modality treatment with two cycles ABVD and 20 Gy involved-field

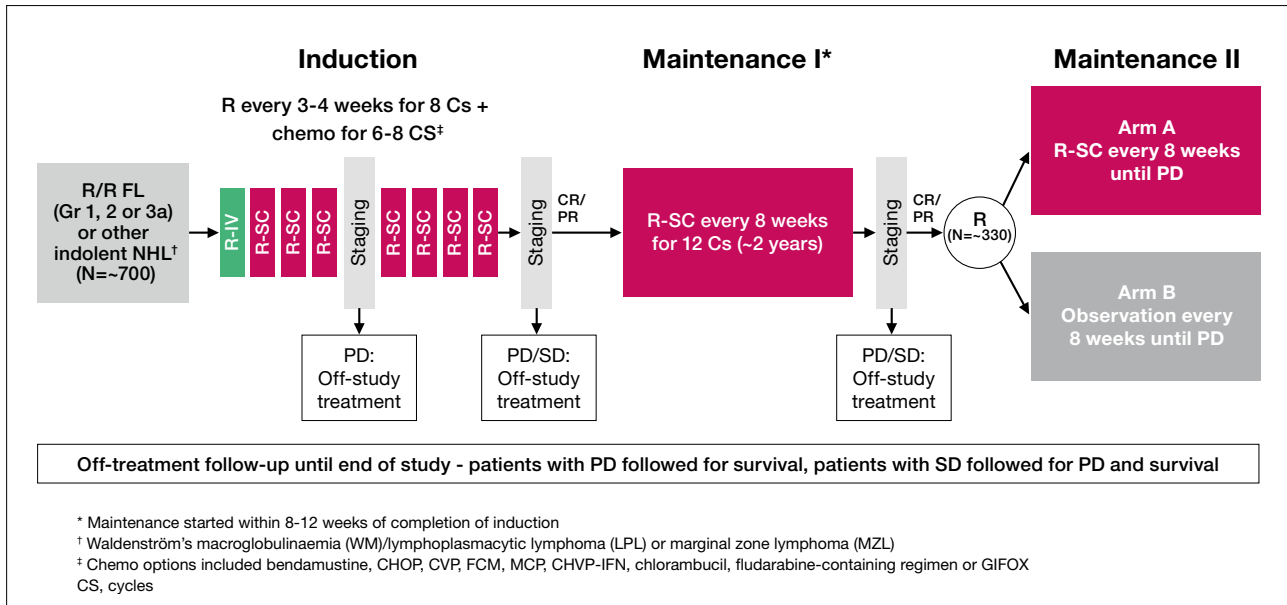


FIGURE 1. Study design of the phase III MabCute trial.⁵

radiotherapy (N= 693) or PET-guided treatment, where involved-field radiotherapy was restricted to patients with a Deauville score ≥ 3 after ABVD (N= 1,007). PET was centrally assessed by an expert panel blinded to the randomization result. Among patients randomized to combined modality treatment, 51% had a Deauville score of 1 to 2; 31% a score of 3; and 18% a score of 4. Among patients randomized to PET, 66% had a Deauville score of 1 to 2; 22% a score of 3; and 12% a score of 4. Clinical stage II and bulky disease at initial staging were associated with an unfavorable Deauville score after two cycles of ABVD. CT-based complete remission as final treatment outcome after involved-field radiotherapy was observed in 344 of 348 patients (99%) with an interim Deauville score of 1 to 2; in 209 of 214 patients (98%) with a Deauville score of 3; and 108 of the 117 patients (92%) with a Deauville score of 4 ($p= 0.016$ for a Deauville score of 1–2 vs. 3–4; $p= 0.0012$ for a Deauville score of 1–3 vs. 4). All six progressions in this trial occurred in the Deauville score of 4 subgroup.⁴

