

## [CCTG LY16 | RELEVANCE published in New England Journal of Medicine](#)

Submitted by lisac on Mon, 09/24/2018 - 11:19 Testing efficacy with two approaches to Lymphoma treatment  
Monday, September 24, 2018



The results of the CCTG LY16 trial of Rituxmab plus Lenalidomide in Advanced Untreated Follicular Lymphoma (RELEVANCE), recently published in New England Journal of Medicine, has the potential to offer a new treatment option to lymphoma patients, that does not require chemotherapy.

“The trial demonstrated similar efficacy with the two approaches to treatment and has generated a lot of interest worldwide,” says Lois Shepherd, CCTG Senior Investigator. “There are two Canadian authors on the publication, Jean Francois Larouche who had the highest accrual in Canada; and, Laurie Sehn, the Canadian LY.16 Study Chair, reflecting the 46 patients we accrued very quickly to this trial led by the Lymphoma Academic Research Organization (LYSARC) group in Europe.”

This study compared the effects of lenalidomide plus rituximab (R2) to chemotherapy plus rituximab (R-chemo) followed by rituximab maintenance in patients with previously untreated follicular lymphoma. The R2 treatment arm did not achieve superiority in the co-primary endpoints of complete response or unconfirmed complete response (CR/CRu) at 120 weeks and progression-free survival (PFS) during the pre-planned analysis (final analysis of CR/CRu and interim analysis of PFS).

This study had different toxicity profiles and showed no difference in efficacy between the two arms. The president of the Lymphoma Study Association (LYSA), Prof. Gilles Salles, said of the study, “This is the first Phase III trial to evaluate a chemotherapy-free regimen to the established standard of care in patients with previously untreated follicular lymphoma and represents a landmark study in this disease setting.”

There was a difference in the safety findings between arms. R-chemo had higher grade 3/4 labs (50% vs 34%) and febrile neutropenia (6% vs 2%). R2 had higher grade 3/4 cutaneous events (7% vs 1%). Secondary primary malignancies occurred in 7% of the R2 patients and in 9% of R-chemo patients. There was no difference between arms in the frequency of grade 5 AEs (1%). The number of patients that completed treatment in the R2 arm was 69% and 71% R-chemo.



The NEW ENGLAND  
JOURNAL of MEDICINE

### LY16 in the New England Journal of Medicine

Morschhauser F, Fowler NH, Feugier P, Bouabdallah R, Tilly H, Palomba ML, Fruchart C, Libby EN, Casasnovas RO, Flinn IW, Haioun C, Maisonneuve H, Ysebaert L, Bartlett NL, Bouabdallah K, Brice P, Ribrag V, Daguindau N, Le Gouill S, Pica GM, Martin Garcia-Sancho A, López-Guillermo A, Larouche JF, Ando K, Gomes da Silva M, André M, Zachée P, Sehn LH, Tobinai K, Cartron G, Liu D, Wang J, Xerri L, Salles GA. Rituximab plus Lenalidomide in Advanced Untreated Follicular Lymphoma. *N Engl J Med* 379: [934-47, 2018](https://doi.org/10.1056/NEJMoa1805104).

<https://www.nejm.org/doi/full/10.1056/NEJMoa1805104>

- The abstract for the [RELEVANCE | LY16 study was also presented at ASCO](#) on June 3rd, 2018