FDA Approves Revlimid for Follicular and Marginal Zone Lymphoma

Approval was based on the results of two clinical trials: AUGMENT and MAGNIFY.

May 28, 2019 By Food and Drug Administration (FDA)

On May 28, 2019, the Food and Drug Administration approved Revlimid (lenalidomide, Celgene Corp.) in combination with a rituximab product for previously treated follicular lymphoma (FL) and previously treated marginal zone lymphoma (MZL).

Approval was based on two clinical trials: AUGMENT (NCT01938001) and MAGNIFY (NCT01996865). In AUGMENT, 358 patients with relapsed or refractory FL or MZL were randomized (1:1) to receive lenalidomide and rituximab or rituximab and placebo. In the single-arm component of MAGNIFY, 232 patients with relapsed or refractory FL, MZL, or mantle cell lymphoma received 12 induction cycles of lenalidomide and rituximab.

In AUGMENT, the primary endpoint was progression-free survival (PFS) in the intent-to-treat population, as determined by an independent review committee (IRC). Median PFS was 39.4 months (95% CI: 22.9, NE) in the lenalidomide arm and 14.1 months (95% CI: 11.4, 16.7) in the placebo-containing arm (HR 0.46; 95% CI: 0.34, 0.62; $p<0.0001$). The objective response rate (ORR) by IRC assessment for patients with follicular lymphoma was 80% (118/147; 95% CI: 73%, 86%) in the lenalidomide arm compared with 55.4% (82/148; 95% CI: 47%, 64%) in the control arm. For patients with marginal zone lymphoma, the ORR by IRC assessment was 65% (20/31; 95% CI: 45%, 81%) compared with 44% (14/32; 95% CI: 26%, 62%), respectively.

In MAGNIFY, the ORR by investigator assessment was 59% (104/177; 95% CI: 51%, 66%) for patients with follicular lymphoma. Median response duration was not reached with a median follow-up of 7.9 months (95% CI: 4.6, 9.2). For patients with marginal zone lymphoma, the ORR by investigator assessment was 51% (23/45; 95% CI: 36%, 66%). Median response duration was not reached with a median follow-up of 11.5 months (95% CI: 8.0, 18.9).

Across both trials, the most common adverse reactions occurring in at least 20% of patients were neutropenia, fatigue, diarrhea, constipation, nausea, and cough.

The prescribing information includes a Boxed Warning alerting health care professionals and patients about the risk of embryo-fetal toxicity, hematologic toxicity, and venous and arterial thromboembolism which may be life-threatening or fatal.

The recommended lenalidomide dose for FL or MZL is 20 mg once daily orally on days 1-21 of repeated 28-day cycles for up to 12 cycles.

View full prescribing information for REVLIMID.

FDA granted this application priority review and orphan drug designation. A description of FDA expedited programs is in the Guidance for Industry: Expedited Programs for Serious Conditions-Drugs and Biologics.

This announcement was originally published on the Food and Drug Administration website.