After a median follow-up of 46 months, the estimated 5-year PFS was 93.2% among patients with a Deauville score of 1 to 2; 92.8% for those with a Deauville score of 3; and only 80.9% among those with a Deauville score of 4. Considering a Deauville score ≥ 3 as a cutoff, the PFS difference between the two treatment groups was just statistically significant, with a HR of 1.71 (95%CI: 1.00–2.93; $p= 0.047$). Adjustment for baseline stratification factors led to similar but non-significant results (HR[95%CI]: 1.73[0.99–3.02]; $p= 0.055$). Using a Deauville score of 4 as cutoff, the difference between the two treatments became more pronounced, indicating a three-

fold risk for treatment failure in patients with a Deauville score of 4 after chemotherapy (HR[95%CI]: 2.94[1.63–5.31]; $p= 0.0004$). The five-year overall survival (OS) was very high, at 98.2% for a Deauville score of 1 to 2; 98.6% for a Deauville score of 3; and 96.5% for a Deauville score of 4.⁴

In summary, radiotherapy cannot be omitted after two cycles of ABVD without substantial loss of tumor control shown by decreased PFS. Patients who are PET-positive (i.e. Deauville Score 4) after two cycles of ABVD have a poorer PFS despite radiotherapy and might benefit from therapy intensification.

NON-HODGKIN LYMPHOMA

NO EVIDENCE SUPPORTING RITUXIMAB MAINTENANCE BEYOND TWO YEARS IN PATIENTS WITH RELAPSED OR REFRACTORY INDOLENT NON HODGKIN LYMPHOMA

The current standard of care for patients with iNHL consists of induction treatment with a combination of chemotherapy and rituximab, followed by rituximab maintenance. However, the optimal duration of this maintenance phase is unknown. MabCute is an international, randomised, open-label phase III trial evaluating the efficacy and safety of prolonging maintenance therapy with R-SC after standard R-SC-based induction and two years of rituximab maintenance in R/R iNHL patients. In order to be eligible for the trial, patients had to be 18 years or older and have R/R CD20+ follicular lymphoma (grade 1, 2 or 3a) or another form of iNHL (Waldenström's macroglobulinemia, lymphoplasmacytic lymphoma or marginal zone lymphoma). In the induc-



tion phase of the trial, all patients received 8 cycles of R-SC (375mg/m² IV in cycle 1, next 1400 mg SC in cycles 2-8) in combination with 6-8 cycles of chemotherapy. After induction therapy, patients with a complete or partial response (CR/PR) were treated with 2 years of R-SC maintenance (12 cycles of 1400 mg R-SC every 8 weeks). After that period, patients with a PR or CR were randomized to prolonged maintenance therapy with R-SC or observation (Figure 1).⁶ Of the 692 patients who started induction therapy, 505 continued to the first maintenance phase and of them, 276 were randomized to prolonged maintenance or observation (N= 138 in both arms). The median age of patients in the study was 64 years and about 60% had Ann Arbor stage IV disease at diagnosis. A third of patients had a high FLIPI score and 43% presented with bone marrow involvement. More than half of the study population consisted of patients with follicular lymphoma (FL), 25% had marginal zone lymphoma and the remaining 20% was made up of patients with Waldenström's macroglobulinemia or lymphoplasmacytic lymphoma.⁵

At the time of analysis only 46 PFSrand events were observed: 19 in the prolonged maintenance arm and 27 among patients in the observation arm. This corresponds to only 36% of the 129 events needed to achieve an 80% statistical power. The median PFSrand was not reached in either arm and the difference in PFSrand between the two treatment arms was not statistically significant (p= 0.410, stratified log rank test). At the end of the study, 10 patients in the maintenance group and 8 patients in the observation group had died. As such, there was not enough information to draw any conclusions with respect to OS. The ORR (CR/PR) at end of the induction therapy was 84.7%, and 77 of 357 patients with a PR at the end of induction achieved a CR by end of initial maintenance, corresponding to a conversion rate of 21.6%.⁵

