

Ninlaro® (ixazomib) - Updated labeling

- On April 28, 2022, the FDA added a limitation of use for Takeda's <u>Ninlaro (ixazomib)</u>, stating that Ninlaro is not recommended for use in the maintenance setting or in newly diagnosed multiple myeloma in combination with lenalidomide and dexamethasone outside of controlled clinical trials.
- Ninlaro is approved, in combination with lenalidomide and dexamethasone, for the treatment of
 patients with multiple myeloma who have received at least one prior therapy.
- In addition to the new limitation of use, a warning and precaution was added to the drug label for increased mortality in patients treated with Ninlaro in the maintenance setting.
 - In two prospective randomized clinical trials in multiple myeloma in the maintenance setting, treatment with Ninlaro resulted in increased deaths.
- In C16019, newly diagnosed multiple myeloma patients who underwent autologous stem cell transplantation, continued on maintenance therapy with Ninlaro for 24 months. There were 27% (105/395) deaths in the Ninlaro arm compared with 26% (69/261) in the placebo arm. The hazard ratio (HR) for overall survival (OS) was 1.008 (95% CI: 0.744, 1.367).
- In C16021, newly diagnosed multiple myeloma patients, not treated with a stem cell transplant who achieved a partial response or better, continued on maintenance therapy with Ninlaro for 24 months. There were 30% (127/425) deaths in the Ninlaro arm compared with 27% (76/281) in the placebo arm. The HR for OS was 1.136 (95% CI: 0.853, 1.514).
- In C16014, in newly diagnosed multiple myeloma patients, the study did not meet the prespecified primary endpoint for progression-free survival (PFS). There were 136 (39%) deaths in the Ninlaro, lenalidomide, and dexamethasone arm compared to 148 (42%) in the lenalidomide and dexamethasone arm. The HR for OS was 0.998 (95% CI: 0.79, 1.261).



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