Ninlaro® (ixazomib) – Updated labeling

- On April 28, 2022, the FDA added a limitation of use for Takeda's Ninlaro (ixazomib), 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).