The incidence of grade >3 adverse events (AEs) (34.8% vs. 29.0%) was similar for prolonged maintenance and observation, as was the case for the rate of serious AEs (22.5% vs. 23.2%). The most common grade ≥3 AEs with prolonged maintenance and observation were neutropenia (8.7% vs. 5.8%), pneumonia (5.1% vs. 2.9%), a decreased neutrophil count (2.2% vs. 0%) and hypertension (2.2% vs. 0%). The most common serious AE with prolonged R-SC maintenance was pneumonia, which was seen in 5.8% of patients (vs. 2.9% with observation).⁵

As such, MabCute indicates that there is no benefit of prolonging the maintenance therapy with R-SC beyond two years in patients with R/R iNHL. However, the event rate in this trial was very low making it difficult to formulate firm conclusions.

RITUXIMAB MAINTENANCE NOT BENEFICIAL IN DIFFUSE LARGE B-CELL LYMPHOMA

With standard rituximab-CHOP chemo-immunotherapy, about 40% of diffuse large B-cell lymphoma (DLBCL) patients will have refractory disease or relapse. Maintenance therapy with an active agent for patients who are in complete remission after induction therapy might improve the prognosis of these patients. For the HOVON Nordic LG phase III study, 398 patients with stage II to IV diffuse large B-cell lymphoma who had a complete response, as determined by PET-CT, for at least 2 weeks following treatment with rituximab-CHOP in a previous randomized trial were randomized to 24 months of rituximab maintenance therapy, given at a dose of 375 mg/m² intravenously every 8 weeks (N= 199) or observation (N= 199). CT scans were performed at 6, 12, 18 and 24 months in both arms. The primary endpoint was disease-free survival (DFS) from maintenance randomization. In total, 18 patients were found to be ineligible after randomization or were excluded for other reasons, leaving 195 in the observation arm and 185 in the maintenance arm.⁶

The median age of patients in the trial was 65 years, 48% were 66 years old or more and 49% were male. Just over half (54%) had a high-intermediate or high age-adjusted International Prognostic Index (aa-IPI) score. A total of 81% of patients in the maintenance arm received all 12 doses of rituximab. After a median follow-up of 79.9 months (maximum 125.7 months), the median DFS was not reached. The 5-year rate of DFS was 79% for rituximab maintenance as compared to 74% with observation. This difference was not statistically significant, with a hazard ratio of 0.83 (95%CI: 0.57–1.19; p= 0.31). The secondary endpoint of 5-year overall survival (OS) was also not significantly different, at 85% vs. 83%, respectively. No clinical subgroup benefited from rituximab maintenance.⁶

The toxicity seen with rituximab maintenance therapy was mild. Among patients who received rituximab maintenance, 17% experienced grade 3 adverse events and 6% suffered a grade 4 adverse event. The most common side effect was infection, with a grade 3 infection occurring in 6% of patients. Grade 3/4 neutropenia was observed in 4% of patients.⁶

COMBINING OBINUTUZUMAB WITH DHAP INDUCES MRD NEGATIVITY IN THREE QUARTERS OF UNTREATED MANTLE CELL LYMPHOMA PATIENTS

It is well established that prolonged MRD negativity after both induction and ASCT is a strong independent prognostic marker in MCL. The current standard of care for younger MCL patients consists of induction therapy with high-dose aracytine- and salt platinum-containing chemotherapy regi-

men (DHAP) in combination with rituximab followed by an ASCT and three years of rituximab. Obinutuzumab is second-generation anti-CD20 monoclonal antibody that was designed to improve the antibody-dependent cell mediated cytotoxicity seen with rituximab. Obinutuzumab is already being used in the treatment of chronic lymphocytic leukemia and *in vitro* experiments suggest that obinutuzumab may also provide better anti-MCL activity than rituximab.⁷

