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IACH 2018 | Lenalidomide and rituximab *versus* chemotherapy and rituximab in patients with untreated follicular lymphoma – the RELEVANCE study

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The [1st Annual Meeting of the International Academy for Clinical Hematology](#) (IACH) took place in Paris, France, on September 27–29, 2018. On Thursday 27 September, a hematology hot news session was held, with an abstract presented entitled “The RELEVANCE study” by Professor [Gandhi Damaj](#) from the [University of Caen Normandy](#), Caen, France.

The RELEVANCE study ([NCT01476787](#)) is a multicenter, open label, randomized, phase III trial evaluating the combination of lenalidomide plus rituximab (R²) *versus* chemotherapy plus rituximab (R-chemo) followed by rituximab maintenance for the treatment of patients with previously untreated follicular lymphoma (FL).

Study overview:

- N = 1030 patients
 - R² arm, n = 513 patients (median age = 59 years; range 30–89)
 - R-chemo arm, n = 517 patients (median age = 59 years; range 23–83)
- Treatment period 1 (6 months): lenalidomide (20 mg per day on Day 2-22/28) and rituximab (375 mg/m²) or chemotherapy (R-CHOP 72%, R-B 23% and R-CVP 5%)
- Treatment period 2 (~1 year): R² arm patients received lenalidomide po and rituximab every two months; R-chemo arm patients received rituximab every two months
- Treatment period 3 (1 year): both treatment arms receive rituximab maintenance
- Co-primary endpoints: complete remission rate (CR) or CRu at 120 weeks and progression-free survival (PFS)

Key findings:

- 120-week CR/CRu: 48% in the R² arm vs 53% in the R-chemo arm
- Best overall response rate: 84% in the R² arm vs 89% in the R-chemo arm, not significantly different
- 3-year overall survival (OS): 94% in both arms
- IRC interim PFS: 77% in the R² arm vs 78% in the R-chemo arm at a median follow-up of 37.9 months; HR = 1.10 (95% CI, 0.85–1.43), *P* = 0.48
- Safety: there was more grade 3/4 neutropenia in the R-chemo arm (50%) compared to the R² arm (32%) and less no hematologic toxicities in R² arm except for rash
- More dose reduction and treatment discontinuation were prevalent in the R² arm

Professor Damaj concluded his talk highlighting that R² did not meet the primary objectives at the first interim analysis and R² treatment did not show superior efficacy in comparison with R-chemo at 120 weeks. Therefore, R-chemo remains the standard of care for patients with untreated follicular lymphoma. R² could be proposed for some selected profile of patients, however, longer follow up and medico-economic data are necessary to help physician decision-making.

References

1. Damaj G. et al. The RELEVANCE study: Lenalidomide and rituximab vs chemotherapy and rituximab in untreated follicular lymphoma. 1st Annual Meeting of the International Academy for Clinical Hematology (2018 IACH), Paris, France.

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