LymphomaHub

FL, MZL

FDA grants priority review to lenalidomide and rituximab combination for the treatment of indolent NHL

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On 26 February 2019, the US Food and Drug Administration (FDA) accepted a supplemental new drug application (sNDA) and granted priority review to the lenalidomide and rituximab (R^2) regimen, for the treatment of patients with previously treated relapsed/refractory (R/R) follicular lymphoma (FL) and marginal zone lymphoma (MZL).

The sNDA for the R2 regimen was based on the results from the multicenter, randomized, double-blind, phase III AUGMENT (NCT01938001) trial, which assessed the efficacy of the R2 regimen compared to single-agent rituximab therapy in patients with R/R FL or MZL. The results from this trial showed that according to independent review committee, progression-free survival in patients in the R2 arm was 39.4 months (95% CI, 22.9–not evaluable) compared to 14.1 months (95% CI, 11.4–16.7) in patients receiving rituximab monotherapy, with a median follow-up of 28.3 months. Further results from the AUGMENT study were presented at the 60th Annual Meeting of the American Society of Hematology (ASH), read more here.

According to the drug manufacturers, the R^2 regimen "has the potential to offer patients with previously treated follicular lymphoma and marginal zone lymphoma a chemotherapy-free option".

References

1. TargetedOnc. Lenalidomide/Rituximab receives priority review designation from FDA for indolent non-Hodgkin lymphoma. https://www.targetedonc.com/news/lenalidomiderituximab-receives-priority-review-designation-from-fda-for-indolent-nonhodgkin-lymphoma [Accessed 2019 Feb 28]