The LYMA-101 study is a prospective and open phase II trial testing the effect of obinutuzumab in untreated MCL patients under 66 years of age who are eligible for intensive therapy. The induction regimen in this trial consisted of 4 cycles of O-DHAP before consolidation with ASCT (BEAM conditioning plus obinutuzumab) followed by obinutuzumab maintenance for 3 years and subsequent on-demand obinutuzumab for MRD positive patients. The primary objective of the trial was the MRD negativity rate after 4 cycles of O-DHAP. In total, the LYMA-101 trial enrolled 86 patients, but one patient withdrew consent before starting treatment. The median age of patients in the trial was 58 years and 73% was male. Almost all patients in the study had Ann Arbor stage III or IV disease and about a fifth presented with B-symptoms. Ninety percent of study participants had extra-nodal involvement and 17% presented with a blastoid disease variant.⁷ The median follow-up for the presented analysis was 14 months. Fourteen patients out of the 85 were not evaluable for MRD, essentially due to purely nodal disease and no detectable MCL clone in peripheral blood or bone marrow. Among the 71 MRD-informative patients, 53 reached MRD negativity in the BM (75%), as measured by qPCR. Following induction therapy, 72 patients underwent ASCT and 61 of them started obinutuzumab maintenance. At one year the PFS rate was reported at 93.4%, with an OS rate of 96%.⁷

In summary, Lyma-101 successfully demonstrated the high efficacy of O-DHAP as induction therapy regimen for patients with MCL yielding an unprecedented high level of MRD negativity. Longer follow-up is needed to evaluate the long-term patient outcome after O-DHAP followed by ASCT and obinutuzumab on-demand maintenance.

OVERCOMING THE “DON’T EAT ME SIGNAL” IN PATIENTS WITH REFRACTORY LYMPHOMA

In aggressive lymphomas, such as DLBCL, first-line chemotherapy cures half of the patients, while in indolent lymphomas (such as follicular lymphoma, FL) frontline chemotherapy induces a remission in the majority of patients. For patients who do not respond to chemotherapy (refractory), or who relapse after a certain amount of time, the situation looks much grimmer. As such, there is a need for new therapeutic strategies that are able to overcome this treatment

resistance. Hu5F9-G4 is a first-in-class IgG4 antibody targeting CD47, a macrophage immune checkpoint with a central role in immunological ‘self-recognition’ that sends a ‘don’t eat me’ signal to immune cells. Many solid and hematological cancers exploit this immune checkpoint and express CD47 on their cell surface to avoid immunological eradication. Moreover, a high expression of CD47 was found to be associated with a worse prognosis in patients with B-cell non-Hodgkin lymphoma. Pre-clinically, Hu5F9-G4 was found to synergize with rituximab in eliminating lymphoma cells by enhancing antibody-dependent cellular phagocytosis. Hu5F9-G4 + rituximab also demonstrated encouraging safety and efficacy in a phase Ib dose escalation study in patients with relapsed/refractory (r/r) DLBCL and rituximab-refractory FL. During EHA 2019, extended follow up data of this phase Ib cohort were presented in addition to preliminary results of the phase II part of this study.⁸

The study enrolled DLBCL patients who were primary refractory or relapsed/refractory to at least 2 prior therapies and who were ineligible for CAR-T therapy, in addition to indolent lymphoma (FL and MZL) patients who also had to be relapsed/refractory to at least 2 prior therapies. Based on a potential dose-response seen in the phase Ib trial, Hu5F9-G4 doses of 30 and 45 mg/kg were tested with rituximab. A total of 115 patients (70 DLBCL, 41 FL, 4 MZL) have been treated across the phase Ib and II studies. The median age of the patients in the trial was 66 years and patients received a median of 3 prior therapies (ranging from 1-10). Overall, 85% of enrolled patients were rituximab-refractory and 72% were refractory to their last line of therapy. Overall, the Hu5F9-G4 + rituximab combination was well tolerated at Hu5F9-G4 doses of up to 45 mg/kg (maximum tolerated dose not reached). No significant dose-dependent toxicities were observed. Treatment-related adverse events (AEs) occurring in >10% of patients included infusion reactions (38%), headache (34%), chills (30%), fatigue (30%), anemia (27%), nausea (24%), pyrexia (23%) vomiting (13%) and back pain (11%). Interestingly, the majority of these AEs were grade 1 and 2 in severity. The only grade 3/4 AE observed in more than 7% of patients was anemia (15%), but this was an expected transient first-dose effect. Treatment discontinuation due to drug-related AEs occurred in only 8/115 (7%) patients.⁸ Of the 115 patients enrolled in the study, 97 were evaluable for efficacy. Among these 97 patients, an overall response rate (ORR) of 45% was reported with a CR in 19%. Not surprisingly, the response rates were higher among the indolent lymphoma patients (FL N= 35, MZL N= 3) where an ORR and CR rate was reported of 61% and 24%, respectively. Among DLBCL patients (N= 59), the ORR was 36% including a CR in 15% of patients. The median time to response



for responding patients was rapid at 1.8 months. At a median follow-up of up to 13 (DLBCL) and 21 months (FL) for patients treated with 10-30 mg/kg (N=22) of Hu5F9-G4 in the phase Ib cohort, the median duration of response had not been reached (duration of response in DLBCL patients ranged from 3.6 to more than 23.8 months and from 6.2 to more than 27.6 months in FL patient). Interestingly, several sustained complete responses (CR) of more than 20 months were observed.⁸

These results convincingly demonstrate the safety and efficacy of the Hu5F9-G4 + rituximab combination in both heavily pre-treated DLBCL and indolent lymphoma patients. Further enrollment in the phase II part of this trial is ongoing. As such, this approach represents a promising new immune checkpoint inhibition strategy. It is to be expected that the potential of CD47 targeting will also be explored on other tumor types.

POLATUZUMAB VEDOTIN + OBINUTUZUMAB + LENALIDOMIDE FOR RELAPSED/REFRACTORY FOLLICULAR LYMPHOMA (FL)

Polatuzumab vedotin is a first-in-class antibody-drug conjugate that targets CD76b, a protein expressed in follicular lymphoma (FL) and DLBCL. The presented open-label, single-arm, phase Ib/II study assessed the safety and preliminary efficacy of polatuzumab vedotin in combination with obinutuzumab and lenalidomide (Pola-G-Len), in patients with relapsed/refractory FL. The primary efficacy endpoint of the trial was complete response (CR) at the end of induction treatment based on PET-CT scans.⁹

In total, 52 patients with R/R Grade 1–3a FL with an ECOG performance status of 0–2 were treated with induction Pola-G-Len induction treatment (six 28-day cycles; Pola 1.4mg/kg or 1.8mg/kg (dose escalation) IV on day 1 of each cycle; G 1000mg IV on days 1, 8, 15 of cycle 1 and on day 1 of cycles 2–6; Len: 10mg, 15mg or 20mg (dose escalation) orally on days 1–21 of each cycle). Patients in CR, or with a partial response (PR) or stable disease (SD) after Pola-G-Len induction received maintenance therapy with G (1,000 mg on day 1 every two months for 24 months) and Len (10mg on days 1–21 monthly for 12 months).

An objective response rate (ORR) of 89% was reported, including a CR in 67%. At a median follow-up of 16.6 months, the median PFS was not reached. At 12-months, the PFS rate was high at 90%.⁹

One fatal adverse event was seen and 75% of patients (N= 39) experienced grade 3/4 adverse events. The most common grade 3/4 side effects were neutropenia (46%), thrombocytopenia (17%) and anemia (12%). Febrile neutropenia (grade 3/4) was reported in 4% of patients. The most fre-

quently reported non-hematological adverse event consisted of infections (12%). In total, 40% of patients suffered from a serious adverse event. Adverse events led to Len dose alteration, or discontinuation in 43 patients (83%).⁹

Pola-G-Len led to a good ORR (89%) after induction and durable responses in R/R FL, with 90% of patients remaining progression-free one-year post treatment. Pola-G-Len has a manageable toxicity profile consistent with the published profiles for each drug. The primary analysis of the trial is expected in the near future

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